July 12, 2018

Alex M. Azar, II
Office of the Secretary
US Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: RIN 0991–ZA49: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar,

On behalf of the more than 13,800 U.S. members of the American Academy of Dermatology Association (AADA), I am writing you regarding the request for information (RFI) for the Department of Health and Human Services’ (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs published on May 16, 2018. The AADA is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology; and supporting and enhancing patient care to reduce the burden of disease. We appreciate the opportunity to provide comments to HHS and hope HHS will take the AADA’s recommendations into consideration when developing future policies.

We were pleased to see the Administration’s commitment to help reduce drug prices and out-of-pocket costs for patients while increasing transparency. Over the past year, we have greatly appreciated the opportunity to work closely with the Administration to advance regulatory relief initiatives that alleviate administrative burdens on physicians and help physicians spend more quality time with their patients while getting them access to the most effective and affordable treatments.

Currently, the growth of patients’ out-of-pocket costs for prescribed drug therapies is unsustainable. Dermatology has experienced increasing prices for both generic and specialty medications. For example, dermatologists and their patients saw an appalling price increase for doxycycline, a common antibiotic, from $20 for 500 tablets in 2013 to $1,849 for the same amount just a few months later. A similar indefensible price increase was also applied to clobetasol, a commonly prescribed topical corticosteroid. The findings of a recent U.S. Government Accountability Office (GAO) report align with what dermatologists are experiencing in their offices. Specifically, the GAO found that, “Topical drugs, such as creams and
ointments...[including: desonide and fluocinonide] ... represented 46 percent of all extraordinary price increases between 2011 and 2012.”

The Academy has made patient access to affordable treatments and transparency in drug pricing a top priority. In March of 2015, an Ad Hoc Task Force on Drug Pricing and Transparency was created, charged with working to preserve physician authority with regards to medical decisions and access to treatments for patients. To that end, the Task Force has led the Academy to research and educate our membership and patients about the issues, develop policy positions and lobby on current federal and state legislation.

As HHS begins to develop drug pricing proposals, we ask that you consider including physician stakeholders’ opinions. We welcome the opportunity to serve as a future reference to HHS on this issue to ensure that the physician’s perspective on helping patients access needed and affordable treatments is considered.

**Access to Reference Product Samples**

*Distribution Restrictions/ Samples for Biosimilars and Interchangeables*

The AADA supports removing barriers to the development and entry of generic drugs in the marketplace, which will increase competition and lower drug prices of pharmaceuticals. This includes the misuse of Risk Evaluation and Mitigation Strategy (REMS), a safety protocol, by brand manufacturers to prevent generic manufacturers from obtaining samples for equivalency testing to create a competitive alternative drug. The AADA respectfully requests that the Administration consider policies in H.R. 2212 / S. 974, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, which is intended to promote a more competitive drug market by creating a pathway to expedite generic drugs to market. The bill would not only facilitate the entry of more affordable drugs to market, but ensure that safety protocols continue to be held to high standards, and reaffirm the Food & Drug Administration’s (FDA) oversight authority in determining safety requirements.

In addition, the AADA supports the FDA’s recent activity to prioritize its review of generic drug applications and streamline REMS requirements and processes. We appreciate that the FDA published a list of drug manufacturers, both brand and generic, that were improperly withholding samples for testing. REMS is intended to protect patients rather than discourage competition.

**Biosimilar Development, Approval, Education, and Access**

*Resources and tools from FDA/ Educating Providers and Patients*

The AADA applauds the FDA proactively educating healthcare providers and patients about biologic products including biosimilars and interchangeable products. This education should also address forced

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non-medical switching, which may result because of formulary changes, and will become increasingly important as interchangeable products come to market.

**Interchangeability**

As the FDA acknowledges, pharmacy-level substitution laws vary from state to state. The AADA advocates for biosimilar substitution only where the biologic product is designated by the FDA as interchangeable; the pharmacist notifies the prescriber by the time of dispensing; and unique nonproprietary names exist to eliminate confusion, allow providers to accurately track the therapeutic effect in a patient’s permanent record, and allow for the collection of adverse event information.

