



Academy of
Managed Care
Pharmacy®

July 16, 2018

The Honorable Alex Azar
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

**RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs
[RIN 0991-ZA49]**

Dear Secretary Azar:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to provide comments in response to the Department of Health and Human Services' (HHS's) request for information on the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs [RIN 0991-ZA49]* (Blueprint). 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, the Academy'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 the Administration's concern about the rising costs of medications and the impact on patients, payers, and providers. In 2017, AMCP identified three key areas where AMCP member pharmacists, physicians, and nurses 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 identified in the Blueprint. AMCP and its members stand willing to collaborate with HHS, Congress and other agencies within the federal government as well as states, commercial payers, providers, and patient organizations to identify solutions to combat the rising cost of medications.

AMCP also cautions HHS and other agencies to proceed cautiously before making substantial changes to existing programs, including shifting coverage of medications from Medicare Part B to Part D and eliminating the ability of Medicare Part D plans to collect rebates. The full implications to patients and the health care and distribution systems must be carefully considered and tested prior to implementation.

The key points of our comments are as follows:

- Overview of AMCP's proactive initiatives and areas that align with issue areas identified in the Blueprint and areas of future opportunities for proactive initiatives;

- HHS should consider pharmacists as key stakeholders in improving patient outcomes and managing medication costs;
- CMS should carefully consider ways to effectively manage medications in Part B, transition coverage of select medications from Part B to Part D and carefully evaluate the impact of beneficiary out-of-pocket costs, access to care, and Medicare Advantage;
- Part D plans should have full formulary flexibility to manage high-cost medications, including the classes of clinical concern;
- CMS should adopt the Medicare Part D formulary coverage policy as proposed in the President's FY2019 budget;
- AMCP supports efforts to curb the inappropriate use of shared system Risk Evaluation and Mitigation Strategy program (REMS) to deter generic entry;
- Food and Drug Administration (FDA) policies should promote biosimilar development and adoption;
- Stakeholder collaboration and a reexamination of current policies are needed to encourage VBC, including the need for a common definition of VBC, best practices, and legal and regulatory infrastructure to support VBC;
- AMCP's Peer-Reviewed *Journal of Managed Care and Specialty Pharmacy* (JMCP) should be considered a resource for research in managed care pharmacy.

Blueprint Objectives Align with Recent FDA Activity Promoting Increased Market Competition and Payor and Manufacturer Communications about Medications to Promote Value-Based Care

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.^{1,2,3} 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.⁴ FDA's 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 adoption of *The Pharmaceutical Information Exchange Act* (PIE) (H.R. 2026).

¹ Food and Drug Administration. Speech by Scott Gottlieb, MD, Commissioner of Food and Drugs. Capturing the Benefits of Competition for Patients (March 7, 2018). <https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm>. Accessed July 6, 2018.

² Food and Drug Administration. Remarks by Scott Gottlieb, MD, Commissioner of Food and Drugs. Advancing Patient Care Through Competition (April 19, 2018). <https://www.fda.gov/NewsEvents/Speeches/ucm605143.htm>. Accessed July 6, 2018.

³ 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). <https://www.fda.gov/NewsEvents/Speeches/ucm606541.htm>. Accessed July 6, 2018.

⁴ 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. <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf>. Accessed July 6, 2018.

AMCP Multi-Stakeholder Partnership Forums and Consensus Recommendations May Help to Drive Consensus on Areas Suggested in the Blueprint

AMCP regularly convenes stakeholder Partnership Forums⁵ 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 communications⁶; the development of AMCP-led Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) that drives active post-marketing surveillance for biologics and biosimilars⁷; and recommendations for VBC adoption, including promotion of a common definition and recommendations for measurement and performance to ensure quality in VBCs.⁸ Recommendations from several of these forums, including biosimilars and VBC, are included in areas of these comments. In late July, AMCP will be hosting a Partnership Forum titled *Designing Benefits and Payment Models for Innovative High-investment Medications* and AMCP will provide additional comments to the docket when these recommendations are approved by the stakeholders. AMCP may also use partnership forums and other stakeholder engagements to consider the issues associated with utilization management in the Medicare Part B program and potentially other areas identified in the Blueprint.

