



July 16, 2018

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

Dear Secretary Azar:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the [policy statement and request for information](#) titled, “Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” as published by the U.S. Department of Health and Human Services (HHS) in the May 16, 2018 *Federal Register*.

Managing prescription drug prices for their patients is an important concern for family physicians. Family physicians have a meaningful interest in the drug pricing debate, in part because of the complexity of care provided and the fact that the number and complexity of conditions, complaints, and diseases seen in family medicine is [far greater](#) than those seen by any other physician specialty. Ensuring access to medications is an integral part of a physician’s role as an advocate for their patients. Unfortunately, and too frequently, family physicians encounter patients who cannot afford their medications or adhere to treatment recommendations. Physicians themselves also face recurrent and burdensome administrative requirements like prior authorizations that create treatment barriers. According to a 2017 American Medical Association [survey](#), 92 percent of respondents reported care delays due to prior authorizations and 78 percent reported that prior authorizations can lead to treatment abandonment.

The AAFP urges the administration to use its administrative authority to address drug prices and furthermore, we encourage HHS to weigh in on legislative proposals that may also further strengthen the nation’s ability to control drug costs and out-of-pocket spending for patients.

Generic Drug Access

Given the public’s reliance on generic products, which represent over 89 percent of medications filled, increasing access to these products must be a top priority. An April 2015 Medscape [article](#) cited many factors that cause escalating costs, including strategies that delay or discourage competition by generic drug manufacturers. Although the Food and Drug Administration’s generic drug approval process has accelerated the generic drug approval process, there continue to be barriers for new generic products. **The AAFP supports policy insuring the availability of effective, safe and affordable medications. We also support initiatives within HHS and the Federal Trade Commission (FTC) to improve generic drug access for patients through efforts to address anti-competitive practices.**

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We are pleased that the administration's blue print includes plans to prevent companies from using the Risk Evaluation and Mitigation Strategy (REMS) process to create barriers for new generic manufacturing. The plan, however, did not address other important practices that contribute to high drug prices. We urge the administration to take a more comprehensive approach and address the following issues.

Reverse Payment Patent Settlements.

During a 2013 hearing before the Senate Judiciary Committee, FTC officials [stated](#) that ending reverse payment patent settlements was a top agency priority. Commonly known as "pay-for-delay," brand and generic companies enter into agreements where the generic companies delay manufacturing pharmaceuticals in exchange for a settlement payment. According to an FTC [study](#), this anticompetitive activity increased drug prices for consumers and taxpayers by an estimated \$3.5 billion. These "pay-for-delay" activities violate the *Hatch-Waxman Act* intent to encourage generic drug access through market competition and the AAFP strongly encourages HHS to end such activities to be consistent with the Supreme Court's *FTC v. Actavis* decision. The AAFP urges the administration to fully support the FTC's enforcement efforts and to bolster legislative proposals to end this practice.

Patent "Ever-greening"

Another strategy to delay generics is "patent ever-greening," in which a variation of a drug is developed — such as a new form of release, a different dose, or a new combination — to extend the life of the original patent. According to a 2017 University of California Hastings College of Law [study](#), 78 percent of new drug patents in FDA records between 2005 and 2015 were awarded to existing drugs. The report also indicates that 80 percent of the top 100 drugs extended their patents at least once. Fifty percent of the same top drug extended exclusivity more than once. Efforts to slow the generic drug process increase drug prices, and should be addressed as a top administration priority. Again, we urge you to work with legislators to advance policies to restrict this practice.

Drug Pricing Principles and Priorities

The AAFP has long supported policies to ensure the availability of effective, safe, and affordable prescription medications. In 2017, the AAFP became a member of the [Campaign for Sustainable Rx Pricing](#) (CSRxP), a nonpartisan coalition of nonprofit medical associations, insurers, and hospitals committed to addressing drug price increases by striking a balance between drug innovation and affordability. **The AAFP supports transparency and stronger regulatory enforcement to lower the cost of prescription drugs. The AAFP also supports the availability of affordable generic medications as a cost-effective substitute for many brand-name prescription medications.** The AAFP is pleased with HHS' commitment to lowering drug prices.

Off-patent drugs

Off-patent drugs represent a significant area of concern. Turing Pharmaceuticals received widespread criticism when it obtained the manufacturing license for the anti-parasitic drug Daraprim and raised its price by 5,556 percent from \$13.5 to \$750 per tablet. Other companies have come under fire for the same practice. Federal officials and policy makers in Congress have examined this issue, but have yet to implement strategies to address rising drug prices among older, off-patent drugs where lack of competition and small patient populations contribute to high drug prices and lack of patient access. We urge the administration to develop strategies for addressing these products.

Site Neutral Payments

Under Medicare Part B and often in Medicaid, physicians are reimbursed comparable amounts for drugs they administer to patients, but the facility fees when drugs are administered at hospitals and hospital-owned outpatient departments are many times higher than the fees charged by physician offices. **The AAFP supports site neutral payment policies for physician-administered drugs and urges HHS to consider further expansion of site neutral payments for outpatient services.**

Researchers [found](#) that payments for physician visits at a hospital were \$68 higher than for those at stand-alone offices. The authors also reviewed changes in price associated with physicians integrated with hospital systems. In the markets studied, they found annual outpatient spending increased by \$75 per Medicare patient, "almost entirely owing to price increases rather than changes in utilization."

