AMCP | Academy of Managed Care Pharmacy®

February 28, 2019

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pension
U.S. Senate
Washington, DC 20510-6300

RE: Request for Information on Steps Congress can take to Address America's Rising Health Care Costs

Dear Chairman Alexander:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to provide comments in response to your December 11, 2018 letter in which you seek input on ways that the Senate Committee on Health, Education, Labor and Pension ("HELP Committee"), Congress and the Administration can address the nation's rising health care costs. AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, AMCP's 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP shares your concern about the rising costs of medications and the impact on patients, payers, and providers. In 2017, AMCP identified three key areas where AMCP members help to improve health outcomes and lower costs. These areas focus on enhancing value for outcomes; enhanced approaches to medication coverage determinations; and market competition for generics and biosimilars to lower costs. Implementation of effective, outcomes-driven value-based contracting (VBC) strategies also remains a key focus area for AMCP and its members. These principles are consistent with many areas previously discussed in HELP Committee hearings and identified by the current administration.[1] AMCP and its members are eager to collaborate with Congress and the administration as well as states, commercial payers, providers, and patient organizations to identify solutions to combat the rising cost of medications.

AMCP also cautions Congress regarding two current proposals that have been discussed – prescription drug importation and government regulation of prescription drug pricing. For several reasons that we will address in this letter, these proposals could lead to an overall

[1] American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018. Available at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf. Accessed February 27, 2019.

negative impact on consumer cost, quality and access to health care benefits. AMCP also cautions Congress to not propose legislation on rebates in the commercial market until the Administration considers comments on a proposed rule on changes to the rebate safe harbor for federal programs.

The key points of our comments are as follows:

1. Overview of AMCP's proactive initiatives and areas that align with the work of the Committee on the rising cost of health care in the United States;
2. Collaboration between Congress, the administration, and other stakeholders to encourage working toward better models for value-base contracts (VBC), including the need for a common definition of VBC, best practices, and legal and regulatory infrastructure to support VBC;
3. Introduce and pass legislation with provisions from "Pharmaceutical information Exchange Act" (H.R. 2026 in the 115th Congress) to create a statutory provision to allow for better coverage decision making by payers and biopharmaceuticals companies for medications in the pipeline;
4. Recommendations from recently-published proceedings of an AMCP Partnership Forum titled "Designing Benefits and Payment Models for High-Investment Medications" could help provide better policy decisions for coverage of gene therapies and other innovative and specialty medications;
5. Identifying legislative and regulatory changes that promote the development and use of safe, efficacious and equivalent generic drugs and biosimilars and remove barriers to new market entrants;
6. Utilizing prior authorization as an essential tool to optimize patient outcomes while reducing waste, error, unnecessary prescription drug use, and overall costs;
7. Employing greater use of health information technology (health IT) to improve patient care and lower system costs;
8. General concerns with legislation or potential legislation on rebates, prescription drug importation and direct government negotiation of prescription drug prices.
9. Recognizing the expertise and training of pharmacists as key members of the health care team in improving patient outcomes and managing medication costs.

1. AMCP Priorities are aligned with Committee's Desire to Reduce the Growth in the Cost of Healthcare

AMCP regularly convenes multi-stakeholder Partnership Forums[2] to drive consensus recommendations and actions on some of the most challenging issues in health care. Past forums resulted in the adoption and approval of policy solutions related to preapproval and post-approval payer and manufacturer communications[3]; the development of AMCP-led Biologics

[2] AMCP Partnership Forums. Available at: http://www.amcp.org/Tertiary.aspx?id=27438&terms=partnership%20forums. Accessed February 27, 2019.
[3] *Ibid.*

and Biosimilars Collective Intelligence Consortium (BBCIC) that drives active post-marketing surveillance for biologics and biosimilars[4]; and recommendations for adoption of VBC, including promotion of a common definition and recommendations for measurement and performance to ensure quality in VBCs.[5] Recommendations from several of these forums, including biosimilars and VBC, are included in areas of these comments. In 2019, AMCP will be hosting Partnership Forums on Pharmacy and Therapeutics (P&T) practices, prior authorization practices, specialty medication benefit design and reimbursement and digital pharmaceuticals.[6] We will share the recommendations reported out from these Partnership Forums to the committee as they become available.

2. Collaboration between Congress, the Administration, and Other Stakeholders to Encourage Adoption of VBCs through a Standard Definition, Identifying Best Practices, and Legal and Regulatory Infrastructure to Support VBC

During the past decade, payment models for the delivery of health care have undergone a shift from focusing on volume to focusing on value. Current laws and regulations present challenges for the development and implementation of value-based contracts. Specifically, lack of clarity about treatment of these arrangements under the Federal Anti-Kickback Statute poses a significant barrier. The recommendations included in this letter are based upon consensus recommendations of an AMCP Partnership Forum, "Advancing Value Based Contracting", held in June 2017. The forum included nearly 40 thought leaders representing diverse health care sectors, including health plans, integrated delivery networks, pharmacy benefit managers, clinical practice, and biopharmaceutical and laboratory companies.[7]

A Common Definition of VBC is Needed to Facilitate Discussion

There are currently several definitions of VBC being used in the marketplace. Having an agreed upon definition will be integral for changes to existing legal and regulatory challenges that are blocking adoption of VBCs today. Participants of AMCP's Partnership Forum developed a consensus definition for VBC that is broad enough to encompass a variety of differing contract types and flexible enough to allow for future innovation:

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[4] Biologics and Biosimilars Collective Intelligence Consortium. Available at: http://www.bbcic.org/ Accessed February 27, 2019.