**Better Negotiation**

*Value-Based Arrangements and Price Reporting*

We commend the Administration’s effort to ensure value and affordability of drugs being purchased under value-based programs. The AADA supports value-based models that engage CMS directly with the manufacturers, linking manufacturers’ payment with health outcomes. The drug prices can be lowered if there is a platform that allows direct negotiations and contracting between the manufacturers and the payers. Value-based prices need to be transparent and accessible. CMS needs to establish clear outcome goals and measure the therapeutic effectiveness levels of the drugs at an individual patient and population level. We also ask that CMS determine ways of measuring and reporting the health outcomes that do not create another administrative burden for the physician treating the patient. The AADA recommends that CMS ensure risk-sharing agreements will not affect the patients adversely, either financially or medically.

In developing value-based models, CMS also needs to help ensure patients are well-informed participants. We believe patient education is an important factor in determining the success of such models since patients are key participants in a value-based, cost sharing program. CMS needs a mechanism to hear from its beneficiaries about the burdens of their diseases as the models are developed. Value is defined differently according to individual patient experience. For some it may mean extending life; for others it may mean improved quality of life or affordability of care. The collection of this type of qualitative data is necessary to incorporate the patients’ perspectives on treatments.

*Indication-Based Payments*

A value-based pricing model, in which the price of a given drug is based on its clinical effectiveness level for different indications, is complex. The AADA is concerned that indication-based payments may actually restrict the ability of providers to treat orphan diseases. For example, dermatology is one of the many specialties that treats a significant number of orphan diseases with infusion therapy. The quality of evidence can vary for a drug or an indication, which can be further challenged for rare diseases. Placing limitations based on indication can restrict access to drugs for patients with rare conditions and may restrict physicians from prescribing what they think is the best medical treatment for their patients.
Long-term Financing Models

The Administration proposes a new Medicaid demonstration authority for up to five states to test drug coverage and financing reforms that build on private sector best practices. Participating states would determine their own drug formularies, establish an appeals process to protect beneficiary access to non-covered drugs based on medical need, and negotiate drug prices directly. While the AADA supports programs that encourage states to engage in constructive and innovative programs that increase access to needed drugs, we caution against granting waivers for programs that would limit such access. For example, earlier this year, Massachusetts submitted a proposal in the form of an 1115 waiver amendment that would potentially limit access to new and innovative drug therapies by imposing a closed formulary with only a single drug per therapeutic class in MassHealth, the state’s Medicaid program. AADA submitted a letter in opposition to the waiver, highlighting how restricting MassHealth’s drug benefits to a closed formulary would limit the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to the state. We appreciate CMS’ recent decision to deny the waiver, but are concerned that CMS stated that they would be open to approving a waiver for this type of closed formulary if the state negotiates directly with manufacturers and forgoes all manufacturer rebates available under the federal Medicaid Drug Rebate Program.

A formulary that includes only one drug per class is an ineffective, draconian approach to reducing health care costs by creating a one–size-fits-all solution. The AADA supports physicians having the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient’s unique circumstances. Each formulary must be developed based on scientifically valid evidence that the selected pharmaceuticals sufficiently provide the most effective therapies for any given condition and that options are available should patients not be able to utilize a given agent due to lack of response, side effects, allergy, etc.

