



July 16, 2018

Department of Health and Human Services  
Office of the Secretary  
200 Independence Avenue, Room 600E  
Washington, D.C. 20201

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To the Department of Health and Human Services:

The Ohio Public Employees Retirement System (OPERS) appreciates the opportunity to submit comments to the Department of Health and Human Services (HHS or Department) regarding the "*HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*," (Blueprint) which was published in the Federal Register on May 16, 2018.

OPERS is the largest public retirement system in Ohio, with more than one million active, inactive and retired members. Of this number, OPERS provides health care coverage for more than 200,000 Medicare and pre-Medicare plan participants. Like many health care payers, OPERS is faced with increasing health care inflation, particularly in the area of prescription drugs, as well as the pressures of maintaining a health plan that is both sustainable and meaningful for our members. As such, cost containment within the broader health care system is extremely important to us.

We are encouraged that the Trump Administration has chosen to highlight prescription drug costs. For too long, patients and payers have shouldered the burden of increased prescription drug costs through plan design and cost-shifting to consumers. However, we are quickly approaching a time when this will no longer be enough to maintain meaningful and sustainable health care coverage. A combination of market-driven solutions and government intervention is needed to address high prescription drug costs and ensure that consumers can afford the medications they need.

While the Blueprint is a good first step toward addressing high prescription drug costs, we encourage HHS to consider solutions beyond those proposed in the American Patients First proposal. Specifically, anti-competitive behavior by drug manufacturers (e.g., "product hopping") and the current lack of transparency in drug pricing (e.g., "shadow pricing") need to be addressed in order to ensure that there is a level playing field for consumers and payers.

With an aging population, drug pricing will only become more important in the coming years. We applaud the Administration's efforts to address this issue and urge HHS to take advantage of the public's awareness and outrage over egregious examples of drug pricing abuses and lack of transparency to require real changes in the behavior of manufacturers and pharmacy benefit managers (PBM), both of whom play key roles in setting prescription drug prices and benefit greatly from increased drug prices.



OPERS has chosen to provide its members with access to health care coverage since 1959, not because we have to, but because we believe that access to meaningful health care coverage is an essential component of retirement security. Out of control health care inflation, particularly in the area of specialty drugs, threatens our ability to provide coverage and puts our members at risk at a time in their lives when they are least prepared to adapt.

We stand ready to partner with you in enacting many of the changes in the American Patients First proposal.

OPERS' specific comments regarding the Blueprint are provided below.

### **A. Increasing Competition**

In 2017, OPERS' total pre-Medicare prescription drug cost was \$142 million, \$65.2 million of which was spent on specialty/biological drugs. While only 4.4 percent of current OPERS retiree health plan participants utilize specialty/biological drugs, these medications accounted for 45.9 percent of the System's overall drug spend and represent the fastest growing segment of our annual drug cost. Without biosimilar and interchangeable drugs to drive price competition, specialty drug costs are projected to grow 14 to 17 percent per year through 2021.<sup>1</sup>

Biosimilar and interchangeable drug competition is an integral part of OPERS' long-term strategy to manage the growth of its health care expenditures and increase patient access to safe, effective and affordable biological medications. These innovative and life-changing drugs have the potential to revolutionize medical care, but only if consumers and payers can afford them.

Currently, marketplace competition is the most effective tool our nation has for managing the cost of prescription drugs. Ensuring that biosimilar and interchangeable products can become viable marketplace alternatives will require that they are treated similarly to their reference products and allowed to compete on an equal footing. It will also likely require regulatory intervention.

Some manufacturers have resorted to anti-competitive behavior in an effort to discourage market adoption of biosimilar and interchangeable products. They use tactics such as product hopping, pay-to-delay agreements, shadow pricing, and most recently, "exclusionary contracting"<sup>2</sup> to tilt the playing field against generic and biosimilar manufacturers. These tactics cost consumers and other payers millions, and must be addressed.