[5] Academy of Managed Care Pharmacy Partnership Forum: Advancing Value-Based Contracting. JMCP 2017 Nov; 23(11), pp. 1096-1102. Available at: www.jmcp.org/doi/pdf/10.18553/jmcp.2017.17342. Accessed February 27, 2019.

[6] 2019 Partnership Forum Series. Available at: http://www.amcp.org/PartnershipForums/ Accessed February 27, 2019

[7] AMCP Partnership Forum: Advancing Value-Based Contracting. Available at: https://www.jmcp.org/doi/full/10.18553/jmcp.2017.17342. Accessed February 27, 2019.

A VBC is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures.

The following guiding principles were also identified:

- The definition should be flexible enough to allow for innovative value-based contracting approaches that have yet to be developed;
- There must be shared accountability for outcomes and costs;
- Outcomes should be designed to engage patients and improve their health outcomes;
- The definition should evolve to align and engage all relevant parties to achieve optimal outcomes;
- The definition does not include contracts that are based on volume or share; and
- Terms and outcomes included in the contract are predetermined.

To ensure consistency in adoption and principles associated with VBC, the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) should consider promoting the definition and principles identified by the stakeholders assembled during AMCP's partnership forum.

Strategies for Advancing the Development and Utilization of Performance Benchmarks are Necessary

There must be trust among health care providers, payers, and manufacturers when entering into a VBC. All stakeholders must be able to build trust that the data will be shared and interpreted in a collaborative and unbiased manner. Strategic fit, both clinical and operational, for the entities involved, is also important for the success and sustainability of VBCs. Successful VBCs must be carefully designed to provide benefits to all parties (including the manufacturer, payer, and patient).

One of the greatest challenges with a VBC is selecting appropriate outcomes to measure and determining how much value to assign to various outcomes. Measure selection can quickly become highly complex and variable based on the medication, patient population, and expected outcomes. However, outcomes should be easily measurable, clinically relevant, and associated with financial and/or clinical improvements. Examples of outcomes that could be measures in VBCs include:

- Health care utilization rates (e.g. inpatient hospitalizations, observation stays, emergency department visits);
- Objective clinical endpoints (e.g. myocardial infarctions, cardiovascular composite endpoints, deaths);
- Cancer-free survival, progression-free survival;
- Cure rates;

- Adverse event rates;
- Laboratory values (e.g. hemoglobin A1c for patients with diabetes);
- Quality of life, activities of daily living (i.e. patient-reported outcomes);
- Medication adherence; and
- Medication persistence.

Best Practices for Evaluating, Implementing, and Monitoring VBCs Should be Identified

In addition to identifying benchmarks, VBC stakeholders must also identify data that will be used for validating whether the outcome is achieved. Factors to consider include the sources of data, how it will be collected, and how it will be analyzed. Once the sources of data are defined, stakeholders must agree on a process for aggregating and analyzing the data in a manner compliant with all state and federal laws. Developing the infrastructure necessary to perform these functions may require substantial resources, but this component of VBC implementation will become more efficient as the market matures.

VBCs that include outcomes that may take longer than a plan or calendar year will require accommodations. These could include outcomes that take several years to demonstrate, such as cardiovascular events in diabetics, when the patient may be enrolled in a different health plan, or treatments that require a large investment but that offer long-lasting benefits. Therefore, VBC timelines may need to be adjusted to account for these realities.

Changes to Safe Harbor Provisions of the Federal Anti-Kickback Statute and the Medicaid Best Price Rule are Essential for the Adoption of Value-Based Contracting

AMCP supports establishing a safe harbor provision that would encourage the development of additional VBCs for the Medicare and Medicaid populations. VBCs have emerged as a mechanism that payers may use to better align their contracting structures with broader changes in the health care system. Establishing a safe harbor for VBCs would help to remove the regulatory uncertainty that currently stands as an obstacle to broader adoption of VBCs. The safe harbor should include a wide range of services to not only address the current construct of VBCs, but also to encourage best practices for future innovation as new advancements in health care are introduced. Examples include but are not limited to interventions that improve medication utilization to promote better outcomes, mobile health products provided to the patient, and analytics related to the potential impact on outcomes and costs for certain patient populations. As another solution, the OIG could issue an opinion or guidance that VBCs do not invoke the Federal Anti-Kickback Statute or clarification of the requirements of the discount safe harbor that would help address this barrier.

The Medicaid Best Price program also creates roadblocks. Manufacturers are required to provide Medicaid programs with a rebate that is the greater of 23.1% of average manufacturer price (AMP) or AMP less the “best price” charged to a set of purchasers. If a VBC includes a large

discount or rebate for individuals who are considered treatment failures, the price paid for the treatment of an individual patient could set a new lowest best price, thereby increasing the rebate paid to all state Medicaid agencies. This requirement makes it challenging for manufacturers to write contracts in which they could potentially risk resetting their best price and increasing rebates paid for all Medicaid patients.