A closed formulary will only complicate physicians’ ability to treat both common skin diseases such as pediatric atopic dermatitis and complicated skin diseases, such as psoriasis or pemphigus vulgaris. For example, a closed formulary, often includes very few topical medications for pediatric atopic dermatitis, resulting in inappropriate or unnecessary treatment. For patients with psoriasis, a closed formulary can result in forced non-medical switching. Abrupt medication withdrawal in these patients can aggravate a quiescent disease and result in psoriasis resistant to previously effective therapy. The consequences, which cannot be predicted for individual patients may, include worsening disease, severe flares including those requiring hospitalization, therapeutic failure, antibody development and risk for greater adverse effects than those associated with current therapy. For many patients, the disease burden extends beyond physical findings; there is lost work and wages and a significant psychological impact. Pemphigus vulgaris is a rare, auto-immune disease that causes blistering of the skin and mucous membranes. Treatment typically involves the prolonged use of steroids and immunosuppressive agents. If left untreated, the complications can be fatal. Each patient who presents with this disease is a unique challenge due to the diversity in the disease. Comorbidities, which include diabetes, hypertension, malignancies, chronic infections, among others, affect the appropriate treatment.
Due to the medical, social and economic consequences listed above, we urge the Administration to not move forward with a Medicaid demonstration that could potentially severely limit access to necessary medications.

*Part B Competitive Acquisition Program*

The Competitive Acquisition Program (CAP) program is an alternative program to the current Average Sales Price (ASP) program where physicians buy and bill Part B drugs. The CAP program became effective in 2006 and was suspended in 2008 due to low enrollment and limited negotiating power. The AADA supports the current payment ASP system for Part B drugs. The CAP program should be restructured to provide greater flexibility and appeal to providers and vendors.

*Part B to D*

The Administration is seeking feedback on a proposal to move some drugs covered under Part B to Part D. The AADA is concerned this transition may lead to access issues for patients who require high cost drugs. There are significant differences in coverage and cost sharing in Parts B and D. In both programs, though, there is no mandated out-of-pocket maximum. If Part B drugs are transitioned to Part D, beneficiaries would likely see higher Part D premiums and increased out-of-pocket costs for some drugs, such as cancer treatments. Additionally, Part D has no supplemental coverage available to help with out-of-pocket costs for these drugs.

The AADA also has concerns that this transition may lead to incidents with the handling of the drugs that require physician administration or an increase in brown bagging. This change may occur, because for drugs covered by Part D there is no way for providers to bill plans for the administration of the drug. Brown bagging is when physician-administered drugs are shipped directly from a pharmaceutical wholesaler to a patient or pharmacy rather than to the physician, after which the patient must transport the medication to the physician’s office, poses significant safety issues for chemotherapy drugs and biologics. Some medications are highly susceptible to changes in light, temperature and humidity. Exposure to adverse environmental conditions can alter the drug’s activity and thus its effectiveness. The AADA opposes insurance plan designs that require patients to utilize this brown-bagging mechanism in order to have physician-administered medications covered, and supports maintaining physician and patient decision-making in terms of what type of arrangement is most appropriate for an individual patient. We urge HHS to consider the impact this proposal would have on treatment access.

Due to the concerns listed above, the AADA requests additional clarification on how this proposal would be structured and implemented.

*Fix Global Freeloading*

The AADA understands the Administration is analyzing different countries’ policies on drug pricing and the comparative impact on what Americans pay for drugs. Importation of drugs from other countries has been mentioned by the Administration as one method to help reduce drug prices. For patients for whom the economic burden or other issues have left little recourse for accessing needed treatments, the AADA
supports the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products meet all FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported. To support patient safety efforts, the AADA will educate its members regarding the risks and benefits associated with drug importation and reimportation efforts.²

Create Incentives To Lower List Prices

Fiduciary Duty for Pharmacy Benefit Managers

The AADA appreciates the Administration’s recognition of the role pharmacy benefit managers (PBMs) play in contributing to the rise in drug prices. Originally created to manage prescription drug plans on behalf of beneficiaries, PBMs have grown into significant stakeholders in the drug supply chain. At present, three PBMs control nearly three-quarters of the PBM market.³ PBMs drive what drugs are available to patients by setting a plan’s formulary, determining which pharmacies are included in a plan’s network, and deciding how much pharmacies are paid. Using "rebates," and other fees, PBMs negotiate with drug manufacturers to receive discounts on products. PBMs set cost-sharing levels, also known as tiers, for the patient and process the prescription claims.