#### **1. Distribution Restrictions**

As noted in the Blueprint, some drug manufacturers misuse the fact that one of their products is subject to a Food and Drug Administration (FDA or Agency) Risk Evaluation and Mitigation Strategies

<sup>1</sup> QuintilesIMS Institute, "Outlook for Global Medicines Through 2021," December 2016.

<sup>2</sup> Jared S Hopkins, "What's Harder Than Making Copycat Biotech Drugs? Selling Them," <https://www.bloomberg.com/news/articles/2017-08-15/what-s-harder-than-making-copycat-biotech-drugs-selling-them>, August 15, 2017.



(REMS) plan as an excuse for denying samples of the drug to generic or biosimilar manufacturers who are seeking to develop market alternatives.

In the current Congress, multiple bills have been introduced to allow generic manufacturers access to the samples they need to develop competing products, including the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, and the Fair Access to Safe and Timely (FAST) Generics Act. In fact, as of this writing, the CREATES Act has been reported by the Senate Judiciary Committee and is the subject of on-going negotiations between its sponsors and drug manufacturers. We urge HHS to consider lending its support to one or both of these legislative initiatives.

OPERS supports both proposals and believes that they could be instructive in addressing the provision of drug samples to generic manufacturers when the reference drugs is subject to a REMS. For example, under the FAST Generics Act, a generic manufacturer must first receive FDA authorization before it can obtain samples of a medication that is subject to a REMS. We believe the introduction of a third-party, objective decision-maker could eliminate the opportunity for anti-competitive behavior on the part of the reference drug manufacturer and ensure that generic manufacturers have access to the product samples they need.

Alternatively, there is some thought that the Federal Trade Commission may be able to utilize the existing antitrust framework to remedy situations where reference brand manufacturers purposely withhold samples of their products in an effort to delay generic competition.<sup>3</sup> Therefore, it may be worthwhile for HHS to offer support for a legislative solution clarifying that current antitrust laws are appropriate in this context.

## **2. Educating Providers and Patients**

OPERS agrees that physician and patient confidence in biosimilar and interchangeable products is critical to increased market acceptance of these products. A central theme of OPERS' outreach and advocacy on this topic is the notion that non-brand biologics should be treated as similarly as possible to their reference products.

OPERS has previously engaged with the FDA on issues of biosimilar naming, labeling and interchangeability, and has consistently pointed out that unnecessary disparities in the treatment of brand and non-brand biologics can cause confusion among providers and consumers regarding whether biosimilar and interchangeable products are bioequivalent to their reference products.

For example, OPERS has commented to the FDA that interchangeable products should have the same non-proprietary name, or at least the same four-letter suffix, as their reference products. We have taken this position because we are concerned that the FDA's decision to "treat two products that have

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<sup>3</sup> Michael A. Carrier, "Sharing, Samples, and Generics: An Antitrust Framework," [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2979565](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2979565), March 7, 2017.



been shown to produce the same clinical result in any given patient”<sup>4</sup> differently will provide reference brand manufacturers with an advantage in the marketplace.

The FDA has gone to great lengths to ensure the safety and efficacy of biosimilar and interchangeable products, but we urge the Agency to consider the ramifications of its final guidance in the areas of biosimilar and interchangeable product naming. In treating brand and non-brand biologic products differently, we are concerned that the FDA’s guidance will create confusion among providers and consumers regarding the bioequivalence of biosimilar and interchangeable products. Perception is key, and biosimilar and interchangeable products are already at a disadvantage because, unlike their generic drug forebears, they cannot be called “identical” to their reference products – even though they may produce an identical result.

In order for biosimilar and interchangeable products to succeed in the marketplace, prescribers, pharmacists and consumers must accept them as they currently do with generic drugs. To the extent the FDA has acted to differentiate the names and labels of biosimilar and interchangeable products, there is a greater need to educate consumers and providers on why they should accept non-brand biologics instead of their neatly advertised and relentlessly promoted reference products.