3. Introduce and Pass Legislation with Provisions from "Pharmaceutical information Exchange Act" (H.R. 2026 in the 115th Congress) to Create a Statutory Provision to Allow for Better Coverage Decision Making by Payers and Biopharmaceuticals Companies for Medications in the Pipeline

AMCP supported H.R. 2026 – The Pharmaceutical Information Exchange (PIE) Act of 2017 in the 115th Congress. The provisions of the bill will improve patient access to emerging medication therapies and devices by codifying a safe harbor for certain health care economic and scientific information communications between biopharmaceutical and medical device manufacturers and population health decision makers. We support the need for timelier and more proactive sharing of preapproval health care economic information (HCEI) between biopharmaceutical and medical device manufacturers and population health decision makers to enable the implementation of value-based contracts, aid in forecasting and budgeting, and expedite coverage decisions for emerging therapies, including those granted breakthrough designation. The need for this proactive communication is especially important now as the U.S. health care system evolves from a fee-for-service payment system to a modernized system rewarding quality, improved patient outcomes, and value. AMCP supported the Food and Drug Administration (FDA) guidance, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers [FDA-2016-D-1307]." That document recognized the importance of modernizing the provisions of the Food and Drug Administration Modernization Act (FDAMA) Section 114 as amended by Section 3037 of the 21st Century Cures Act (Cures) and the creation of a safe harbor for the exchange of preapproval communications. AMCP also appreciates that provisions in the final guidance document align with recommendations issued by AMCP through collaboration with other stakeholders.

Legislation such as the PIE Act would:

- Create a legal precedent to allow biopharmaceutical manufacturers to share proactively with population health decision makers truthful and not misleading clinical and economic information about medications and devices in the pipeline, as well as new uses of approved products, prior to FDA approval during the forecasting and rate setting process. Passing a law PIE will confirm that the proactive dissemination of certain information does not violate the prohibitions against preapproval promotion and does not run afoul of the labeling, misbranding, and intended use provisions of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

- Facilitate communication from biopharmaceutical manufacturers to an appropriate audience of population health decision makers who need this information for financial forecasting and planning purposes only.
- Extend PIE to investigational products not approved/cleared for any use and investigational uses of approved/cleared products for which there is an intent to file a supplement. The rationale for PIE applies equally to both. Factors such as product information, indication sought, clinical data, anticipated approval timeline, pricing information, targeting/marketing strategies and product related programs or services are unique to each indication. Anticipating a new indication and properly planning for the impact on budget and expansion of patient populations eligible to receive such medication or device are vital for population health decision makers.
- Allow for bidirectional exchange of information and sharing of health care economic or scientific information. Such information would include data from pivotal clinical trials, pharmacoeconomic data, as well as data relating to patient centered outcomes (health related quality of life, treatment satisfaction, etc.), and could also include other material items, such as anticipated indications, place in therapy, and routes of administration.

AMCP believes that furthering communications between biopharmaceutical and medical device manufacturers and population health decision makers prior to approval/clearance by the Food and Drug Administration (FDA) will help to shift the U.S. health care system to a focus on value and promote good outcomes for patients.

4. Recommendations from Recently-Published Proceedings on an AMCP Partnership Forum: "Designing Benefits and Payment Models for High-Investment Medications" Could Help Provide Better Policy Decisions for Coverage of Gene Therapies and Other Innovative and Specialty Medications

High-investment medications, such as gene therapy and innovative specialty medications, offer breakthrough treatments that can greatly improve outcomes to patients with serious health conditions. However, many of these therapies are associated with significant costs that create barriers to patient access and affordability. Such innovative treatments have higher short-term costs compared with current standards of care but are anticipated to deliver substantial benefits that may persist over a long period of time, such as reduced mortality, improved health and quality of life, reduced health care costs, improved productivity, and reduced disability.

The effect of these changes on patterns of treatment costs can vary significantly over time across payers. For example, the initial payer who covers a one-time treatment invests more resources than a payer that covers a cured enrollee later in life. Thus, high-investment medications raise questions about how costs are managed and distributed across systems and payers, including patients.

As more high-investment medications are approved, some stakeholders are concerned that the current system for managing these medications will become unsustainable. Innovative and novel

strategies are needed to support patient access to these new treatments, while addressing concerns about sustainability of the health care system in the United States.

To explore new benefit designs and payment models for high-investment medications, the Academy of Managed Care Pharmacy convened a stakeholder forum on July 24-25, 2018. Health care leaders representing academia, health plans, integrated delivery systems, pharmacy benefit managers, employers, national professional associations, the federal government, and biopharmaceutical companies participated in the forum. During the forum, participants engaged in thoughtful discussions regarding challenges and opportunities associated with innovative strategies for providing coverage for high-investment medications. The goals of the forum were as follows: (a) gain insights based on participants' unique perspectives on how the managed care ecosystem views high-investment medications for chronic versus curative diseases; (b) develop new solutions for benefit designs and overall value assessment for high-investment medications; (c) identify nontraditional contracting methods and reimbursement models to address high-investment medication challenges; (d) learn how to work with CMS and state Medicaid officials to garner support and coverage of these medications; (e) determine whether any legal or regulatory barriers exist for new types of benefit designs and look for opportunities to address those barriers; and (f) develop best case solutions of high-investment medications in order to overcome potential challenges and achieve sustainable appropriate use.