Pharmaceutical manufacturers will introduce drugs at a higher price with the intention of negotiating the price downward with PBMs and insurers to gain access to the formulary. However, as recently noted by CMS, this savings is not typically passed on to the patient. In most instances, cost sharing is based on the list price, or the pre-rebate price, meaning at point-of-sale the patient pays higher coinsurance than they would if their cost sharing was based on the negotiated price or post-rebate price. Insurers will contend that rebate savings are passed on through lower premiums, but the high out-of-pocket costs make some therapies out of reach for patients, leading to decreased compliance, increased complications, and higher overall health care spending.

The use of rebates has risen sharply in recent years. For example, a recent Office of Inspector General report found that the, “Total rebate dollars for all brand-name drugs in Part D more than doubled (a 155 percent increase) across the 5 years, from $9 billion in 2011 to $23 billion in 2015.”⁴ This trend has likely increased due to the rising list prices and the concentration of supply chain stakeholders.

In April 2016, a biosimilar was approved by the FDA, but to date very few PBMs have placed it on a formulary despite being introduced at a 15 percent discount of the wholesale acquisition cost (WAC) of the reference product. In instances where a biologic has enough market share, the PBM is unable to switch because of its reliance on the rebate. To avoid increased costs due to the loss of rebate, the PBM would be forced to switch all stable patients to a biosimilar that is not interchangeable, which is not recommended. If the PBM fails to switch patients to the biosimilar, the PBM risks losing the rebate of the reference product

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² D-100.983 Prescription Drug Importation and Patient Safety; AMA Policy Compendium Sept 2015
³ Health Strategies Group, Research Agenda 2017: PBM Trends & Strategic Implications, February 2017
and incurring a higher total cost. This dynamic prevents biosimilars from achieving preferred status on a formulary and may lead to pharmaceutical companies ceasing the development of the lower cost biosimilars.

**Reducing the Impact of Rebates**

The AADA strongly supports transparency in how PBMs operate in setting drug prices, so patients, physicians, pharmacists, and employers, including the federal government, know the true cost of prescription drugs. This includes cost transparency for the full compendium of medications, as well as how copayment and coinsurance levels are determined so that patients continue to have access to a wide range of treatment options. The processes for determining how drug prices are negotiated, both specialty and generic, should be readily transparent to demonstrate that patients receive the full benefit of any cost lowering measures. To help ensure that cost considerations are a meaningful part of the decision-making process, the AADA believes access to real-time cost information should be available to patients and physicians at the point of prescribing. Consolidation of the industry and current financial arrangements must be monitored to avoid conflict of interest. Further investigation is necessary to determine the extent to which PBM negotiations and arranged rebates affect formularies, tiers, and drug prices.

The AADA supports legislation that requires more transparency on the part of PBMs. The AADA respectfully requests that the Administration consider policies proposed in H.R. 1316, the Prescription Drug Price Transparency Act, and S. 637, the Creating Transparency to have Drug Rebates Unlocked (C-THRU) Act. H.R. 1316 would ensure patient choice of pharmacy, require drug price lists to be frequently updated, and would require PBMs to disclose sources used to establish drug pricing standards. S. 637 would require more transparency on the part of PBMs regarding rebates and discounts they receive from drug manufacturers for Medicare Advantage and Medicare Part D. The bill would enable consumers and employers to be better educated about the savings, if any, passed on to patients. The AADA urges HHS and CMS to take into consideration costs those PBMs could pass on to patients as it considers regulatory action.

CMS recently requested comments in the Part D proposed rule on whether it should require Part D plans to include at least a minimum percentage of manufacturer rebates received for a covered Part D drug in the drug’s negotiated price at the point of sale. CMS also proposed to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS, even when such concessions are contingent upon performance by the pharmacy. To protect propriety and cost information, and to ensure high cost drugs are targeted by this proposal, the AADA supports CMS’ recommendation to explore requiring plan sponsors to pass through at least a minimum percentage of rebates at the point of sale only for specific drugs or drug categories or classes. We also encourage CMS to examine the impact of this change in the redistribution of rebates on premiums.