### **3. Interchangeability**

OPERS supported the passage of the *Biologics Price Competition and Innovation Act* (BPCIA) in 2010. It was our hope that the law would have the same effect of fostering generic competition and building market acceptance of biosimilar and interchangeable products as the Hatch-Waxman Act did for generic drugs. OPERS has eagerly awaited the full implementation of the BPCIA, and we are appreciative of the Agency’s efforts to provide guidance for America’s developing biosimilar marketplace.

OPERS has provided comment on many aspects of the BPCIA, including the determination and designation of interchangeability. When the FDA published its proposed guidance on interchangeability, “*Consideration in Demonstrating Interchangeability with a Reference Product*,” in January 2017, OPERS commended the Agency for (1) supporting the extrapolation of interchangeability for additional indications for which the reference product is licensed, and (2) not requiring numerous additional clinical studies to demonstrate interchangeability. However, we also urged the FDA to reconsider several parts of its proposed guidance in order to incentivize manufacturers to develop interchangeable products and ensure that interchangeable products are treated as similarly as possible to their reference products. We continue to believe that these changes will improve the interchangeability of biosimilar products with minimal impact to either drug safety or efficacy. As the FDA finalizes its guidance on interchangeability, we ask that the following items be considered.

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<sup>4</sup> United States Food and Drug Administration, “Biosimilar and Interchangeable Products,” <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm>, last updated October 23, 2017.



a. Data and information to support a demonstration of interchangeability

While OPERS understands the reasons why the FDA has required a higher data burden of proof for interchangeability compared to biosimilarity alone, we believe that this could be largely accomplished by increasing reliance on innovation in the use of non-clinical analytical techniques to characterize all structural and functional differences between the interchangeable product and reference product. As these non-clinical analytical techniques continue to advance, they should begin replacing the need for clinical studies to reduce residual uncertainty regarding interchangeability just as they do today for biosimilarity and comparability in support of manufacturing changes.

We are concerned that if the FDA requires a broad approach to clinical studies necessary to demonstrate interchangeability, it will increase manufacturers' costs and potentially, development time, which could either reduce the incentive to develop more affordable interchangeable products or increase the cost of the interchangeable products. In either case, consumer access to more affordable biological drugs will be reduced. After all, an interchangeable product will be a biosimilar product on which additional studies have been completed, not a newer or better product. This is all the more evident as the FDA is encouraging sponsors to apply for a biosimilar license first, and only then pursue interchangeability as the second regulatory hurdle. As products themselves are the same, there is little need for additional clinical studies.

b. Considerations for the design and analysis of a switching study or studies to support a demonstration of interchangeability

While we appreciate that switching studies are likely the most expeditious way to meet the requirements in Section 351(k)(4)(B) of the Public Health Service Act to demonstrate interchangeability, we are concerned about the proposed FDA requirements of conducting a switching study or studies on patients only and requiring at least two separate periods for the two products in the switching arm.

These study requirements can be burdensome in terms of the length of time required for review and substantial patient study size. We believe they will delay patient access to interchangeable products, as well as increase manufacturer costs, which will ultimately be passed onto consumers and other payers. And, in the end, the interchangeable product demonstrated will be the same product that was already approved as biosimilar.

It is important that the FDA's approval process for interchangeable products strikes an appropriate balance between bringing safe and effective interchangeable products to the market and maximizing patients' access to these more affordable biologics.

c. Recommendations regarding the use of a United States licensed reference product in a switching study or studies

OPERS is concerned that the FDA's recommendation that sponsors use a United States licensed reference product in a switching study or studies could delay patient access to interchangeable products and increase manufacturer costs that ultimately will be passed to consumers and other payers.



As noted above, sponsors currently have difficulty accessing some United States licensed reference products due to anti-competitive behaviors such as misusing the FDA's REMS requirements to deny product samples. This lack of access to reference products would be extremely harmful to sponsors that need reference product samples to conduct bioequivalence testing in order to gain an FDA interchangeability designation.

