ERIC
The ERISA Industry Committee
Driven By and For Large Employers
701 8th St., NW, Suite 610, Washington, DC 20001 • (202) 789-1400 • www.eric.org
James Gelfand, Senior Vice President of Health Policy

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The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Mr. Secretary:

The ERISA Industry Committee (ERIC) is pleased to submit these comments in response to the recently-issued request for information (RFI) pursuant to the President's "*American Patients First*" blueprint.

ERIC'S INTEREST IN THE BLUEPRINT AND LOWER DRUG PRICES

ERIC is the only national trade association that advocates exclusively on behalf of large employers on health, retirement, and compensation public policies on the federal, state, and local levels. ERIC supports the ability of its large employer members to tailor retirement, health, and compensation benefits to meet the unique needs of their workforce, providing benefits to millions of workers, retirees, and their families across the country.

ERIC's member companies offer comprehensive group health benefits to their employees in compliance with the myriad federal requirements placed upon group health plans subject to the Employee Retirement Income Security Act (ERISA), and other federal laws including Medicare. Furthermore, large employers typically pay 75% (or more) of the costs of health insurance for their employees. While prescription drugs are not the largest cost-driver within employer-sponsored health insurance, they are the fastest growing, least predictable, and often times, the most opaque.

BACKGROUND

ERIC member companies are the vanguard of innovation in health coverage, laying the groundwork for the entire movement from volume to value. ERIC companies were the first to implement innovations such as accountable care organizations and care coordination programs, they pioneered health information technology and the widespread adoption of electronic medical records, and they invented wellness programs to help incentivize healthy living. However, systemic problems in the prescription drug market are preventing innovation, competition, and movement toward value. This Administration has a historic opportunity to move the ball forward and create opportunities for plan sponsors to offer even better coverage to our beneficiaries at even better prices, but only if bold steps are taken.

ERIC applauds the actions already taken by this Administration. Reductions in the Food and Drug Administration (FDA) generic approval backlog are critical to bringing competition and affordability. Other changes at FDA are also likely to spur more competition and enhance the availability of generic drugs, which are crucial to controlling costs. And laying the groundwork for a robust and competitive market for biosimilars is also vitally important, and the Administration's actions on billing codes for biosimilars will help make this a reality.

These comments will focus on issues laid out in this RFI, as well as other actions the Administration can and should take – some of which can be accomplished unilaterally, and others which may require negotiations with Congress in order to enact fully.

COMMENTS

I. IMPROVE COMPETITION

ERIC applauds efforts to crack down on the gaming of FDA rules, which continue to have an ill effect on availability and competition in the prescription drug space. Many of the current problems in the prescription drug market are a result of failure by various parties to live by the "rules of the road" established by the 1984 Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), usually referred to as the Hatch-Waxman Act. The law laid out a roadmap wherein innovator companies are granted market monopolies, for a limited duration of time, and then must face competition from generic products. Various strategies are now used to delay or escape entirely from that competition, and the result has been unconscionable prices and costs to plan sponsors and patients.

Risk Evaluation and Mitigation Strategies (REMS) and Safety Protocol Abuse

The Administration appears to be taking steps to reduce the use of safety protocols such as REMS to thwart generic competition. While certain drugs are potentially dangerous and should absolutely be properly tracked and overseen, safety protocols should never be used as an excuse to prevent generic manufacturers from being able to enter the marketplace and compete. **We urge the Administration to go further to ensure that safety protocols are properly enforced but cannot be used to generate market exclusivity.** The same goes for biosimilar and interchangeable product manufacturers – the Administration should ensure that these companies have access to the samples they need in order to develop competing products.

Biosimilar "Interchangeability" Scare-Mongering

A competitive market for biosimilars is critical for controlling drug costs, and we applaud the Administration's actions thus far in improving access and education in this space. But there is more to be done. **For instance, FDA should clarify that all biosimilars are approved as safe and effective based on a reference product**. Right now, there is confusion about the "interchangeability" designation, which some manufacturers or others may seek to use to prevent biosimilar adoption and take-up. The Administration should stop these efforts in their tracks by finalizing the interchangeability guidance.

Biosimilar Education

It is also important for the Administration to continue efforts to educate providers, payers, and patients about the benefits of biosimilars. Patients need to know that biosimilars are only approved when FDA is satisfied that they are safe and effective substitutes for reference products, and that for patients who take expensive branded specialty medications, a new and more affordable alternative may now be available.

Value-Based Purchasing, Medicaid Best Price, Stark & Anti-Kickback

Plan sponsors are very interested in moving forward with value-based purchasing arrangements with pharmaceutical and medical device manufacturers. However, these manufacturers are often hesitant to take risks in this way due to possible adverse effects under the Medicaid Best Price rules. **As such, we urge the Administration to take immediate steps to except value-based payments from the Medicaid price calculation, and also to remove other barriers related to Stark and anti-kickback rules which might hamper the advance of value-based payment.**

Patent Evergreening

Another way that branded manufacturers are able to avoid competition, is by a process termed "patent evergreening," in which market exclusivity for a product is extended over and over via new patents, usually on a very minor change in preparation, the drug's delivery mechanism, or a new indication to be treated by said drug. This strategy has allowed some of the highest-grossing drugs ever to maintain a market monopoly far longer than envisioned by current rules. **As such, when a branded company attempts to extend market exclusivity for an existing drug, unless that attempt is justified by a significant innovation, FDA should deny additional exclusivity.** This will help to focus on development of the innovation pipeline, rather than creation of a "patent thicket" to thwart market competition.

