OPERS Health Care Federal Policy Statement

OPERS supports the expeditious development, approval and execution of policies and laws that encourage cost-effective innovations to improve health care for patients and plan sponsors.

We are supportive of, and request, ongoing legislative and regulatory support of the following:

Generic and Biosimilar Drug Competition

- **Congress should support the Fair Access for Safe and Timely (FAST) Generics Act (HR 2841) and Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S3056).**
  OPERS believes biologic drug manufacturers should not be allowed to continue misusing Risk Evaluation and Mitigation Strategies to block the development of competing biosimilar and generic drugs.

- **Congress should support the Price Relief, Innovation and Competition for Essential Drugs (PRICED) Act.**
  OPERS believes seven years of exclusivity (rather than twelve) will not discourage investment in biologic drugs and would enhance marketplace competition by allowing biosimilar drugs into the market sooner, and therefore help OPERS and other payers better manage the growth of their biologic drug spend.[i]

- **Congress should support the Preserve Access to Affordable Generics Act (S2019).**
  OPERS believes pay-for-delay arrangements between drug manufacturers should be illegal because they stifle market competition.

- **The FDA should finalize, as soon as possible, a biosimilar pathway that encourages the development of safe and effective biosimilar and interchangeable biological drugs**.
  OPERS is concerned that it has been seven years since the passage of the Biologics Price Competition and Innovation Act and the FDA has not finalized the biosimilar pathway. OPERS is also concerned that certain FDA-proposed guidance such as naming and labeling will decrease market adoption of biosimilar and interchangeable biological products and negatively impact access to these safe, effective and affordable biologicals.

- **The FDA should have an efficient and effective approval process for generic and biosimilar drugs.**
  OPERS is concerned that the FDA does not provide priority review of competing drugs where there are monopolies or oligopolies for brand drugs with high drug cost inflation.

Pay-for-Value

- **Congress should support legislation and regulations that change how we pay for drugs from pay-per-pill to pay-for-value through value-based purchasing.**
  OPERS is supportive of value-based purchasing tools such as risk sharing agreements based on outcomes that have been included in the second phase of the CMS Medicare Part B Drug Payment Model.

- **Congress and the FDA should support amendment of current laws and regulations to allow for drug manufacturers to share health care economic information, such as pricing, for new medications 12 to 18 months prior to FDA approval.**
  OPERS supports such changes because they are needed by health plans, pharmacy benefit managers and pharmaceutical manufacturers to engage earlier in value based purchasing efforts, such as indications-based pricing.

- **Congress should support public and private research on drug pricing and value.**
  OPERS supports comparative effectiveness research and cost effectiveness research provided by public research entities such as the Patient Centered Outcomes Research Institute (PCORI) and private entities such as the Institute for Clinical Economic Review (ICER). This research is the foundation to value based purchasing tools for high cost drugs and drug categories.

Plan Design and Utilization Management

- **Congress should oppose legislation that removes plan sponsors' ability to manage drugs through plan design and utilization management.**
  OPERS opposes federal and state legislation that places restrictions and/or limitations on our ability to create plan designs for our retirees, such as co-insurance levels and formulary drug tiers. We also oppose legislation that provides limitations on utilization management tools such as step therapy and prior authorization.

About OPERS

OPERS has 222,000 non-Medicare and Medicare Retiree Health Care Program participants. In 2015, OPERS' total prescription drug cost was $706 million, $174 million of which was spent on specialty drugs, including biologic medications.[ii] Current studies project spending on specialty drugs to increase at an average of 17-26 percent per year over the next three years.[iii]

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[i] http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf

[ii] Specialty Drugs are commonly a biologic drug (derived from living organisms, examples are therapeutic proteins and monoclonal antibodies), high cost, used to treat complex or rare, chronic conditions for a relatively small population and require special handling, storage, administration and handling.

[iii] Artemetrx, Specialty Drug Trend Across the Pharmacy and Medical Benefit, 2013