HHS Should Consider Pharmacists as Key Stakeholders in Improving Patient Outcomes and Controlling Medication Costs

Pharmacists are an important member of the health care team who serve as the medication management experts to help patients achieve clinical goals, reduce overall health care costs, and improve patient satisfaction.⁹ Pharmacists' training and expertise support their role as leaders to develop and implement care plans through medication therapy management and collaborative drug therapy management agreements. Through the delivery of patient care services, pharmacists, in collaboration with physicians, nurses, other health care providers and patients, provide valuable ongoing, comprehensive assessment and management of drug therapy resulting in improvement in quality of care, achievement of patient specific clinical outcomes, and reduction in overall costs of care.

Pharmacists and the team-based approach to health care play an integral role in the successes demonstrated in Medicare Part D and the commercial market, including in the areas of benefit design strategies, medication therapy management, and case management for mental health conditions and opioids. Therefore, AMCP strongly encourages HHS to include pharmacists as key stakeholders in improving patient outcomes and controlling prescription drug costs through a collaborative approach to medication management.

⁵ AMCP Partnership Forums. <http://www.amcp.org/Tertiary.aspx?id=22438&terms=partnership%20forums>. Accessed July 6, 2018.

⁶ *Ibid.*

⁷ Biologics and Biosimilars Collective Intelligence Consortium. <http://www.bbcic.org/>. Accessed July 6, 2018.

⁸ Academy of Managed Care Pharmacy Partnership Forum: Advancing Value-Based Contracting. JMCP 2017 Nov; 23(11), pp. 1096-1102. Accessible here: www.jmcp.org/doi/pdf/10.18553/jmcp.2017.17342. Accessed July 6, 2018.

⁹ Pharmacists: One the Front Lines – Addressing Prescription Opioid Abuse and Overdose. Centers for Disease Control and Prevention; Cochran, G et al. Medicaid prior authorization and opioid medication abuse and overdose. *Am J Manag Care*. 2017;23(5):e164-e171; Reynolds, V et al. The role of pharmacists in the opioid epidemic: an examination of pharmacist-focused initiatives across the United States and North Carolina. *North Carolina Medical Journal*. 2017; 78(3); 202-205.

CMS Should Carefully Consider Ways to Effectively Manage Medications in Part B, Transition Coverage of Select Medications from Part B to Part D and Consider the Impact of Beneficiary Out-of-Pocket Costs, Access to Care, and Medicare Advantage

AMCP is pleased to see a commitment by HHS and the Centers for Medicare and Medicaid Services (CMS) to evaluate methods to move from quantity and process-oriented payment systems for medications covered by Medicare Part B to payment policies focused on rewarding higher quality and improved patient outcomes. When considering a potential shift of medications from Medicare Part B to Part D, AMCP recommends that HHS consider specific disease states that are prevalent in the Medicare population that have multiple therapies available with non-significant differences in clinical benefit but significant differences in cost of therapy, such as the treatment of age-related macular degeneration. In addition, CMS should consider disease states and medication categories where biosimilars are entering the marketplace, such as psoriasis, rheumatoid arthritis, and white blood stimulants. Some products that CMS may consider shifting to Medicare Part D include injected or infused medications that are regularly self-administered by a patient or have some coverage under Medicare Part D already, such as immunosuppressants. CMS's approach to payment structure changes should consider the total health care needs of the patient and ensure that mechanisms are in place to consider medical costs associated with the changes. Any changes should be considered in tandem with changes to physician payments under Medicare. AMCP also recommends that CMS consider comments and concerns submitted by patients, payers, and providers to the 2016 docket, *Medicare Program; Part B Drug Payment Model* (CMS-1670-P) as part of any plans to change payment methodology under Medicare Part B or to shift coverage of certain medications from Part B to Part D.

Specifically, CMS should also evaluate unintended consequences to beneficiaries, such as decreased access to care or a reduction in the quality of care provided. AMCP believes it is critical for CMS to have mechanisms in place to not only measure successes from any benefit changes, but also to measure any negative consequences that arise from the changes and to have a system in place to suspend the changes if harms to beneficiaries are identified. Supplemental insurance is available, and widely used, by Medicare beneficiaries for cost-sharing obligations under Parts A and B, but it is not applicable to Medicare Part D. Beneficiary out-of-pocket costs could therefore be greatly impacted, even if their access to care is not impacted. A sharp increase in out-of-pocket costs could also lead beneficiaries to not seek care. Therefore, AMCP strongly encourages CMS to include a mechanism for monitoring unintended consequences to beneficiaries and a strategy for suspending the changes, in part or in their entirety, if beneficiary harms are identified.