Additionally, sponsors will likely incur significant additional costs if mandated to use United States licensed reference products. These reference products are twice as expensive as obtaining the same biological product from the European Union and account for between 25 and 30 percent of switching study costs.<sup>5</sup>

Lastly, the requirement of using a United States licensed reference product does not make sense from a scientific perspective, especially for those sponsors who have previously used bridging studies with the same product approved elsewhere to establish the initial biosimilar approval for their product.<sup>6</sup>

d. Considerations for developing presentations, container closure systems and delivery device constituent parts for proposed interchangeable products

OPERS is also concerned that the FDA's proposed requirement that sponsors developing a product for licensure as an interchangeable biologic should be limited to seeking licensure for the same presentation rather than the focus remaining on the same clinical outcome for the patient. We are concerned this will delay patient access to interchangeable products as reference product manufacturers use intellectual property blocks on their devices. Additionally, this requirement limits presentation improvements that could be provided by interchangeable products.

e. Considerations in regulating post-approval manufacturing changes of interchangeable products

OPERS believes comparability requirements should be the same for all approved biological products. If the FDA appears to impose a higher standard for interchangeable products for post-approval manufacturing changes, we are concerned this will create uncertainty in the process. For example, if both the interchangeable product and its reference product are undergoing manufacturing changes concurrently, it will be unclear who has to match whom.

OPERS opposes unnecessary disparities in the treatment of reference, biosimilar and interchangeable products as these can confuse prescribers and consumers, discourage market acceptance of biosimilar and interchangeable products, and ultimately, reduce confidence in the safety and efficacy of non-brand biologics that will likely undergo many post-approval manufacturing changes.

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<sup>5</sup> King, S. "Spotlight On: Will sourcing acceptable reference products make US biosimilar interchangeability studies cost-prohibitive?" <https://www.firstwordpharma.com/footer/benefits?tsid=17> QuintilesIMS Institute. Outlook for Global Medicines through 2021, December 2016.

<sup>6</sup> For example, Sandoz utilized an EU-approved comparator in their switching study to support FDA approval for their biosimilar Erelzi™ (etanercept).





The FDA has more than two decades of experience using comparability in support of manufacturing changes, and we have every confidence that the Agency will apply that knowledge equally and appropriately to biosimilar and interchangeable products in the future.

f. Conditions of use that are licensed for a reference product after an interchangeable product is licensed

OPERS supports extrapolation of indications as a key concept behind the abbreviated biologics pathway established under section 351(k) of the Public Health Service Act. If a new condition of use is licensed for the reference product after an interchangeable product is licensed, once any exclusivities or other intellectual property for the new condition expire, the interchangeable biologic sponsor should be able to seek licensure for the new condition of use, as long as the sponsor provides sufficient scientific justification for extrapolating data to support determination of interchangeability for the new condition. This would require the same scientific reasoning as any extrapolation already applied to the biosimilar and/or interchangeable product and would not necessarily involve the expectation of any further clinical studies.

## **B. Better Negotiation**

### **1. Value-Based Arrangements and Price Reporting**

OPERS has consistently supported the trend towards value-based insurance design and payment arrangements. We appreciate that HHS is contemplating extending these arrangements to prescription drug pricing, as we believe that policymakers, prescribers and payers should seek evidence (e.g., demonstrable improvements in quality of care and health outcomes) that our nation's health care dollars are being spent effectively.

As HHS considers how best to incorporate the value-based arrangements included in the Blueprint, we respectfully request that the Administration be forthcoming and realistic regarding the time required to demonstrate the results of any value-based actions tested or taken to reform the American drug market. As such, we believe the amount of time (e.g., five-year Medicare demonstration projects) required to evaluate each strategy, as well as some recognition of the interdependencies between strategies, should be taken into account as HHS moves forward with this proposal.

Additionally, we recommend that HHS invite industry experts from all relevant stakeholder groups (e.g., providers, payers, industry representatives, consumer advocacy groups) to proactively identify and discuss the potential risks associated with each proposed value-based arrangement so that time is not wasted by waiting until after an arrangement is tested to identify the unintended consequences such as those referred to in the Blueprint as examples of "game-playing" by manufacturers.