While consensus was not reached by all forum participants, broadly, the implementation of innovative payment models will require that stakeholders address legal and regulatory challenges, implement strategies that improve transparency, support access to real-world evidence, and strengthen industry partnerships. Enhanced preapproval information exchange, as discussed in Section 3 above, was identified as another avenue for improving management strategies. Manufacturer communications with payers about products in development allows payers to be better prepared to manage the products when they are approved. Participants discussed areas for which preapproval information would be helpful for payers during the development of coverage policies and programs. These areas included anticipated costs, patient populations, required ancillary services, and expected outcomes.

5. Congress Should Work with the Administration to Identify Legislative and Regulatory Changes that Promote the Development and Use of Safe, Efficacious and Equivalent Generic Drug and Biosimilars and Remove Barriers to New Market Entrants.

AMCP is particularly pleased by recent actions by FDA to promote value and access, including recent speeches focusing on the need for increased biosimilar and generic market competition.[8,9,10]

Increasing the development and adoption of biosimilar medications

AMCP has long-supported the development of an abbreviated licensure pathway for the approval of biosimilars. Biosimilars could have an increasingly important role in the country's health care system – both in terms of scientific improvements in the treatment of disease and reduced medication costs if the legal and regulatory infrastructure and market competition promote uptake and utilization. Currently, in the United States only 3% or $3.2 billion in biologic spending is attributed to market competition.[11]

A recent comment in the *New England Journal of Medicine* by economist Richard Frank suggests that a variety of legal, regulatory, payment policies and misunderstanding of biosimilars contribute to limit uptake and adoption.[12] Therefore, it is essential that FDA policies, payment systems, and other laws and regulations support the biosimilar market and do not discourage development by manufacturers. AMCP supports biosimilar competition with reference biologic products and therefore opposes any delays in this competition, including utilizing the FDA's Risk Evaluation and Mitigation Strategies (REMS) program to block the development of biosimilars, additional patents to prevent biosimilar competition, and the requirement that a biosimilar manufacturer must provide a 180-day notice to the reference product sponsor from the date of FDA approval before a commercial launch.

AMCP is concerned that proposed or final guidance documents released by FDA are hindering a robust biosimilars pathway in the United States. The final guidance, *Nonproprietary Naming of Biological Products*[13] establishes a framework to assign a random four-letter suffix for use in

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[8] Food and Drug Administration. Speech by Scott Gottlieb, MD, Commissioner of Food and Drugs. Capturing the Benefits of Competition for Patients (March 7, 2018). Available at: https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm. Accessed February 27, 2019.

[9] Food and Drug Administration. Remarks by Scott Gottlieb, MD, Commissioner of Food and Drugs. Advancing Patient Care Through Competition (April 19, 2018). Available at: https://www.fda.gov/NewsEvents/Speeches/ucm605143.htm. Accessed February 27, 2019.

[10] Food and Drug Administration. Speech by Scott Gottlieb, MD, Commissioner of Food and Drugs. Keynote Address by Commissioner Gottlieb to the 2018 FDLI Annual Conference (May 3, 2018). Available at: https://www.fda.gov/NewsEvents/Speeches/ucm606541.htm. Accessed February 27, 2019.

[11] IQVIA Institute for Human Data Science. Medicines use and spending in the U.S.: a review of 2016 and outlook to 2021. May 2017.

[12] Frank RG. Friction in the Path to Use of Biosimilar Drugs. N Engl J Med. 2018;378(9):791-793.

[13] FDA. Guidance for Industry Nonproprietary Naming of Biological Products. January 2017. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf, Accessed February 27, 2019.

conjunction with the international nonproprietary name (INN) both prospectively for all biosimilar products and retrospectively for all currently marketed biologic reference products. Healthcare providers in the United States are accustomed to and trained to refer to medications that share the same active ingredient by the INN. The purpose of utilizing the same INN is to identify products with the same active ingredient and similar efficacy and safety profiles even when slight differences in pharmacokinetic and pharmacodynamic profiles exist.

The establishment of a unique suffix for biological reference products and biosimilar products may be interpreted to indicate that biosimilar products have substantially different safety and efficacy profiles and therefore may not be substituted or interchanged.[14] These perceived differences may cause patients and health care providers to not use, prescribe, or dispense these products because of concerns over safety and efficacy. If this situation occurs, particularly with early approvals of biosimilars, it could have a chilling effect on the success of biosimilars for years to come. FDA must address the potential unintended consequences and unnecessary challenges that arise from the naming guidance. Therefore, AMCP recommends reconsideration of the naming conventions for biologic and biosimilar products.

AMCP also supports revision or recession of an FDA draft guidance on determining whether a biosimilar is interchangeable with the reference product.[15] AMCP believes that the existing guidance should be substantially changed to promote interchangeability without unnecessary burdens on sponsors. To this end, FDA should re-consider its use of bridging studies and permit the use of studies outside of the United States. A 3-way clinical bridging study adds $5-10 M in additional costs.[16] Due to the multiplier effect of required repetition of these comparative studies by each biosimilar applicant and for the same US-licensed reference product, the collective costs are substantial. Given these burdens associated with the current interchangeability guidance, AMCP recommends FDA revise or rescind the existing draft guidance or allow for stakeholders to provide additional comments on ways to better-achieve interchangeability without unnecessary burden.