Any plan should also address the issue of Medicare Advantage, which covers approximately one-third of Medicare beneficiaries. Any changes in benefit design should also adjust Medicare Advantage benchmarks, as they are likely to decrease in correlation with Part B drug costs if expected savings are realized.

AMCP Specific Recommendations on Implementing Utilization Management in Medicare Part B

Create an Allowance for Formularies and Utilization Management Tools in Medicare Part B

Currently, the Medicare Part B statute and CMS regulations do not allow for the use of pharmacy and therapeutics (P&T) committees established by health plans and pharmacy benefit managers to develop formularies for Medicare Part B or allow for the use of utilization management tools. P&T committees and utilization management that have been key to the success in decreasing costs, improving quality, and increasing value in Medicare Part D and the commercial market. Use of health plan or PBM-established formularies and allowance for utilization management tools are necessary for the success of initiatives to improve outcomes and lower costs.

AMCP supports the use of well-designed and evidence-based formularies that enhance the quality of pharmaceutical care while lowering medication costs. A formulary is a continually updated list of prescription medications that represents the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. Formularies often contain additional prescribing and clinical information that assist health care professionals as they promote high quality, affordable care to patients. Generally, a formulary is developed and maintained by a P&T Committee comprised of physicians, pharmacists, and other health care professionals, that meets regularly to review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience and economic data, and provide recommendations to determine which drugs are the safest, most effective, and produce the best clinical outcomes. Since a formulary is dynamic and continually revised document, the P&T Committee regularly evaluates the formulary and adjusts it to reflect the best medical practices, newly marketed medications, and new clinical and economic evidence that may have an impact on which medications are included or excluded.

Furthermore, implementation of well-designed, evidence-based utilization management tools, such as prior authorization and step therapy, optimizes patient outcomes by ensuring patients receive the most appropriate medications while reducing waste, errors, adverse effects, and unnecessary prescription drug use and cost. Utilization management tools and requirements for coverage are based on clinical need, therapeutic rationale, and the desired outcome for the patient. Studies show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, better patient adherence to the treatment plan, fewer adverse side effects, and better overall outcomes. Such efficient and effective use of health care resources helps to keep overall medical costs down, improves the consumer's access to more affordable care, and provides the patient with an improved quality of life.

Lowering costs and improving outcomes in Part B relies on the use of formularies and utilization management tools, which have been successful in the commercial market and in Medicare Part D.

Changes to the System Must Incorporate Identifiable Metrics to Evaluate Value and Outcomes

Release of detailed quality metrics and patient outcomes that will be used to determine what constitutes ultimate success is critical to outline in advance of any proposed changes. Quality metrics used in this model should be based on existing metrics proven to improve outcomes and

not rely on process-based measures. Therefore, AMCP strongly encourages CMS to release detailed plans to evaluate success in the model and the clinical endpoints (such as quality of life, patient-reported outcomes, and survival rates) that it is striving to achieve.

Require Documentation of Part B Drug Claims Using National Drug Codes (NDC)

A current barrier to accurately evaluating product use and identification under Part B is the current method of documenting drug claims using Healthcare Common Procedure Coding System (HCPCS) codes rather than national drug codes (NDCs). The ability to track a medication administered to the specific NDC number is critical to truly implement new payment models as they are used today in Medicare Part D and in the commercial market. Documentation of NDCs will allow for specific data analysis and meaningful assessment that can be actioned. Therefore, AMCP strongly encourages CMS to require documentation of the NDCs on all Medicare Part B claims. In the final rule “*Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016*,”¹⁰ CMS noted that it will be developing an approach for using manufacturer-specific modifiers, such as NDC numbers, on Part B claims. AMCP strongly urges CMS to move forward with development of this process to require NDCs on all Part B claims to allow for meaningful assessment of changes to Part B payment.

Use A Comprehensive Approach to Develop Evidence-Based Clinical Practice Guidelines

AMCP supports a comprehensive and holistic evaluation by P&T Committees and providers of all the existing evidence, including the use of various methodologies such as comparative effectiveness research (CER), real world evidence (RWE), pharmacoeconomic information, and other value frameworks. AMCP does not support the endorsement of one framework or clinical practice guideline, but rather CMS should support medication product selection by P&T Committees and providers using the totality of the evidence.