Pay-for-Delay Agreements

The RFI discuss the issue of "pay-for-delay," in which a branded manufacturer may pay a generic manufacturer to keep generic competition off the market for a period of time. Specifically, the RFI considers allowing generic competitors to access the market in the case of an agreement in which the first-out generic company decides to "park" their application. **These arrangements serve only to increase costs and reduce competition, and as such, the Administration should take immediate steps to ban pay-for-delay agreements in the future, curtail those currently in effect, and issue strong guidance to fully prohibit this practice in the future.**

Sovereign Immunity Schemes

It has also come to ERIC's attention that some branded manufacturers have entered into arrangements with entities that possess varying degrees of sovereign immunity, such as Native American tribes, to thwart competition and patent challenges by subverting the authority of FDA and the U.S. Patent Office. **These practices should be immediately banned by whatever means necessary – including legislative options to affirmatively prohibit them, and investigation and enforcement by the Administration**.

II. BETTER NEGOTIATION

The blueprint includes numerous proposals to change the structure of Medicare programs that would more closely align them to private sector coverage, and ERIC applauds those proposals. The inability of these programs to have a meaningfully limited formulary, to be agile in adapting to market changes, and to properly categorize products, is resulting in ill effects for the entire health care system.

Global Freeloading

ERIC companies have long been told that it is necessary that U.S. purchasers pay much higher costs than purchasers in other countries, or else the innovation pipeline would dry up, and patients would suffer. This is not a fair deal. The President has stated that this Administration will work to end these cost disparities, so that other nations with similar economic conditions will equally shoulder the burden – which should justify lower costs here in the states. **We urge the Administration to make good on that commitment, which will require more than publishing studies – trade deals and multilateral agreements need to address disparities in prescription drug costs going forward**.

CMMI Demonstrations & Large Plan Sponsors

As HHS and CMS move forward with demonstration projects to test value-based purchasing for prescription drugs, employers should be consulted and perhaps offered the opportunity to participate. Efforts to change the health care system have the greatest chance of success when there is coordination between the public and private sectors. **ERIC has worked with stakeholders to improve coordination between bodies such as the Center for Medicare and Medicaid Innovation (CMMI) and the private sector, and efforts on prescription drugs should similarly be multi-lateral to enhance their ability to be transformative and successful**.

Medicare Part D vs. Part B Payments

Currently, the disparity in reimbursement rates for drugs under Medicare Parts D and B may be creating perverse incentives for drug manufacturers. To the degree possible, Medicare programs should improve coordination and streamline purchasing and reimbursement policies. Plan sponsors are in favor of changes that will incentivize innovator companies to develop products that will reduce costs by being used in low-cost settings of care, rather than require inpatient settings to be administered. Additionally, ERIC members have had success in the use of reference pricing and site-neutral payments – to the extent possible, the Administration should seek to emulate this success under government health care programs. That includes proven strategies that work well in Part D, including tiered formulary design, prior authorization and step-therapy, and quantity limits.

III. CREATING INCENTIVES TO LOWER LIST PRICES

The way that drugs are priced in the U.S. makes very little sense to any outside observer. Sky-high list prices are developed, which no actual payer pays. New prices are negotiated and paid, and then later, some amount of money may flow back to the payer based on myriad other factors such as volume or competitive pressures. This labyrinthine process does not accrue to the benefit of payers or patients.

The Administration can and should take proactive steps to further the cause of price transparency, and to reduce the confusion caused by rebates. ERIC members and plan beneficiaries would benefit from a system where it is clear what products cost. If that necessitates changes to antitrust law so that manufacturers are not vulnerable to lawsuits for negotiation of up-front volume discounts, then this should be considered. Conversely, the Administration should be cautious about any proposal that could enshrine the current rebate system. One caveat – in the case of value-based purchasing arrangements, there may be a need for payments in addition to an initial purchase cost – so efforts to disrupt the rebate system must retain adequate flexibility to allow value-based purchasing payments.

List Prices on Direct-to-Consumer Advertising

ERIC is unsure what effect mandating list prices in direct-to-consumer advertising might have. As discussed above, no payer or patient actually pays the list price. Setting aside concerns about free speech or FDA's regulatory authority, it is not clear whether posting of list prices will actually cause manufacturers to lower those prices in the long run.

Treating PBMs as Plan Fiduciaries

ERIC also is unsure what the results might be of treating a pharmacy benefit manager (PBM) as a fiduciary. More information is needed about how this would be arranged and how this might affect plan sponsors' costs before ERIC can take a position on this proposal. PBMs are a valued service partner for plan sponsors, and have helped achieve billions in cost savings, so changes to the PBM-plan relationship must be carefully considered.

Limiting Copay Discount Cards

One proposal in the RFI which ERIC strongly supports is limiting the effect of copay discount cards. In both public and private plans, formularies are developed to ensure access to needed treatments, but at the same time to help control costs for all beneficiaries. Right now, copay discount cards (and other manufacturer-provided or funded coupons) are distorting those formularies, preventing steerage, and incentivizing patients to choose high-cost drugs. Further, they serve to hide the outsized costs of medications, thus eliminating market pressure to reduce costs. ERIC member companies are taking proactive steps to limit the harmful effects of this steerage by branded companies, including by not counting copay coupons toward beneficiaries' deductibles or out-of-pocket maximums. **To the degree possible, public programs should follow private plans in placing limitations on copay coupons.**

IV. REDUCING PATIENT OUT-OF-POCKET SPENDING

It is imperative that patients, and providers, have ready access to what the costs will be when filling a prescription – especially as this may lead to different choices in what medication to prescribe, whether to seek a lower-cost alternative or generic, etc. However, it is equally imperative to note, that focusing on out-of-pocket costs is mostly a distraction in the political debate over drug prices.

For years, the producers of the highest cost drugs have steadily insisted that list prices were irrelevant. The reasons they gave were that (1) nobody actually pays the list price, and (2) most of the price of drugs is paid by a third party, and all that consumers really care about is the price they pay at the pharmacy register. While the issue of misleading list prices is discussed above, the second issue is equally misleading. One way or another, plan participants will pay the overall costs of prescriptions covered by the plan – what this means is, shifting costs away from copays and coinsurance will simply result in higher health insurance premiums. It is true that the move toward high-deductible health plans (HDHPs) has increased patients' awareness of the costs of prescriptions, especially medications. However, patients have always borne a part of these costs – it was just contained within the premiums. In fact, patient awareness of drug costs is critical if cost control is ever to be achieved.

Point-of-Sale Rebates

Requiring that plans pay rebates directly to consumers will not lower drug costs. It will reduce spending for a small subset of patients who fill certain branded prescriptions. However, it will raise costs for all plan participants (including the patients who receive the rebate), by causing premiums to increase. It will also increase the likelihood of individuals choosing to fill a branded prescription instead of a lower-cost or generic alternative, which will have the net effect, again, of raising premiums for all plan enrollees. And perhaps worst of all, this change would perpetuate the current system of rebates, thus taking the wind out of the sails of efforts to make drug purchasing more transparent and straightforward. This "solution" is strongly supported by branded manufacturers, but payers are aware of the adverse effects it presents. Not to mention, point-of-sale rebates create fiduciary issues for plan sponsors, as ERISA has very strict rules about the treatment of "plan assets." **The Administration should eschew efforts to mandate point-of-sale rebates.**

Redefine Preventive Services in HDHPs

A much better option to reduce patients' costs, while also improving value in the health care system, would be to change the Internal Revenue Service (IRS) definition of preventive care, in order to permit HDHP plan sponsors to provide coverage of chronic condition management and medications as first dollar coverage. Because insurers and plan sponsors want to reduce inpatient care, they are likely to consider offering discounts on medications such as insulin for diabetics, inhalers for asthmatics, and the like. However, current IRS rules forbid this, and so no experimentation has been able to be tried in HDHPs. **IRS should immediately broaden their overly restrictive definition of preventive care in order to enable value-driven plan design in HDHPs.**

Medicare & Medicaid Steerage to Biosimilars

The Administration has also proposed changes that would reward individuals who choose biosimilar products over branded specialty medication to pay lower copays. This is good policy, and is consistent with private sector plan design, where steerage towards lower cost products rewards not only the individual filling the prescription, but all plan beneficiaries. In the case of Medicare, the benefit will accrue to all enrollees and the taxpayers as well.

Gag Clauses

At this point, all of the major PBM companies have stated that they do not include so-called "gag order" clauses in their contracts with pharmacies. These clauses would prevent a pharmacist from alerting a patient that their prescription might be cheaper to fill simply paying cash, rather than the negotiated rate under their insurance coverage. However, the issue continues to be discussed, and as such, may well require additional attention. **As such, we support efforts to ban gag clauses – the Administration should prohibit these clauses in Part D plans, and Congress should take action to prevent these clauses in private sector and other plans**. Further, the Administration should explore whether the use of electronic prescribing in Part D allows prescribers to notify the patient what the price of the drug will be at the pharmacy counter and whether lower cost alternative medications are available.

ERIC appreciates the opportunity to provide feedback at this time. We are fully committed to efforts to lower prescription drug costs. We hope to serve as a resource through the regulatory process, and look forward to working with the Departments on regulations that recognize the important role of large plan sponsors and the benefits they provide to millions of workers, retirees and families.

Sincerely,

James P. Gelfand
Senior Vice President, Health Policy