The interchangeability designation is important, because many state laws governing pharmacist substitution rely on the FDA's determination of a product's interchangeability as a minimum

[14] 42 USC §262(k)(4)(A) - To be approved as an interchangeable in the United States, in addition to the requirements to demonstrate biosimilarity, the biosimilar product must also produce the same clinical result as the reference product in any given patient, and the risk in terms of safety or diminished efficacy between alternating or switching between use of the reference product and the biosimilar is not greater than the risk of continuation with the reference product. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

[15] FDA. Draft Guidance for Industry: Considerations in Demonstrating Interchangeability with a Reference Product, January 2017. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf Accessed February 27, 2019.

[16] Webster, C. J., Woollett, G. R. (2017). A "Global Reference" Comparator for Biosimilar Development. *Biodrugs*, *31*(4), 279–286. Available at: http://doi.org/10.1007/s40259-017-0227-4. Accessed February 27, 2019.

standard for substitution. Unfortunately, several states have already enacted legislation that would place additional burdens on pharmacists that wish to substitute a biosimilar that has been deemed interchangeable by the FDA. AMCP also recommends that the Administration and the HHS encourage state legislatures and state boards of pharmacy to amend or rescind any notification requirement for pharmacists. These laws and regulations require pharmacists to notify prescribers prior to the substitution of interchangeable biosimilars and are in stark contrast to state laws that allow (or sometimes require) pharmacists to substitute generic small-molecule drugs when one is available. These notification laws are premature, since the FDA has yet to finalize guidance concerning interchangeability or approve a biosimilar product as interchangeable. Furthermore, these requirements act as an unnecessary barrier to the adoption of biosimilars that could discourage manufacturers from investing in their research and development.

AMCP encourages HHS, CMS, FDA, and other relevant agencies to work collectively to harmonize regulations and guidance to promote adoption of biosimilars in the United States.

AMCP Activities to Promote Biosimilar Adoption

To support post-marketing surveillance of biologics and biosimilars, in 2015, AMCP launched the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC). BBCIC is a nonprofit, scientific public service initiative that monitors biosimilars and corresponding novel biologics for effectiveness and safety to provide assurances that physicians and patients need to confidently prescribe, dispense and use biologics and biosimilars. BBCIC is the only research network dedicated to monitoring biosimilars and biologics and draws on large sets of deidentified medical and pharmacy data to harness cutting-edge distributed research network and surveillance methods.[17]

AMCP also understands the importance of educating pharmacists, physicians, nurses and other health care providers on biosimilars to improve understanding and confidence in their safety and effectiveness. To help address this need, AMCP launched a Biosimilars Resource Center (BRC), an unbiased, policy-neutral repository of educational resources and information on biosimilars. The site was developed in partnership with leading national pharmacy organizations and can be accessed at the BRC.

AMCP also supports the release of final guidance allowing payors and manufacturers to communicate health care economic information prior to FDA approval of a product.[18] FDA's

[17] BBCIC *Ibid* at 7.

[18] Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities — Questions and Answers: Guidance for Industry and Review Staff. Food and Drug Administration; June 2018. Available at:

action is an important step toward greater value and greater access for patients to emerging and breakthrough drug therapies. The FDA's guidance also represents significant progress in the move toward adopting value-based health care models, which require payer access to better and timelier information during the decision-making process. The preapproval communications identified in this final guidance may be more widely adopted by the passage and the *The Pharmaceutical Information Exchange Act* (see above).

AMCP Supports Efforts Curb the Inappropriate Use of Shared System Risk Evaluation and Mitigation Strategy (REMS) to Deter Generic Entry

AMCP agrees with FDA Commissioner Scott Gottlieb that the REMS requirements, while protecting patient safety, can also be leveraged by manufacturers to deter generic entry into the market. One method that such companies have utilized to stop generic and biosimilar competition is to assert that the REMS program allows them to deny samples. In fact, FDA Commissioner Scott Gottlieb wrote, "We see problems accessing testing samples when branded products are subject to limited distribution . . . in some cases, branded sponsors may use these limited distribution arrangements, whether or not they are REMS – related, as a basis or blocking generic firms from accessing the testing samples they need.[19]" Secretary Azar recently stated that "we know that certain brand-name manufacturers are abusing the system by blocking access to samples and hiding behind FDA's rules when they do it.[20]" This problem is growing and patient access to safe and affordable generic and biosimilar medication is being unnecessarily delayed.

AMCP strongly supports S. 340 and H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act," bipartisan legislation to increase competition and patient access to safe and affordable generic and biosimilar medicines.

The opposition to this legislation has argued that this legislation will endanger patient safety. It should be noted that generic drug developers are already required to adhere to safe handling and other procedures that protect patient safety, and this applies every time brand companies permit the sale of samples for generic drug development. This legislation would simply close an existing loophole.

With nearly nine out of ten Americans (87%) in favor of "making it easier for generic drugs to come to market in order to increase competition and reduce costs"[21] and 50 health care

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https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf. Accessed February 27, 2019.

[19] FDA Voice, FDA Working to Lift Barriers to Generic Competition by Scott Gottlieb, M.D. June 21, 2017. Available at: https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612018.htm. Accessed February 27, 2019.

[20] Prepared Remarks on Drug Pricing Blueprint by Alex M. Azar II, May 14, 2018. Available at: https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html. Accessed February 27, 2019

[21] Kaiser Family Foundation, "Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs," May 2017.

stakeholders representing diverse interests including physicians, patients, health plans calling for congressional action to provide "generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors,"[22] support for this legislation continues to increase.

To ensure that the practices of a handful of brand companies that prevent generic drug developers from obtaining samples necessary to bring new accessible generic and biosimilar drugs to patients and payors, Congressional action is imperative. The CREATES Act would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics.