### **2. Indication-Based Payments**

Under a value-based purchasing model, the price of a drug paid by a purchaser (e.g., group plan sponsor, health plan or consumer) should vary depending upon the drug's efficacy, which, in turn, would depend on its medical indication for use. In an ideal world, maximum reimbursement would be



provided for drugs associated with the highest efficacy and/or clinical value in treating conditions for which the manufacturer has received FDA approval for use.

Correspondingly, a value-based insurance design by plan sponsors and health plans should align with a value-based purchasing model, but work in reverse. A drug determined to be most effective in treating a given condition should require a lower patient out-of-pocket cost compared to other drugs that are deemed less effective in treating the same condition, or drugs that are prescribed for an off-label use indication.

OPERS encourages HHS to utilize indication-based payments and value-based insurance designs (e.g., value-based formularies) within the Medicare and Medicaid programs. Our nation's largest health care payers should be focused on the value of the treatments they are purchasing for their members, rather than simply paying a price for a service. We also expect that a decision by Medicare to test and implement value-based insurance designs will reverberate throughout the Medicare supplement market as Medicare prescription drug plans align themselves with Medicare's new focus on value.

### **3. Medicare Part B to Part D**

Generally, OPERS supports providing the Centers for Medicare and Medicaid Services with authority to move drugs from Medicare Part B to Medicare Part D when potential savings are expected and documented. However, we recognize this is a complex subject matter with possible ramifications for our Medicare-eligible members' out-of-pocket costs.

While we are supportive of the Administration's desire to lower costs within the Medicare Part B program (including Medicare Part B premiums) by taking advantage of Medicare Part D's negotiating power, we are concerned that manufacturers will simply shift costs to ensure they are made financially whole.

We urge the Department to anticipate and proactively address the potential impacts on beneficiaries (e.g., increased out-of-pocket costs) that could result from a movement of drugs from Medicare Part B to Medicare Part D.

### **4. Site Neutrality for Physician-Administered Drugs**

If everything else is equal (e.g., patient safety), OPERS believes that HHS should consider use of a reference-based price (RBP) for drugs that can be administered at different sites of care. The RBP would include the costs associated with administering drugs at those different sites and should be set at the lowest cost site of care.

We believe that provider reimbursements and patient plan design (e.g., out-of-pocket costs) should prioritize and incentivize the use of the lowest cost sites of care. Use of sites of care that exceed the RBP would result in lower reimbursement to the provider and higher out-of-pocket costs to the patient.

We believe there are substantial, long-term benefits to encouraging patients to become conscientious consumers of health care. Incorporating a RBP would raise awareness of the relationship between the site and cost of a physician-administered pharmaceutical treatment.





## **C. Create Incentives to Lower List Prices**

### **1. Fiduciary Duty for Pharmacy Benefit Managers**

OPERS supports the establishment of a transparent prescription drug pricing model wherein list prices are reduced and maintained at or below the current pricing structure, which is list price minus rebates (if any). Under the current model, the amount of rebates flowing to the plan sponsor is a subject of negotiation between plan sponsors and their PBMs. Because of this, plan sponsors' shares of rebates can differ widely and are largely dependent on their size and negotiating power.

Although plan sponsors like OPERS can negotiate as much as 100 percent pass-through of manufacturer rebates, there may still be hidden revenue that is not disclosed by the PBM, and that plan sponsors cannot know about, because they are not party to agreements between manufacturers and PBMs. Additionally, plan sponsors have no way to audit or substantiate the amount of rebates PBMs say they will be passing through. This lack of transparency provides a perverse incentive for PBMs to increase rebates while not necessarily seeking the lowest net drug cost for their clients.

Because rebates negotiated between manufacturers and PBMs are dependent on the size and negotiating power of the parties involved, there is an incentive for PBMs to grow ever larger through consolidation in order to improve their negotiating position with pharmaceutical manufacturers. In countering these moves, manufacturers will themselves seek to consolidate and/or manipulate their book of business in order to control more of a certain drug or product line, thereby increasing their negotiating power. This consolidation does not support increased competition or lower drug prices.

Earlier this year, the president's Council of Economic Advisors released a report finding that "[p]ricing in the pharmaceutical drug market suffers from high market concentration in the pharmaceutical distribution system and a lack of transparency."<sup>7</sup> The Council's report continued, "[t]hree [pharmacy benefit managers] account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves."<sup>8</sup>

We believe that PBM's various revenue streams and administrative costs should be made more transparent so that plan sponsors like OPERS can be aware of the revenue received by PBMs on their account, as well as administrative fees they receive from plan sponsors and/or other entities.

Under the present system of rebates and hidden revenue, there is limited information available to consumers (and often, payers) that would allow them to compare or understand drug pricing. Payers and consumer groups have long argued for increased transparency in drug pricing. From research and development to marketing and distribution, there is virtually no data available with which the people

<sup>7</sup> The Council of Economic Advisers, "Reforming Biopharmaceutical Pricing At Home and Abroad," <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>, February 2018.

<sup>8</sup> Id., citing Sood, N., Shih, T., Van Nuys, K., and Goldman, D. "The Flow of Money through the Pharmaceutical Distribution System." Leonard Schaeffer Center for Health Policy and Economics, University of Southern California. [http://healthpolicy.usc.edu/documents/USC%20Schaeffer\\_Flow%20of%20Money\\_2017.pdf](http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf). 2017.



and institutions paying for prescription drugs can hold manufacturers accountable. OPERS believes this needs to change.

A good first step would be to introduce a degree of transparency into the drug distribution system. If all purchasing decisions were based on the same list price, payers and consumers could better understand the true cost of the medications and perhaps change their purchasing behavior to select lower-priced, higher-quality alternatives.

## **2. Reducing the Impact of Rebates**

As described above, OPERS supports a drug pricing model that prioritizes lower list prices over higher rebates. Moving away from the rebate model would decrease out-of-pocket expenses for our retirees because their co-insurance payments are based on drug list prices, not the post-rebate prices.

If we assume that doing away with rebates would result in lower list prices (at or below our current post-rebate drug prices), we do not believe that this change will increase premiums for our members. Rather, we anticipate lower list prices would cause claim costs to decrease at the same rate or better than our current pricing structure (i.e., claims minus rebates, if any).

However, there is no guarantee that manufacturers will, in fact, reduce their list prices to the point that the resulting decrease in OPERS' claim costs would offset the loss of our current rebate revenue. To the extent this does not happen, the higher list price (relative to the current "list price minus rebate" level) would result in higher plan premiums for our members. Further, we are concerned that PBMs could simply increase administrative costs for all clients in an attempt to recoup lost rebate revenue.

## **D. Reduce Patient Out-of-Pocket Spending**

### **1. Federal Preemption of Contracted Pharmacy Gag Clause Laws**

OPERS supports removing all barriers that prevent health care providers from assisting patients in maximizing the value of their health care dollars. Contractual provisions restricting pharmacies from informing consumers that a drug could be purchased at a lower price without using their insurance are incompatible with HHS' goals of lowering drug prices and reducing patient out-of-pocket costs.

While we do support removing gag clauses, we are aware of two unintended consequences that could occur if the elimination of these contractual provisions results in consumers not using their drug plans to purchase their prescriptions, thereby preventing the processing of their claims through a PBM's adjudication system. First, the removal of all gag clauses would make it more difficult to accurately gather and measure patient utilization data; and second, it could result in pharmacists missing opportunities to protect patient safety at the point of sale.

Regarding the first unintended consequence, if all gag clauses were eliminated, payers like OPERS might not be aware of some drug utilization because those transactions were not processed through its PBM's adjudication systems. Theoretically, this could result in some lost prescription drug information used by the PBM, medical plan administrator and/or plan sponsor.



The second unintended consequence – pertaining to patient safety – is more concerning. If a patient were advised to pay cash for a prescription, as opposed to running the prescription through a PBM's adjudication system, the pharmacist and prescriber could miss the opportunity to prevent potentially dangerous drug interactions, contraindications, etc.

With all that said, contractually-required gag clauses are not the most effective solution in either case. Additional controls could be established to capture utilization data and ensure patient safety, while also improving transparency in drug pricing and allowing patients to make better-informed decisions regarding their health care purchases.

We urge the Department to work with relevant stakeholders (e.g., PBMs, plan sponsors) to identify comprehensive methods of tracking all utilization data and ensuring patient safety, while concurrently allowing pharmacists to assist consumers with information that is in their best financial interest at the point of sale.

## **2. Inform Medicare Beneficiaries with Medicare Parts B and D about Cost-Sharing and Lower-Cost Alternatives**

OPERS believes that significant efforts should be taken to educate all consumers, regardless of Medicare status, about how to evaluate and/or recognize "value" in health care.

Price transparency is a good place to start; however, it is unlikely, by itself, to significantly impact consumer behavior. The reason for this is that most patients are insulated from the high cost of expensive drugs in large part due to industry (e.g., coupons) and statutory and regulatory consumer protections (e.g., ACA maximum out-of-pocket limits for commercial plan enrollees, minimal cost-sharing imposed upon Medicaid recipients and coverage gap and catastrophic coverage protections afforded Medicare beneficiaries).

Unless changes are made in the nature of the consumer protections provided, the best pricing transparency tools in the world are unlikely to have a major impact on patients' care-seeking decisions and, specifically, their use of expensive prescription drugs.

If the above shortcomings of price transparency are addressed, pricing information should be coupled with clinical quality or efficacy information so that patients and prescribers can engage in shared decision making in support of selecting the best value and most appropriate treatment course for the patient.

## **Conclusion**

Thank you for the opportunity to provide comments on the *"HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."* The issues addressed in this Blueprint are immensely important to OPERS. We appreciate the Administration's efforts to identify and rectify the behaviors and abuses that serve only to preserve unsustainable prescription drug prices. We are hopeful that HHS will carefully consider the remarks it receives from payers and consumer groups that are struggling with and continually fine-tuning plan design in order to provide their members with meaningful health care



coverage. For too long, these groups have been asked to shoulder the burden of health care cost increases. We eagerly await HHS' actions to level the playing field.

Ensuring that biosimilar and interchangeable products have a real chance to take hold and flourish in the marketplace is a necessary first step. Equally important is drug price transparency, which we believe will result in lower list prices, as well as lower costs for plan sponsors and consumers. Additionally, there is an on-going need to educate providers, pharmacists and consumers regarding the importance of non-brand biologic medicines. With these three actions, HHS can lay the groundwork for a competitive and vibrant marketplace where consumers can afford to access the life-changing biologic and specialty medications they need. In the same way, it is critical that we, as a nation, continue to move away from failed policies of the past, like fee-for-service treatments. We urge HHS to support and implement value-based arrangements that focus on outcomes and quality.

As noted above, we encourage HHS to consider all available options in addressing the current high cost of prescription drugs. Anti-competitive behaviors, from product shopping to gag clauses, are harming our members in the form of higher drug prices and increased out-of-pocket costs. Currently, marketplace competition is the most effective tool our nation has to ensure that drug prices remain sustainable. We ask that HHS take whatever steps are necessary to promote marketplace competition and allow those in the health care industry to compete on the value of their products and/or services, as opposed to the strength of their negotiating position.

If you have questions or would like additional information regarding OPERS' comments, please contact Tonya Brown, Director of Member Operations, at 614-224-6204.

Sincerely,

A handwritten signature in cursive script that reads "Karen E. Carraher".

Karen Carraher  
Executive Director