Recently, some insurers, such as UnitedHealthcare and Aetna, announced they are devising strategies to pass rebates on to patients in their fully insured markets. The AADA encourages insurers to share these savings, and pass rebates on to patients.
Additionally, the AADA encourages HHS to consider the following recommendations as it looks to assess the drug supply chain and explore innovative methods to ensure patients have access to affordable and effective drugs. Specifically, the AADA recommends that HHS:

- Evaluate mergers and acquisitions, including vertical integration, and the potential effects on the drug supply chain and proposed policies outlined in this RFI;
- Explore the impact of new entrants into the pharmaceutical supply chain, including the impact this has on the market;
- Monitor potential instances of pay-for-delay and evergreening.

**Incentives to Lower or Not Increase List Prices**

HHS requests comments on implementing a lookback period for manufacturers to determine whether there is a price increase or discount during that set time and how a price change can potentially affect formulary placement or reimbursement in Parts B and D. While the AADA recognizes the concern of fluctuating drug prices and the impact it can have on treatment plans, we have concerns this proposal can lead to an abundance of flexibility in formulary management for plans with the potential to cause access issues.

This proposal may potentially allow, for example, Part D plans to only require a minimum of one drug per category or class rather than two if there is a significant price increase. It also expands plans’ abilities to make mid-year changes to the formulary. The AADA worries this could create access issues for patients on high cost biologic medications. Part D benefits should not limit patients’ access to the medical therapy judged by the treating physician to be the most efficacious choice. The AADA reiterates that allowing the most appropriate and efficacious therapy as judged by the treating physician can also result in long-term cost savings.

Patients often choose plans based on drug formularies, and those should remain consistent for the entire plan year. If a mid-year formulary change were to occur, patients should have advance notice. Plans should also be required to update their formulary at the time any changes are made.

**Copay Discount Cards**

The AADA believes that limiting cost-sharing requirements will improve patient access to treatments and reduce financial disability while helping to constrain health care costs. This will also help improve adherence to the medication. It is recommended that patients who use copay cards or similar discount cards have access to information on how these policies affect their deductible and out-of-pocket maximum spending. Language in plan contracts must clearly state how a coupon is processed and accounted for in that specific plan.

**The 340B Drug Discount Program**

**Program Growth**
The AADA recommends preserving the 340B program reimbursement levels as both rural and urban facilities benefit from the 340B program by having the ability to increase access to affordable drugs for the patients they serve. HRSA found that “institutions eligible for the 340B program save a mean of 50% on their drugs purchased through the program, but the range varies significantly.” These cost savings help these facilities manage rising drug prices while ensuring low income patients have access to low cost outpatient drugs. Rural sole community hospitals (SCHs) would likely be in debt if it were not for the 340B program. Those hospitals serve a disproportionate share of uninsured patients and often struggle with keeping their doors open due to growing healthcare costs.

While the AADA is supportive of the program, we recommend CMS work to ensure the program is more transparent. CMS previously proposed establishing new claims modifiers to better track drugs purchased under the 340B program. AADA requests that CMS provide data on the use of the program after the implementation of these modifiers to determine if it is successful in tracking the use of the drugs. CMS should request that participating institutions delineate clearly how the income that is generated by the 340B rebates is used for low-income patients as Congress intended. At the same time, the Academy would appreciate if continued efforts are made to reduce the administrative burden associated with the program. The complexity of administration of the program can be crippling, particularly for small and public hospitals.

**Duplicate Discounts**

The AADA understands there is some concern about the increasing number of contract pharmacies utilized in the 340B program. We recommend the Administration review the recently released GAO report on contract pharmacies to determine the extent to which duplicate discounts are taking place before updating any policies.