6. **Prior Authorization is An Essential Tool to Optimize Patient Outcomes while Reducing Waste, Error, Unnecessary Prescription Drug Use, and Overall Costs;**

Formularies that Include prior authorization (PA) and utilization management (UM) are widely used by managed care organizations (MCOs), including health plans and pharmacy benefit management companies. UM criteria are essential to optimizing patient outcomes and reducing waste, error, unnecessary drug use and cost.

Effective PA is an evidence-based process to ensure that plan members receive the medication therapy that is safe, effective for their condition, and provides the greatest value. PA may also be referred to as a "coverage determination," as under Medicare Part D. Requiring prior authorization in a pharmacy benefit can effectively help avoid inappropriate medication use and promote the use of evidence-based medication therapy. In a time when the rising cost of health care is a concern for both public and private insurers, efficient and effective use of health care resources can minimize overall medical costs, improve health plan member access to more affordable care and provide an improved quality of life.

Guidelines and administrative policies for PA are developed by pharmacists and other qualified health professionals. Each managed care organization develops guidelines and coverage criteria that are most appropriate for their specific patient population and makes its own decisions about how they are implemented and used. AMCP supports the NCPDP SCRIPT standard-based electronic Prior Authorization (ePA) which reduces health care costs, improves patient and prescriber experience and provides real-time responses.

CMS recognizes the importance of PA and is providing Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs in a way that lowers costs and improves the quality of care for Medicare beneficiaries. MA plans will have the choice of implementing step therapy to manage Part B drugs, beginning January 1, 2019 as part of broader care coordination activities that include patient rewards and incentives.[23] Generally,

[22] https://www.csrxp.org/wp-content/uploads/2019/02/FINAL-CREATES-Act-2.5.19.pdf. Accessed February 27, 2019.
[23] CMS, Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. Available at: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf

AMCP supports the addition this provision to allow greater management of Part B medications through MA plans. The flexibility to implement well-designed, evidence-based utilization management tools optimizes patient outcomes by ensuring that patients receive the most appropriate medications while reducing waste, errors, adverse effects, and unnecessary prescription drug use and cost. AMCP believes that after CMS provides further clarification, including allowing sufficient time for implementation, this change is a positive step to balance affordability and accessibility of Part B covered products.[24]

7. Employing Greater use of Health Information Technology (health IT) to Improve Patient Care and Lower System Costs

Managed care pharmacy has developed a broad range of innovative and integrated strategies using state-of-the-art technology to effectively manage prescription benefits for given patient populations. Industry standards have been developed, adopted for electronic prescribing, and are being utilized in a protected environment that allows access to and the use and protection of patients' health records in a productive and efficient manner. Technology for accurate dispensing has been adopted in most pharmacy settings. The further implementation of standards for interoperability of electronic health records and electronic prescribing offers opportunities not only to improve patient care, but also to combat fraud, waste and abuse within the health care system.

Integrated health IT systems can encourage the use of evidence-based clinical guidelines. Interoperable electronic prescribing systems can also help health plans and law enforcement monitor and share information regarding potentially fraudulent activity, or suspected abuse or drug diversion activities. At a time when some estimate that inappropriate or unnecessary care, fraud, and abuse account for almost one- third of overall health spending, health IT offers opportunities to reduce health care costs without reducing the quality of care.

Electronic Health Records (EHRs)

CMS has recognized the value of technology in the provision of medical care via its adoption of standards and its promotion of the use of electronic health records. EHRs have been shown to reduce errors through computerized prescriber order entry (CPOE) systems and lower costs due to reduced paperwork and fewer duplicate treatments and tests. Patient safety is improved as such systems facilitate the management of chronic conditions. Electronic transmission of prescription information offers benefits over written and oral prescriptions in terms of accuracy, storage capacity, accessibility, security, and productivity.

Accessed February 27, 2019.

[24] AMCP, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS-4180-P]. January 25, 2019. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=24180. Accessed February 27, 2019.

Benefits of electronic prescriptions include the reduction of errors due to misinterpretation of handwritten prescriptions, confusion between similarly sounding drug names during oral transmission of prescription orders, and order-entry errors. Electronic prescribing systems alert prescribers to potentially harmful drug interactions, patient drug allergies, and duplicate or overlapping drug therapy, enabling the prescriber to adjust the prescription before the pharmacy dispenses the drug. Electronic prescribing systems can also allow prescribers to access the formulary for a patient's prescription drug benefit, ensuring that they select a therapy for which the patient has coverage, in addition to any clinical edits that may be present.

Dispensing Systems Technological advances have led to the development of innovative systems for automated drug counting, labeling, filling and delivery of prescription orders. The use of these systems is accepted as standard practice in community, hospital, and mail order pharmacies. Automated systems for dispensing allow the pharmacist to participate in appropriate medication selection and management of positive patient outcomes.

AMCP supports the adoption and use of national standards that promote system interoperability among providers and payers, and the use of requisite sets of functional elements necessary for optimizing medication access, safety, and cost-effective utilization. Such standards have been developed to protect patient confidentiality and assure the accuracy and completeness of every transmission and record. The use of information systems and technology advance productivity, improve customer satisfaction, and allow pharmacists to concentrate on clinical outcomes. Patients are the ultimate beneficiaries of these technological Concerns with Prescription Drug Importation and Direct Government Negotiation of Prescription Drug Prices

8. General Concerns with Legislation or Potential Legislation on Rebates for Pharmaceutical Products, Prescription Drug Importation and Direct Government Negotiation of Prescription Drug Prices.

