NRLN
NATIONAL RETIREE
LEGISLATIVE NETWORK

Congress Should Mandate HHS Competitive Bidding on Prescription Drugs

The NRLN is unique in that that our members have retired from over 300 U.S. companies and public entities. A significant number of the NRLN's board members and total membership are experienced senior and mid-level executives, corporate pension plan managers; HR; PR; R&D; product and process quality engineers; manufacturing managers and purchasing staff members. Other members bring hands on experience in producing, delivering and installing American goods and services at high quality world-class standards.

We are dedicated to objectively using our experiences in a business-like manner in support of non-partisan public policy that protects income and healthcare security for seniors, their kids, grandkids and all consumers. Our legislative agenda is directed to protecting seniors from losing more benefits and from the effect of a rising cost of senior living; particularly the cost of healthcare, including prescription drugs and the effect cost of living will have by the year 2060 when one in four Americans (25%) will be over age 65.

The prescription drug industry's influence is evident in various forms. Repeated campaign contributions, pressure on HHS regulatory rules and self-serving industry data sent to members of Congress. The "non-interference" clause that bans Medicare from competitive bidding for prescription drugs has resulted in an unwarranted shifting away from the basics of World-Class business operational practices. The current prescription drug procurement model economically disadvantages Americans who are paying for the industry's abusive pricing.

The prescription drug market was different in 2003 when the Medicare Modernization Act (MMA) became law. Then, generics drugs filled a small portion of physicians' prescriptions. Today generics fill 90% of them. The pressure to fund FDA to accelerate generic drug product approval has brought price relief only as patents expire.

As patents expire, industry tactics turn to unreasonable requests to extend patents, pay-for-delay (still not prohibited by law), brand companies buying generic companies, and generic companies buying other generic companies. Pricing strategies drive revenue and profit by company. So, it's no wonder that generic prices are on the rise 6-7% or more annually. Why? No competitive bidding! Pricing is bifurcated between very expensive brand drugs and generics but pricing policy alternatives have not caught up.

Branded drug pricing issues in general center around very expensive drugs for which there are few or no generics. Where there are no generics to treat a medical condition, a new set of policies are needed to address the drug manufacturers 2nd generation patents. But where generics can solve a health problem without violating patents or where patents are licensed to generic manufactures, the only long-term permanent Medicare solution to this bifurcated pricing problem is an HHS competitive bidding program.

The path to business excellence in any business starts with competitive production or purchasing of products and services, always in a competitive Request for Quote (RFQ) / Bidding system and through managing efficient delivery and service from suppliers. That's what HHS and FDA should value as their job. Legislation should be passed to free HHS to do competitive bidding. Hopefully, HHS has an effective purchasing staff on board now. The job is not complex and delivery can be contracted to those who do it best. The 2003 MMA terms instituted non-standard prescription drug industry policies and practices that disguise non-value-added costs e.g. pharmacy benefit managers (PBMs) and other practices that have made pricing baffling. Nowhere is this more apparent than in the relationship between HHS as it serves Medicare beneficiaries. Congress must enact policy that mandates HHS to implement a competitive bidding model (**see following chart**) that will permit direct purchasing of prescription drugs from manufacturers. Competitive bidding will not create bigger government, it will make HHS more efficient and save Medicare billions annually!

The NRLN's attached model describes conditions that address the bifurcation issue and highlights the standard competitive bidding process used in by U.S companies and how readily it can be adapted to manage procurement of prescription drugs by HHS. The model would fit global procurement should Congress approve prescription drug importation from Canadian and other foreign suppliers that meet FDA quality standards. We offer the Executive Summary of our whitepaper on prescription drugs. The entire whitepaper can be requested from Alyson Parker at executivedirector@nrln.org or call 813-545-6792.

Competitive Biddle Model vs Negotiating Model

NRLN advocates removal of the "MMA" prohibition on Medicare competitive bidding and replacing it with a competitive bidding mandate to be applied whenever (1) two or more FDA approved generic drugs or (2) two or more brand drugs or (3) a generic and brand drug (upon patent expiration) treat the same medical condition.	***H.R. 275 / S.62 Empowering Medicare Seniors to Negotiate Drug Prices Act* would allow the Secretary of Health and Human Services to directly negotiate with drug companies for price discounts for the Medicare Program, eliminating the "non-interference clause that bans Medicare from negotiating for better prices.**
General Business Model Applied to HHS for Competitive Bidding	**Negotiating Model for Drug Price Discounts**
Demand for generic or brand drug. Establish formulary specification and post it. Determine annual demand, quality systems definitions, monthly scheduled release quantities, and Manufacturers FOB drop site for distribution and billing date and other terms. Need one boiler plate.	Identify medical condition: Diabetes. Drug needed: Insulin.
Identify potential suppliers with capability to produce the generic or brand drug. Solicit bids from potential suppliers via a request for quote (RFQ) that includes generic specifications, volume level(s) to quote and capability of meeting time frame for shipments and billing requirements.	Establish Insulin formulary. Identify brand-name and generic producers (if any) of Insulin.
Select the top two or three bids (best prices) with capability of delivery on time. Examine capacity, service and quality capabilities; verify on site if new business - use FDA to qualify manufacturers. Determine percent of business to award two or more suppliers.	HHS Secretary (or his staff) initiates negotiations with drug makers for price discounts.
Award business to two or more suppliers with combined capacity of at least 150% of demand or whichever is required to assure continued supply in the event one supplier cannot perform over a short period. Develop price, quality, service and overall performance ratings of each supplier annually. Change suppliers to gain compliance if warranted.	Drug makers decide whether to agree to HHS' requested discount. If no Drugmaker agrees to provide discount – there is no reduction in price. HHS must provide Medicare patients with Insulin without a discount.
Terms: Sellers to HHS may not offer a lower price to its other Medicare D RX buyers at a lower price at the volume levels agreed to with HHS. HHS will mark and sell to contracted distributors, resellers or retail customers as needed.	