A [report](#) by the Government Accountability Office (GAO) showed between 2007 and 2013, the number of hospitals that achieved vertical integration with physician practices increased from 1,400 to 1,700, while the number of physicians with a hospital affiliation increased from 96,000 to 182,000. The report indicated Medicare paid \$51 more for midlevel evaluation and management visits performed in a hospital outpatient setting compared to those at independent physician practices. The agency noted, "the inconsistency in Medicare payment policy is not justified. While vertical consolidation has potential benefits, we found that the rise in vertical consolidation exacerbates a financial vulnerability in Medicare's payment policy: Medicare pays different rates for the same service, depending on where the service is performed," the GAO report stated. The AAFP calls on HHS to address these inconsistencies.

Value-Based Drug Pricing

The HHS request for information asks how CMS could develop demonstration projects to both lower drug prices and encourage value-based care.

In March of 2016, CMS proposed a value-based drug pricing demonstration project that establishes a common reimbursement for Medicare Part B drugs, implements purchasing agreements with drug manufacturers based on drug effectiveness, and includes clinical decision support tools. The transformation of our health care system requires fresh perspectives and new ideas regarding payment and delivery of health care services. The AAFP [applauded](#) CMS' efforts to apply common-sense, value-based payment (VBP) principles to the delivery of physician-administered pharmaceutical and biologic treatments. VBP involves linking payment for drugs to patient outcomes and cost-effectiveness rather than solely to the volume of sales. **Physicians, hospitals, and other Medicare providers are aggressively pursuing VBP models, and HHS should explore the applicability of VBP principles and models to the pharmaceutical industry.**

Medicare Negotiation Authority

The HHS RFI discusses that more can be done across the Medicare and Medicaid programs to provide beneficiaries with lower costs and greater price transparency resulting from better negotiation. According to a 2016 [article](#), from 2004 to 2014, Medicare's share of U.S. drug expenditures increased from 2 percent of total U.S. drug spending, or \$193 billion, to 29 percent, or \$298 billion. Unfortunately, the 2003 *Medicare Modernization Act* prohibits CMS from engaging in drug pricing negotiations.

The AAFP encourages HHS to take steps to ensure Medicare and Medicaid prescription drug programs can best take advantage of recent developments in value-based purchasing so all

parts of the U.S. health care system benefit from market-based negotiating efforts to lower drug prices. Researchers have also concluded the federal government could save \$15.2 billion to \$16 billion annually if it negotiated with drug manufacturers and achieved the same prices as those paid by Medicaid or the Veterans Health Administration. Furthermore, there are legislative proposals within Congress to require that generic drug companies provide a rebate to Medicaid programs if prices exceed the rate of inflation. Currently, brand name drugs follow this rebate formula, and this strategy should be tested in the context of brand name drugs as well. The AAFP urges the administration to advance this policy.

Prevention First

Health promotion and prevention of disease are critical and foundational components of primary care and family medicine. The AAFP strongly encourages practicing physicians, family medicine residents, and medical students to practice evidence-based, cost-effective preventive medicine in the delivery of health care. In support of its members, the AAFP advocates for policies and payment that advance, stimulate, and facilitate preventive services. **The AAFP urges HHS to embrace a “prevention first” approach when considering ways to lower drug prices by reducing the nation’s disease burden. In doing so, the AAFP urges the administration take a multi-pronged strategy to prioritize disease prevention, ensure patient access and encourage competition for prevention-related drugs.** According to the U.S. Centers for Disease Control and Prevention (CDC), chronic diseases are the leading causes of mortality and morbidity in the United States adult population. These conditions are associated with higher drug utilization and higher out of pocket costs for individuals. The AAFP supports preventive health measures as a first-line approach for tackling our nation’s drug pricing crisis. Though this approach does not address the actual cost of medications, strategies that improve health, and therefore reduce patients’ reliance on prescription drugs or the number of recommended medications, could result in significant reductions in health care spending and better patient outcomes. Family physicians work to ensure patients lead healthier lives and need fewer medications.

Controlling drug costs is also of importance to physicians with lower income patients who have chronic illnesses, a common scenario in family medicine settings. Results from a 2013 National Center for Health Statistics [survey](#) indicated that chronically ill low-income patients are twice as likely to skip drug doses, delay treatment, reduce dose frequency, or fail to identify alternative therapies. This lack of medication adherence may exacerbate their conditions and result in higher health care spending over the long term. According to a 2015 [survey](#), individuals described as in poor health (i.e., those with multiple chronic health conditions) and those taking multiple drugs or living on fixed or lower incomes, indicated that the cost of prescription drugs was a “serious” concern for them.

According to a Commonwealth Fund [report](#) that compared drug spending in nine developed countries and the United States, both drug spending and patient utilization costs are higher even though utilization levels are about the same. The study suggests that centralized negotiation may help improve spending. The study also indicated that insurance coverage and benefit design may lower out-of-pocket costs for individuals, which is an important patient-centered outcome that ensures better treatment adherence. For example, 47% to 60% of adults in all countries report taking one or more prescription drugs regularly. In the United States, 59% of adults fall into this category. The AAFP believes drug pricing and patients’ out-of-pocket costs should be addressed by ensuring individuals have access to high quality health insurance that includes robust drug coverage.

The following are examples of areas that might be prioritized under a prevention first agenda:

Infectious Diseases

It is imperative healthy individuals have access to medications to improve population health outcomes. A 2016 [report](#) published in *Health Affairs* indicates the annual economic costs of vaccine-preventable diseases for adults is between \$4.7 billion and \$14 billion. As a matter of longstanding AAFP policy, the AAFP endorses the following policies:

- All children and adults, regardless of economic and insurance status, should have access to all immunizations recommended by the AAFP.
- Vaccine manufacturers and distributors should have payment policies that minimize the physicians' financial risk involved in maintaining a vaccine inventory.
- Government programs that subsidize the costs of vaccines at no cost to medical practices should be adequately funded by the federal and state government.
- All public and private insurers should include as a covered benefit, immunizations recommended by the AAFP without co-payments or deductibles.
- Vaccine manufacturers and distributors should deliver adequate, timely, and complete orders of immunizations recommended by the AAFP to family physicians in a prioritized manner to most effectively achieve vaccination of patients within their medical home.
- Where medical practices incur a cost for vaccines, the AAFP calls for adequate payment for the vaccine itself and all associated overhead costs (i.e., acquisition, storage, inventory, insurance, spoilage/wastage, etc.) of all immunizations recommended by the AAFP and their administration with no patient cost-sharing, as well as covering an evaluation and management (E/M) service during the same visit, when a significant and separately identifiable E/M service is provided and documented.
- Vaccine manufacturers should develop contingency plans for the timing and prioritization of vaccine supplies if an ample supply of the immunizations recommended by the AAFP is delayed and/or reduced.

Contraceptives

A Guttmacher Institute [report](#) indicated that the *Affordable Care Act's* birth control access policies resulted in \$356 billion in savings by reducing unplanned pregnancies. The AAFP understands achieving public health outcomes requires multi-pronged approaches, many of which may occur outside the physician's office, but the return on investment of certain prescription interventions has been proven to be substantial.

Diabetes

Diabetes prevention and care should also be a priority issue for the administration. A 2016 [study](#) published in the *Lancet* indicated the cost of treating diabetes has increased from \$245 billion in 2012 to \$347 billion in 2016. According to a 2014 American Diabetes Association [report](#), diabetes care accounts for one of ten dollars spent on health care. We understand there has been a rise in new cases of patients diagnosed with diabetes, but more than half the costs of diabetes care are due to higher prescription drug prices. Diabetes patients have four times more treatment options than they did 20 years ago, but some newer drugs cost 100 times more than older treatments. The AAFP urges a demonstration program to prevent diabetes, ensure drug access, promote medication adherence, and spur comparative effective research. Under such a plan, HHS could evaluate a drug's clinical effectiveness, comparative effectiveness, safety, and patients' prescription adherence as part of drug formulary review process.

Transparency

According to President Trump's call to action, HHS may "make Medicare and Medicaid prices more transparent, hold drug makers accountable for their price increases, highlight drugs that have not taken price increases, and recognize when competition is working with an updated drug pricing dashboard" in order to provide information to help patients make informed decisions and predict their cost-sharing.

Transparency policies do not directly lower drug costs, but may provide more data that could help federal agencies and policy makers increase accountability and would allow physicians and patients to make more informed treatment choices. In recent years, public and congressional accountability measures identified that EpiPen had been misclassified as a generic drug for years within the Medicaid Drug Rebate Program. This issue highlights the importance of having strong transparency policies in place. This is reflected in the fact that 30 states have begun to review their own transparency laws. The AAFP urges HHS to require pricing transparency, including for off-patent and generic drugs.

Medicare Part B Drugs

The RFI discusses moving some drugs from the Medicare Part B to the Part D program and asks commenters to highlight drugs or classes of drugs that would be good candidates for the shift. The AAFP cautions against proposals that might restrict patient access to essential health care services and drugs, especially in family physician offices.

Six Protected Drug Classes

In 2014, the AAFP [opposed](#) a CMS rule that would restrict patients' access to necessary medications. The CMS proposal would have removed antidepressants and antipsychotics from the list of medications that are required to be included in all Part D formularies. Medicare formularies have included six protected drug classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection) since 2005, and the AAFP opposes any change to their status that could limit a patient's access to physician-prescribed medications. We recognize there may be noteworthy proposals under consideration that may result in lower costs, but urge the Administration to prioritize patient access to these essential drugs.

Thank you for the opportunity to comment on current drug pricing policies. For more information, please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "John Meigs, Jr.", with a stylized flourish at the end.

John Meigs, Jr., MD, FFAFP
Board Chair