Rebates for Pharmaceutical Products

On January 31, 2019 HHS released a proposed 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 Management Service Fees* to expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans and Medicaid managed care organizations. This would effectively eliminate negotiated rebates for pharmaceuticals under Medicare Part D and managed Medicaid programs. AMCP believes that focusing only on rebates is a diversion from coming up with real solutions to lowering drug costs. The rebate system is the model currently in place, and it's unclear what would replace this important lever that payers now use to lower drug costs for millions of Americans. The HHS proposal suggests that prices would automatically fall in the absence of rebates, but we think this is unrealistic. We

believe in a competitive marketplace that allows payers to negotiate prices with manufacturers to ensure lower overall costs for consumers. Any new system must include the use of proven managed care pharmacy levers, such as formularies and utilization management tools, to help people get the right medications, at the right time and at the right cost. AMCP suggests that the Congress delay consideration of legislation that will potentially apply rebates to commercial markets until comments to the regulatory docket have been considered and the potential implications fully considered. AMCP will provide comments to the docket and is happy to forward these comments to the committee for further consideration.

Prescription Drug Importation

AMCP has concerns with legislative proposals that would allow the commercial importation of prescription drugs for sale in the United States. We understand such proposals are being offered to address the growing inaccessibility to affordable prescription drugs; equalize global pricing disparities; and encourage the international community to share reasonably in the costs of pharmaceutical research and development. However, as an organization representing health care professionals, AMCP cannot support these proposals until there are adequate resources to monitor the importation of prescription drugs, ensuring that their quality and safety have not been compromised.

Generally, legislative language related to importation would allow pharmacies and drug distributors to purchase FDA-approved pharmaceuticals for sale in the United States from other countries such as Canada. The rationale behind such proposals is to use the international pharmaceutical market as a source of low-cost prescription drugs. AMCP supports the goals of improving access to prescription drugs at lower prices and reducing overall health care costs. Subject to acceptable provisions held in place, the general populace could benefit from the importation of prescription drugs for sale insofar as such legislation makes it possible for the consuming public to purchase prescription drugs at a cost lower than what is asked today.

However, the anticipated savings generated through importation programs is uncertain. Several factors may influence whether significant savings will be realized from the importation of prescription drugs. How the import price compares with domestic price will vary depending on the specific drug. For example, while certain brand-name (innovator) products sold in Canada have been shown to be priced considerably lower than in the United States, the price differential of other drugs, particularly generics, are minimal.

Such a program will also depend on the foreign availability of the product. Foreign supplies of domestically produced drugs may be inadequate to support large-scale importation, thus limiting the potential savings available to American consumers. Moreover, how the importation might affect the exporting country's pharmaceutical market, such as drug shortages or drug price increases, must be considered.

Finally, savings may not be fully realized because of the additional cost manufacturers must assume for significant importation, such as registration fees, the transporting of products, and investments in technology to secure the supply chain. The impact importation legislation would have on the drug distribution system warrants study, as allowing importation may pose unintended financial and health consequences for American consumers.

Government intervention in the marketplace may result in increased overall consumer prices, increased numbers of uninsured, and decreased pharmaceutical innovation. Allowing the importation of pharmaceuticals may result in these negative effects and bring downstream cost-shifting by manufacturers to compensate for lost profits. Legislation permitting prescription drug importation also presents potential patient safety issues. For instance, quality and integrity cannot be assured with reimported products and implementing any appropriate safeguards addressing these concerns is a challenge. Prudent importation legislation must ensure maintenance of quality assurance standards throughout the international drug distribution system.

In order to guarantee patient safety, agencies such as the FDA, the U.S. Customs and Border Protection, and the U.S. Immigration and Customs Enforcement must have the technological and financial resources to address these safety concerns. Until more conclusive data are available as to the likely impact of importation on the cost of drugs and the risks posed to the American citizens, AMCP will oppose legislation that would allow the importation of prescription drugs in the United States.

Direct Government Negotiation of Drug Prices

AMCP is concerned that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care benefits. Regulated prices may cause cost- shifting to other consumers and may inadvertently discourage appropriate drug prescribing, dispensing and utilization.

The negative consequences of government intervention in the pharmaceutical marketplace have been illustrated by the best price provisions of the Medicaid prescription drug rebate program, which required manufacturers to provide large rebates to state Medicaid programs.[25] In response to the legislation, drug manufacturers attempted to recoup their lost profits in the government-regulated market by charging more to consumers in other unregulated markets and gradually raising prices to all markets over time. As a result, well-organized commercial purchasers such as health maintenance organizations (HMOs) and group purchasing organizations (GPOs), as well as public purchasers such as the Veterans' Administration (VA) and the Department of Defense (DOD), experienced price increases.[26] Drug cost increases could result in higher health insurance premiums, increased consumer co-pay or co-insurance requirements, and reduced or

[25] Established by the Omnibus Reconciliation Act of 1990 (OBRA '90) (P.L. 101-508).
[26] See also AMCP's Where We Stand on the Best Price Requirements of the Medicaid Rebate Program. Available at: www.amcp.org/positionstatements. Accessed February 27, 2019.

eliminated pharmacy benefits. Most importantly, employers and individuals may be forced to discontinue their health care insurance altogether, pushing consumers into public health programs (such as Medicaid or Medicare) or publicly subsidized health insurance coverage options, increasing costs to taxpayers.