Evaluate Potential Market Shifts and Impact to Overall Costs

As noted above, AMCP cautions CMS to carefully consider how changes may result in a market shift of costs from Medicare Part B to other payment areas and care settings with greater costs. For example, costs may shift to Medicare Part D should providers opt to cease maintaining an inventory of specific medications for office administration and instead advise patients to purchase the drug from a pharmacy pursuant to a prescription and return to the office with the medication for administration. Alternatively, costs may also shift to Medicare Part D should prescribing patterns begin to favor oral therapeutic alternatives for injectable Part B drugs that are covered under Part D. Costs may also shift to care settings associated with greater costs such as hospital outpatient departments (HOPDs). Finally, the potential shift towards HOPD’s may also result in an increase in 340B payments to hospitals. Potential shifts would not only impact federal funding of these programs but would also impact patient out-of-pocket costs and potentially impede access to care. Therefore, AMCP encourages CMS to carefully consider potential market shifts that may arise because of changes to payment models and address how increased expenditures would be addressed.

¹⁰ Available at <https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf>. Accessed July 6, 2018.

Medicare Part D Plans Should Have Full Formulary Flexibility to Manage High-Cost Medications, Including the Classes of Clinical Concern

AMCP supports granting Part D plan sponsors through P&T committees the ability to make formulary changes during a plan year. The prospect of changes to formulary placement, or coverage entirely, could act as a deterrent against mid-year price increases by pharmaceutical manufacturers. This would reduce risks for plans and could reduce costs for beneficiaries if a lower-cost alternative therapy is available. By allowing formulary flexibility, Part D plan sponsors can moderate overall health care costs for beneficiaries and taxpayers. If an equally efficacious medication enters the market at a lower cost than an existing therapy, a health plan can save costs for a patient population by moving the higher cost drug to another drug tier. CMS recognized the importance of this in the *Calendar Year 2019 Medicare Advantage and Part D Payment Policies and Final Call Letter* by giving Part D plan sponsors the ability to immediately change formulary placement for branded drugs once a generic equivalent becomes available at the pharmacy and reducing the required period of notice from 60 days to 30 days when a Part D plan sponsor wishes to move a higher cost single-source drug to another drug tier when adding a lower-cost therapeutic alternative¹¹.

When a medication first enters the market after FDA approval, some possible side effects or problems might not be known for all potential patient populations. A health care plan may review data from initial use by patients in a real-world environment and determine that a particular medication compromises patient safety in a patient population and wish to remove it or place it on a more restrictive tier. When a better product or one that costs less, including a generic, enters the market during the plan year and plans make changes to the formulary to include that product, then the health care plan should be able to encourage its use.

Additionally, AMCP has long supported the ability of plans to manage medications in all categories and classes, including the classes of clinical concern (the “protected classes”). The protected classes reduce the ability of plans to negotiate lower prices for these medications, thereby increasing costs to beneficiaries and the government. In 2014, CMS proposed to rescind the “protected class” designation from three of the six classes (antidepressants, antipsychotics, and immunosuppressants), though this proposal was not finalized.¹²

Requirements to include all or substantially all medications on a formulary in the protected classes also result in potential safety concerns, because plans have limited ability to use standard utilization management tools to discourage use of inappropriate medications. Furthermore, formulary placement determinations related to cost sharing also relate to the plan’s P&T committee’s evaluation of the safety profile of medications. Often, newer medications with less reliable safety and efficacy data in comparison to other medications are placed on higher formulary tiers which require beneficiaries to pay additional costs and are designed to encourage use of safer medications. If a beneficiary requires a medication not covered by the formulary,

¹¹ Centers for Medicare and Medicaid Services. Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 2, 2018). <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2019.pdf>. Accessed July 6, 2018.

¹² 79 FR 29847 (May 23, 2014). <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CMS-4159-Final-Rule.pdf>. Accessed July 6, 2018

plans are required to have a formulary exceptions process in place to ensure the beneficiary can access the medication. Given these protections and CMS' formulary review process, continued restrictions on plan management of agents in these three classes are unnecessary. Beneficiaries can access necessary medications even if not covered under the formulary by using the exceptions process required by Medicare.

CMS Should Adopt the Medicare Part D Formulary Coverage Policy as Proposed in the President's FY2019 Budget

In the FY2019 Budget Proposal, President Trump proposed reducing the coverage requirements for Medicare Part D formularies in order to give Part D plan sponsors additional leverage in negotiations with manufacturers. Currently, plans are expected to cover at least two drugs from each therapeutic category or class. While in most categories and classes, Part D plan sponsors commonly cover in excess of the minimum, this requirement can put plan sponsors at a disadvantage when there are only two drugs in a category or class. Because manufacturers know that plans are expected to cover both drugs, there is little incentive to negotiate.