**Reduce Patient Out-of-Pocket Spending**

**Part D End-of-year Statement on Drug Price Changes and Rebates Collected**

HHS proposes that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending and drug price increases. HHS seeks feedback on whether this information should be distributed on the explanation of benefits (EOB) or by the pharmacist. The EOB currently shows what the plan, member, and others paid for the drug. The AADA believes the more information the beneficiary has about their expected drug costs, the better equipped they will be to plan for healthcare costs that year. High out-of-pocket costs can significantly impact the ability of patients to access the treatments they need, costing patients hundreds, and in some cases, even thousands, of dollars per month for a single medication. This can place medically necessary treatments out of reach for average Americans. Knowing when a drug is rising in price and if there are alternatives available would be helpful information for any patient. However, requiring this information on an EOB or end of year statement may not be the most

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practical methods of presenting the cost data. Part D enrollees currently receive an EOB each month they fill a prescription. They would have already filled the prescription by the time they are notified of a large price increase. Depending on when the price increase takes place, they may be able to set up an appointment with their physician to discuss other treatment options for the remaining part of the year. The cost information on the end of year statement would be too delayed for them to take any action for that year’s plan. Another option HHS should consider, in addition to the proposed reporting, is to require pharmaceutical manufacturers to provide notice on the end of year statement of any price increase of a drug (generic, brand or specialty) by 10% or more each year or per course of treatment and provide the justification for the price increase. Ongoing significant price fluctuations of drugs make it increasingly difficult for dermatologists to prescribe the most affordable and effective treatment for patients. This policy would help protect patients against large price spikes.

In addition to the information on the drug price increases, we recommend including any coverage changes on the enrollee’s end of year statement. We encourage HHS to continue to explore ways to increase the transparency of drug cost and coverage information to both the provider and patient.

*Federal Preemption of Contracted Pharmacy Gag Clause Laws*

Drugs prescribed for skin diseases have been disproportionately impacted by rising drug prices. When drugs become cost-prohibitive for patients with life-altering, but not life-threatening diseases, they often go without. A recent study⁶ published in the Journal of the American Medical Association (JAMA) found that of 9.5 million insurance claims reviewed, 23% of prescriptions filled through insurance cost more than if the patient had paid for the drug out-of-pocket. The list of prescriptions includes prednisone, a drug used to treat many dermatologic conditions, including severe contact dermatitis, and autoimmune diseases, which was among the drug claims where patients on average made overpayments about 50 percent of the time.

The AADA strongly supports legislation pending in the Senate that lifts the “gag clause” by health insurance providers and PBMs that restricts pharmacists from informing patients that a certain drug is cheaper if paid for out-of-pocket, rather than going through their insurance. The AADA respectfully requests that the Administration consider policies proposed in S. 2553, the Know the Lowest Price Act, and S. 2554, the Patient Right to Know Drug Prices Act. S. 2553 would prohibit this restriction for drugs covered by Medicare Advantage and Medicare Part D, while S. 2554 would prohibit this restriction for drugs covered under the individual market exchange plans, as well as group health plans covered by the Employee Retirement Income Security Act (ERISA).

*Inform Medicare Beneficiaries with Medicare Part B and Part D about Cost-sharing and Lower-Cost Alternatives*

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Stakeholders in the drug supply chain claim they are exploring innovative ways to provide real-time information on drug costs and alternatives, but we have seen no evidence that this information is accessible. There is an immediate need for this drug coverage and cost information to be more readily available to patients, prescribers and pharmacists. The constant price fluctuations of drugs and lack of accurate price information at the point of prescribing continues to disrupt the physician-patient relationship. Physicians want to prescribe the most effective and affordable treatments for their patients. When a patient goes to the pharmacy and realizes they are not able to afford the prescribed treatment it creates a sense of distrust between the patient and the physician. The AADA supports patients’ and physicians’ access to real-time cost information available at the point of prescribing to ensure cost considerations are a meaningful part of the decision-making process. The AADA recommends that HHS require that plans and PBMs keep pricing information up to date, and require integration of this data with EHR vendors. Furthermore, the AADA supports HHS reviewing the work of the National Council for Prescription Drug Programs (NCPDP) on electronic transactions for electronic prior authorizations. These standards aim to both streamline the prior authorization process and provide real-time prescribing and pricing information for physicians.

Overall, the AADA recommends HHS convene stakeholders, including but not limited to physician groups, hospital groups, insurers, PBMs, and pharmacies, to discuss barriers to implementing this technology.