Government-regulated prices could greatly impair the ability of MCOs to design a competitive benefit offering that integrates clinically sound, evidence- based medication choices with delivery systems and co-payment alternatives that provide beneficiaries with substantive choice. MCOs have developed formulary systems alongside prudent purchasing practices to encourage appropriate drug prescribing, dispensing and utilization. As outlined in the consensus document Principles of a Sound Drug Formulary System[27], formulary systems are complex structures that are dependent on a variety of components whose interactions result in patients having access to the medications they need in an affordable manner. Prescription drug prices which are regulated by the government would inappropriately separate therapeutic evaluations of a drug from cost-effectiveness considerations. For example, the government could mandate or negotiate a low price for a prescription drug which a MCO may have decided to leave off their formulary for safety reasons. If the product is publicly listed as the lowest-cost drug in its therapeutic class, however, MCOs may have no alternative but to add the medication to formulary based on public and government-driven demand. In therapeutic classes with multiple acceptable treatment alternatives, MCOs are also able to use formulary placement to move market share, giving the MCO leverage when negotiating price discounts with manufacturers. Government- regulated prices could eliminate the manufacturer's motivation to negotiate, resulting in increased costs and decreased quality of benefit coverage and services.[28]

Legislators may also be tempted to regulate prescription drug prices at the retail level. While legislation that would regulate retail-level drug prices, such as controlling the amount a pharmacy could charge a customer at the point-of-sale, may generate a short-term savings to the self-paying customer, it could result in fewer pharmacies staying in business, reduced competition among retail pharmacies and reduced access to pharmacy services. As the number of retail pharmacies decreases, the remaining pharmacies will gain negotiating power, driving up the cost of services to MCOs.

Government regulation of prescription drug prices may also jeopardize the research and development of new pharmaceutical products. Government-regulated prices could dampen innovation due to costly research and development. Fewer pharmaceutical products could result in increased utilization of more costly and risky therapies, such as surgery and hospitalizations.

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[27] Principles of a Sound Formulary System, consensus document endorsed by AMCP, Alliance of Community Health Plans, American Medical Association, American Society of Health-Systems Pharmacists, Department of Veterans' Affairs, Pharmacy Benefits Management Strategic Healthcare Group, National Business Coalition on Health, U.S. Pharmacopeia (October 2000). Available at: www.amcp.org. Accessed February 27, 2019.

[28] See also AMCP's Future of Medicare Part D: Reliance on Medicare Part D Plan Sponsors to Negotiate Prices with Pharmaceutical Manufacturers. Available at http://www.amcp.org/Sec.aspx?id=8620, and AMCP's Where We Stand on Formularies. Available at www.amcp.org/positionstatements. Accessed February 27, 2019.

The net result, again, could be an increase in costs and insurance premiums and a decrease in health care quality. In addition to the negative impact on the health care industry, reduced pharmaceutical research & development could impact our global balance of trade, since the U.S. is the world's major exporter of drugs, and could impact other related industries, such as agriculture and chemicals.

Past government intervention has resulted in increased pharmacy pricing for many consumers. Legislation that would allow the government to regulate prescription drug prices, though well intentioned, could result in increased costs for many consumers in the short term and for all in the long term. Government-regulated prices may ultimately increase the number of uninsured and decrease quality of care, exacerbating the very problem that these pricing laws are intended to solve.

9. AMCP's Peer-Reviewed *Journal of Managed Care and Specialty Pharmacy* (JMCP) Should be Considered a Resource for Research in Managed Care Pharmacy

JMCP publishes peer-reviewed original research manuscripts, subject reviews, and other content intended to advance the use of the scientific method, including the interpretation of research findings in managed care pharmacy. *JMCP* is dedicated to improving the quality of care delivered to patients served by managed care pharmacy by providing its readers with the results of scientific investigation and evaluation of clinical, health, service, and economic outcomes of pharmacy services and pharmaceutical interventions, including formulary management. *JMCP* strives to engage and serve professionals in pharmacy, medicine, nursing, and related fields to optimize the value of pharmaceutical products and pharmacy services delivered to patients. The editorial content is determined by the Editor-in-Chief with suggestions from the Editorial Advisory Board and the views and opinions do not necessarily represent official policy of AMCP or its authors unless specifically stated.[29]

As an example of content that might provide insight to the HELP Committee on topics in the RFI, in 2018, AMCP awarded a peer-reviewed article titled, *Using Performance-Based Risk-Sharing Arrangements to Address Uncertainty in Indication-Based Pricing* with the JMCP Award for Excellence.[30] This is one example of the types of articles available through a search of JMCP's table of contents. AMCP is willing to share additional articles with you and committee staff.

[29] Journal of Managed Care Pharmacy website. Available at: https://www.jmcp.org/. Accessed February 27, 2019.
[30] AMCP Awards Program. Available at: http://www.amcp.org/Awards/. Accessed February 27, 2019.

AMCP looks forward to continuing work with Congress on these issues. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Government Affairs, Chris Topoleski at ctopoleski@amcp.org and can be reached at 703-684-2620.

Sincerely,

Susan A. Cantrell. RPh, CAE

Chief Executive Officer