Changing the requirement to one drug in a therapeutic category or class would enable plan sponsors to negotiate more competitive pricing with manufacturers in classes with only two options. These lower costs could lead to lower premiums and costs to beneficiaries and taxpayers.

AMCP Supports Efforts Curb the Inappropriate Use of Shared System 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. In particular, 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."¹³ 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."¹⁴

To this end, AMCP supports the *Creating and Restoring Equal Access to Equivalent Samples* (CREATES) Act (S. 974), introduced by Sen. Chuck Grassley (R-IA) and Sen. Dianne Feinstein (D-CA).¹⁵ AMCP also looks forward to working with the FDA to address this issue.

¹³ FDA Voice, FDA Working to Lift Barriers to Generic Competition by Scott Gottlieb, M.D. June 21, 2017. <https://blogs.fda.gov/fdavoices/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drugcompetition/>. Accessed July 6, 2018.

¹⁴ Prepared Remarks on Drug Pricing Blueprint by Alex M. Azar II, May 14, 2018. <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>. Access July 6, 2018

¹⁵ Letter to Sen. Chuck Grassley and Sen. Dianne Feinstein, June 7, 2018. <http://www.amcp.org/WorkArea/DownloadAsset.aspx?i3604>. Accessed July 6, 2018.

FDA Policies Should Promote Biosimilar Development and Adoption

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.¹⁶

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.¹⁷ 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 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*¹⁸ establishes a framework to assign a random four-letter suffix for use in 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.¹⁹ 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

¹⁶ IQVIA Institute for Human Data Science. Medicines use and spending in the U.S.: a review of 2016 and outlook to 2021. May 2017

¹⁷ Frank RG. Friction in the Path to Use of Biosimilar Drugs. *N Engl J Med*. 2018;378(9):791-793.

¹⁸ FDA. Guidance for Industry Nonproprietary Naming of Biological Products. January 2017. <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>, Accessed July 13, 2018.

¹⁹ 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.

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 rescission of an FDA draft guidance on determining whether a biosimilar is interchangeable with the reference product.²⁰ 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.²¹ 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 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. To this end, 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 non-profit, 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 de-

²⁰ FDA. Draft Guidance for Industry: Considerations in Demonstrating Interchangeability With a Reference Product, January 2017.

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf>
Accessed July 6, 2018.

²¹ Webster, C. J., & Woollett, G. R. (2017). A "Global Reference" Comparator for Biosimilar Development. *Biodrugs*, 31(4), 279–286. <http://doi.org/10.1007/s40259-017-0227-4>.

identified medical and pharmacy data to harness cutting-edge distributed research network and surveillance methods.²² BBCIC's work includes:

- Comparative effectiveness to compare biologics to biosimilars.
- Descriptive analysis research in the areas of insulins, G-CSF, anti-inflammatories, and erythropoiesis-stimulating agents.
- A completed evaluation on the impact of switching. The results are being compiled to release consensus recommendations for how to approach medication switching patterns in observational, claims-based studies.
- Mapping the use of ICD-9 to ICD-10 codes and issues related to NDC and HCPCS use for biologics and biosimilars.²³

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 www.biosimilarsresourcecenter.org.

Stakeholder Collaboration and a Reexamination of Current Policies are Needed to Encourage 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 these agreements. 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 Academy of Managed Care Pharmacy (AMCP) Partnership Forum, Advancing Value Based Contracting (VBC), held in June 2017. The forum included nearly 40 thought leaders representing diverse health care sectors, including health plans, integrated delivery systems, pharmacy benefit managers, clinical practice, and biopharmaceutical and laboratory companies.²⁴

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:

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.

²² BBCIC *Ibid* at 7.

²³ *Ibid*.

²⁴ AMCP VBC Partnership Forum at 8.

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, HHS and 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);
- Hard 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 lower 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.

Long-Term Financing Models for High Investment Medications

AMCP will be hosting another Partnership Forum in late July, entitled *Designing Benefits and Payment Models for High-Investment Medications*. AMCP will provide additional comments to the docket after the completion of this Forum as allowed by the RFI.

AMCP Opposes ‘Gag Clauses’ Preventing Pharmacists from Disclosing Cost Information

AMCP opposes any contracts between pharmacy benefit managers, health plans, and pharmacies that prevent pharmacists from discussing lower out-of-pocket costs options with beneficiaries.