**Additional Feedback**

5-Part Plan to Modernize the Medicare Part D Program

In the 2019 budget, the Administration proposes a 5-part plan to update the Part D program. It includes substantial changes to the Part D program. HHS emphasizes in the RFI that the 5 parts of the plan are meant to be implemented together. The AADA has concerns with one of the proposals to allow Part D plans to only require a minimum of one drug per category or class rather than two. This proposal also permits plans to increase the use of utilization management practices for drugs in the protected classes. This will severely limit access to medically necessary drugs. Patients already face many administrative hurdles getting access to the drugs they need, and this will dramatically increase the time it takes for patient to obtain access to a drug. Additionally, patients may experience increased out-of-pocket costs for some drugs if this were to be implemented. Higher out-of-pocket costs can lead to patients abandoning their medication at the pharmacy. According to the Centers for Disease Control and Prevention (CDC), “nearly 18% of chronically ill Americans report underusing medications and delaying or not fulfilling therapeutic recommendations because of cost,” and “56% of American adults with common chronic diseases self-report nonfulfillment of medication as a result of financial hardship.”

While we understand the need to contain costs, there must be a recognition that when patients can adhere to a treatment plan it improves health outcomes and lowers long-term healthcare costs. For the high cost drugs, which this proposal would likely target, there are often minimal or no alternatives available.

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Dermatologists continue to be committed to providing the most effective and cost-efficient care and therapies to their patients. A recent study found that in general dermatologists prescribe their patients, covered by Part D plans, less brand medications than other specialties except for when a biologic is necessary for the patient as that often has no available generic alternative."8 Patients suffering from chronic, disabling conditions need access to affordable medication that is not only necessary, but also life changing and often lifesaving. We urge the Administration to consider the negative long-term impacts of implementing this proposal.

*Anti-kickback Statute*

While value-based arrangements hold the potential to promote greater care coordination and generate cost savings, turning this into a sustainable reality means reassessing outdated fraud and abuse laws that were designed for a fee-for-service environment. The federal anti-kickback law and its derivative Medicare and Medicaid regulations were designed to prohibit payment, receipt, offering or solicitation of remuneration in exchange for referral services or items covered by CMS. We recommend that when contemplating changes to the anti-kickback statute for purposes of this request for information, it would be beneficial to all stakeholders that the Secretary of HHS is able to exercise discretionary waiver protection authority and be able to grant safe harbor protection to any value-based arrangements based on the specific nature of such arrangements and consistent with the need to have greater transparency in drug pricing programs, including but not limited to fair market value/pricing and other compliance mechanisms that balance patient access to critical medications with the need to avoid further unnecessary and burdensome regulatory compliance requirements for clinicians.

*Current Regulations or Government Policies Related to Prescription Drug Pricing That Impose Burden on Providers*

The AADA commends HHS for its commitment to reduce regulatory burdens for physicians. We would like to highlight two issues that continue to be a barrier to dermatologists providing the most affordable and effective treatments for patients.

*Prior Authorizations*: Physicians are facing significant burdens meeting Medicare Part C and D plans’ prior authorization requirements for medically necessary drugs. The AADA recommends requiring CMS to alleviate this burden by requiring Medicare Advantage and Medicare Part D participating plans to shorten the turnaround time for prior authorizations and to extend the length of the prior authorization appeal period. Additionally, patients, who are stable on a therapy and switching to a plan where a prior authorization is necessary for that treatment, should continue to have access to that same therapy for at least 60 days. The AADA also recommends that CMS encourage plans to provide detailed explanations for prior authorization denials, including the clinical rationale, the covered alternative treatment and details on the provider’s appeal rights. Furthermore, the AADA recommends that CMS standardize the prior

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authorization form across all Medicare Advantage and Medicare Part D plans in order to streamline the process.

Physicians also face difficulties in accessing the prior authorization requirements for specific plans, including state-run and federally subsidized Medicaid plans. The AADA believes plans must make the following information available to the physician in an electronic medical record(EMR) at the point of care: the prior authorization requirements, documentation and information necessary for completing a prior authorization, and a direct telephone number for physicians and their staff to call regarding prior authorizations (not the main prior authorization line). CMS should require health plans to accept prior authorization requests directly from the EMR systems and not force physicians to use the individual systems set up by each health plan, that require a separate login and password. Additionally, the AADA recommends that all exceptions decisions be made by a provider who is of the same specialty, and subspecialty, whenever possible, as the prescribing/ordering provider.

Lastly, the AADA encourages CMS to continually review the list of drugs requiring prior authorizations. A reduction in the number of drugs subject to prior authorizations, especially those that are commonly approved, should be considered on an annual basis. CMS should also require plans to restrict prior authorizations to outlier clinicians and exempt those who have demonstrated very low denial rates due to their consistent use of evidence-based standards.

**Drug Shortages:** Drug shortages continue to plague dermatologists and their patients as our members across the country have reported unavailability and difficulty obtaining needed local anesthetics for many months at a time. Manufacturers and suppliers are filling backorders at an unpredictable and slow pace, placing patients at risk. Physicians are running out of their stocks before they can obtain replacements. Physicians also worry that the shortage will lead to increased prices for local anesthetics. We ask that the FDA take immediate action to address these critical shortages.

The AADA is very concerned about the adverse impact these shortages have on patients. Lidocaine with epinephrine, for example, is used in biopsies and skin cancer surgery. Dermatologists are having to use these drugs sparingly and are facing disrupted workflows. They worry about uncontrolled intraoperative bleeding without having access to epinephrine. Increased bleeding can lead to an obscured operative site, which forces physicians to delay surgeries. Intraoperative bleeding can also increase the risk of postoperative bleeding. This critical drug shortage is a threat to patient safety especially as it can lead to other costly complications when the drug is not accessible.

The only ways to obtain any information regarding the matter are to check the FDA drug shortage website or contact the drug manufacturer or supplier directly. The resupply dates continue to be pushed back with little explanation, which becomes increasingly concerning as more and more physicians run out of supplies. The suppliers receive unpredictable shipments of the drug from manufacturers and fill it on a first-come, first-serve basis or however they choose to prioritize customers, but are unable to keep up with the backorders. The alternatives to lidocaine with epinephrine are limited and often cost prohibitive. We anticipate that this situation will worsen and repeat, given the small number of manufacturers producing the drug, and that some have stopped producing it all together.
The AADA recognizes that shortages occur for a variety of reasons, such as difficulty accessing raw materials or increased demand. With a multifactorial issue such as drug shortages, there is still more to be done. We ask that the FDA:

- Monitor the prices of generic drugs during and after a shortage;
- Create incentives for manufacturers to produce lidocaine with epinephrine and other local anesthetics during a shortage;
- Allow temporary importation of lidocaine with epinephrine due to the severe backlog of orders;
- Require manufacturers to have plans in place to deal with production issues or delays.

Provider associations frequently become aware of shortages early on, know when it escalates, and can be a resource to the FDA. Overall, there is a need for greater transparency regarding what the FDA is doing to address drug shortages. We hope that the FDA will work with the manufacturers to resolve this shortage quickly for the sake of, the safety of and access for our patients.

**Conclusion**

We welcome the opportunity to engage with you and to continue our partnership with HHS in these efforts to reduce drug costs for patients. In particular, we strongly encourage HHS to engage the physician community as it looks to develop these policies. To that end, we welcome the opportunity to serve as a resource on any of these topics. Please contact Ashley John, Senior Specialist, Advocacy and Policy at (202) 609-4355 or ajohn@aad.org if you have any questions or if we can provide additional information.

Thank you for your consideration.

Sincerely,

[Signed]

Suzanne Olbricht, MD
President
American Academy of Dermatology Association

cc:

Elaine Weiss – Executive Director and CEO, American Academy of Dermatology
Barbara Greenan – Senior Director, Advocacy and Policy, American Academy of Dermatology Association
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