Copay Cards and Other Coupon Discounts Could Increase Long-Term Costs

AMCP believes that pharmaceutical manufacturers, charitable organizations, plan sponsors, health plans, pharmacy benefit managers, states and retail pharmacies should have the common goal of improving patient access by making medications affordable. AMCP also recognizes that many patients today depend on high-cost specialty medications that rarely have therapeutic alternatives. However, AMCP is concerned that certain copay offset programs may undermine formulary development and utilization management techniques and can also increase costs for health plans and, ultimately, patients themselves.

Several different patient assistance and direct to consumer coupon programs have entered the marketplace. These programs are discussed below.

- Patient assistance programs (PAPs) are generally offered through either manufacturer (manufacturer PAPs) or charitable groups (charitable PAPs). Patients who are uninsured, under insured or indigent are offered free drugs or financial assistance, usually based on economic need and/or the appropriateness of the treatment for a patient. Many programs benefit patients taking high-cost specialty medications, that generally do not have therapeutic alternatives, and frequently have a higher member cost share than traditional prescription drugs. AMCP is supportive of means-tested programs that provide patient access to the most appropriate drugs that may be otherwise unaffordable.
- Manufacturer coupons serve to promote use of specific branded medications that commonly have sub-optimal formulary placement (non-preferred or not covered) due to other products in the same therapeutic class providing the desired patient outcome at a lower cost. These coupons, which intended to reduce a patient's cost-sharing responsibility for a certain prescription drug, are generally offered directly to consumers with commercial insurance (except Massachusetts) and are considered illegal in Medicare and Medicaid and therefore increase product utilization outside of the confines of traditional insurance's processes.
- Manufacturer coupon programs typically limit the number of prescriptions that qualify for the coupon (e.g., 12 refills over 12 months) or the amount of time that the coupon is valid (e.g., end of the calendar year) so patients do not receive an indefinite benefit. After the period of time, a patient may have to be transitioned to a formulary product or the patient will seek a formulary exception for the medication which then results in increased costs associated with covering the non-formulary product. AMCP is opposed to manufacturer coupon programs that are promotional in nature and are not means-tested. Health plans typically encourage patients to take less expensive drugs by placing the preferred drug on a lower cost-sharing tier of the formulary. However, some manufacturer coupons reduce, or even eliminate, the cost differential to the patient between two prescription drugs, diminishing the incentive for a patient to choose the lower-cost equally effective option.

By distorting economic incentives used by health plans and pharmacy benefit managers to encourage patients to use prescription drugs with lower overall costs, manufacturer coupons can undermine the formulary development process and utilization management techniques. Perhaps counter - intuitively, they also raise the risk of increased overall costs for patients. While the patient has a lower cost-sharing responsibility at the initial point of sale, the health plans,

pharmacy benefit managers or plan sponsors are responsible for the reimbursement cost to the pharmacy. This raises the costs of administering pharmacy benefits as a whole, which in turn leads to higher premiums for patients.

AMCP is supportive of programs that help patients afford their prescription medication. However, some programs can needlessly encourage the use of more expensive brand-name products over their generic counterparts. They can also undermine the formulary development process by encouraging the use of products that have lower cost therapeutic alternatives. Patient safety can also be threatened when prescriptions are frequently transferred between retail pharmacies.²⁵

AMCP Perspective on Direct-to-Consumer Advertising

AMCP strongly discourages advertising aimed at consumers that promotes the use of specific prescription drug products. In general, such advertising aims to increase a product's market share or create a new market for the products. AMCP advocates for the appropriate use of prescription drug products and encourages providers to select products based on the needs of the patient in conjunction with prescription drug benefit designs.²⁶

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.²⁷

As an example of content that might provide insight to HHS 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*.²⁸ 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 that focus on the areas in the RFI.

²⁵ AMCP Where We Stand. Co-Payment Offset Programs. <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=23269>. Accessed July 16, 2018.

²⁶ AMCP. Where We Stand: Direct-to-Consumer Advertising. <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22038>. Accessed July 9, 2018.

²⁷ Journal of Managed Care Pharmacy website. <https://www.jmcp.org/>. Accessed July 6, 2018.

²⁸ AMCP Awards Program. <http://www.amcp.org/Awards/>. Accessed July 6, 2018.

Thank you for the opportunity to submit comments on the Blueprint. AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues, including further insight into high cost, innovative medications, managing Medicare Part B medications, and VBC. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "SCantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer