American Association of Clinical Endocrinologists
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Alex Azar
Secretary
U.S. Dept. Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

On behalf of the American Association of Clinical Endocrinologists (AACE), I thank you for the opportunity to provide comments on the *American Patients First,* the Administration's blueprint for lowering drug prices and reducing out-of-pocket costs.

As the largest association of clinical endocrinologists in the world, AACE represents more than 7,500 endocrinologists in the United States and abroad. The majority of AACE members are certified in Diabetes, Endocrinology and Metabolism and concentrate on the treatment of patients with endocrine and metabolic disorders including diabetes, thyroid disorders, osteoporosis, growth hormone deficiency, cholesterol disorders, hypertension, and obesity.

Clinical Endocrinologists are specialists in diabetes who treat patients with some of the most complex and uncontrolled diabetes. Patients with type 1 diabetes need insulin for survival and frequently insulin is the only drug that can control the diabetes of patients with type 2 diabetes. In recent years, the cost of insulin has nearly tripled, which has placed tremendous hardship on many patients with diabetes. Patients who can no longer afford their insulin may take less insulin than is prescribed, leading to poorly controlled diabetes, which can lead to premature death in some cases. Without adequate control of their diabetes, people with diabetes have a higher risk of developing microvascular complications such as blindness, kidney disease and nerve damage, and macrovascular complications including heart attacks and strokes. Therefore, it is imperative that people who require insulin be able to obtain it at a cost that is affordable.

Solutions to the high cost of prescription drugs – including insulin – have been elusive to date; however, we believe the Administration can be a real catalyst for progress on this critical issue. We applaud you for proposing concrete actions to lower drug prices and reduce patients' out-of-pocket costs and appreciate the opportunity to provide comments on your proposals related to the following issues:

1. Increasing Competition
   a. Approval Pathway for Biosimilars/Interchangeability
   b. Educating Clinicians and Patients on Biosimilars/Interchangeability
2. Better Negotiation
   a. Changing Drugs from Medicare Part B to Medicare Part D
   b. Access to Medically Necessary Drugs/Formulary Stability
3. Create Incentives to Lower List Prices
4. Reduce Patient Out-of-Pocket Costs
   a. Information/Tools to Help Physician Knowledge about Formulary Options
   b. Zero Copays or Fixed Cost Cost-Sharing

1. Increasing Competition

    a. Approval Pathway for Biosimilar Interchangeability

Biosimilars are medicines that could be cost-saving alternatives for patients requiring specialty drugs called biologics, which are large molecule, complex therapeutic agents typically given by an injection or infusion, such as insulin.

The size, complexity, and heterogeneity of biologics, and thus biosimilars, necessitate a greater degree of scrutiny in their analytical evaluation than what is required for small molecule generics. Due to the complexity of biologics, separate regulatory approval and dispensing pathways were created to ensure effectiveness and protect patient safety. In addition to adequate pharmacokinetic and pharmacodynamics studies, clinical data are necessary to ensure the safety and efficacy of biosimilars, and to provide the necessary level of confidence for their use by patients and physicians.

Congress authorized the FDA to provide two pathways for biosimilar approval: 1) biosimilar agents that have equivalent safety, purity, and potency as original biologics; and 2) a higher level of interchangeable biosimilars in which alternating or switching between an original biologic and biosimilar would not be predicted to cause any changes in efficacy or safety. Most state legislatures have passed laws that will allow substitution of an interchangeable biosimilar for a reference product, with the necessary notification of the prescriber to ensure patients receive drugs consistent with their provider's treatment plan.

The FDA must ensure that regular and interchangeable biosimilars are safe and effective. None of the follow-on biologics for insulin approved to date have been approved as interchangeable for the branded version.
In January 2017 the FDA released draft guidance outlining requirements for manufacturers to use robust switching studies to determine whether alternating between a biosimilar and its reference product impacts the safety or efficacy of the drug. The requirement for multiple-switch studies to demonstrate the safety of interchangeability is particularly vital to proper enforcement of the law, which requires studying "alternating" or repeatedly switching. It is our hope that once the guidance is finalized, it will allow for the development and designation of interchangeable biosimilars to proceed, accelerating the availability of less expensive biologics that provide safe, effective, and accessible treatment options for patients.

AACE strongly supports a rigorous pathway for demonstrating biosimilar interchangeability and we believe that it is imperative that the proposed draft guidance issued by the FDA in 2017 be finalized, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times in one patient care episode impacts the safety or efficacy of the drug.

AACE also supports the implementation of FDA policy or additional steps the agency may take to prevent the pharmaceutical industry from using a Risk Evaluation and Mitigation Strategy (REMS) to block or restrict access to reference product samples by generic drug developers so they can do the testing required to bring a drug to market.

    b. Educating Clinicians and Patients on Biosimilars/Interchangeability

As a growing number of follow-on biologic or biosimilar drugs make their way to the market, prescribing physicians should understand how regulators, pharmacists, and payers may affect delivery of these complex molecules to their patients. A biosimilar or follow-on biologic is not necessarily interchangeable with its

reference product, though eventually these drugs may be deemed interchangeable through a forthcoming approval pathway. Without the proper designation in the FDA's Purple or Orange book, a pharmacist is not likely to make a substitution, and a growing number of state laws are currently being enacted to ensure that no biosimilar substitution is made without first contacting the prescribing physician. A prescribing physician should also be mindful of how a patient's insurance formulary treats these comparable treatments. A formulary will consider whether one treatment may be substituted for another and decide to cover just one of the two. In those circumstances, a physician may need to prescribe the preferred medication as "dispense as written," and insurers that exclusively cover one treatment will need an explanation of medical necessity to cover the other. Ultimately, the physician should discuss these concerns with the patient and make a decision based on the treatment plan best suited for that patient.

2. Better Negotiation

    a. Changing Drugs from Medicare Part B to Medicare Part D

AACE is very concerned about the impact of the proposals to change drugs from Medicare Part B to Medicare Part D (the voluntary prescription drug program). Patients with diabetes may use infusion pumps to receive their insulin and help them maintain stable glucose control. Patients who are insulin-dependent and take their insulin by using an infusion pump have their insulin covered as part of the durable medical equipment (DME) benefit under Medicare Part B. Other patients who do not use infusion pumps but rather inject insulin with syringes obtain their insulin under the Part D program.

The Average Sales Price (ASP) on which the payment for Part B drugs is based, includes all sales net of all discounts and rebates. Therefore, the ASP includes discounts and rebates that are negotiated by commercial payers and those discounts and rebates are available to Medicare beneficiaries at the point of sale when their insulin is covered under Part B. Part D plans get discounts and rebates, but they don't pass them on to beneficiaries at the point of sale.

There are other factors that help reduce costs for patients receiving drugs under the Part B program, including the difference between deductibles under Part B ($183 deductible for all Part B services) and Part D ($405 separate deductible just for drugs); coinsurance under Part B (20%) versus Part D (25% until a beneficiary is in the catastrophic phase); and beneficiary utilization of supplemental coverage that will cover all of the Part B coinsurance and none of the Part D coinsurance.

Moving drugs from Part B to Part D without requiring that the full rebate received by a Part D plan be passed on to the beneficiary would significantly increase the cost of insulin for beneficiaries that use an infusion pump to help manage their disease on a daily basis and exacerbate what is already a challenging situation for these patients. We fully support the proposal to share with patients at the point of sale the rebates that Part D plans and pharmacy benefit managers (PBMs) negotiate with drug manufacturers to reduce out-of-pocket costs for patients. Also, we believe it is imperative that a cost analysis be performed prior to moving any Part B drugs under the Part D program with a comparison of the costs to the patient being the determining factor for such a change.

    b. Access to Medically Necessary Prescription Drugs/Formulary Stability

AACE opposes any policies that restrict access to medically necessary prescription drugs. Such policies, which include preferred drug lists with prior authorization requirements, restrictive formularies, fail-first requirements,

monthly prescription limits, and tiered co-payment structures, fail to achieve their intended purpose of reducing overall healthcare costs. Such policies also prolong human suffering and reduce the potential for an individual with a medical condition to make a full recovery. Moreover, restrictive policies fail to acknowledge that practitioners and patients should make individualized treatment decisions.

We believe that decisions resulting from these policies should always be clinically based and that best practice treatment planning will provide long-term cost containment. Decisions rendered by the Medicare Part D prescription drug program's plan administrators should not supplant what a physician believes is the best course of treatment for a patient based on the physician's best clinical judgement. If implemented based upon the evidence, such protocols can be useful in ensuring appropriate access to medical care and medications leading to quality improvement and reduced healthcare costs. AACE urges you to require that all Medicare Part D prescription drug plans adhere to the following policies:

1. Eliminate "fail first' requirements and step therapy programs;
2. Enforce "Dispense as Written" designations on prescriptions to prevent automatic switching at the pharmacy point of sale;
3. Implement a "grandfathering" policy to ensure that consumers who are successfully being treated on a non-preferred drug are not forced to switch;
4. Review and update preferred drug lists periodically based on clinical evidence and scientific consensus, considering efficacy and safety. Appropriate specialty representation should be required on panels adjudicating the medications prescribed by a specialist;
5. Require that prior authorization processes establish criteria for a timely response, and clear appeals and grievance procedures that will not to delay access medication or deter the prescriber from ordering medications that will have optimal benefits; and
6. Mandate that decisions on prior authorization requests and subsequent appeals be made by a practitioner from the same specialty as the requesting prescriber.

There is also considerable variation in prior authorization criteria and requirements among plans. The lack of standardization causes significant burdens for physicians, who must identify and follow each plan's unique requirements. Compliance with these policies imposes extreme administrative burdens and uncompensated costs on physician practices. Prior authorization programs should be in an electronic format and have standardized criteria, including the reasoning for the prior authorization requirement and recommended alternatives for a particular drug requiring prior authorization, to promote uniformity to reduce administrative burdens. We also recommend that medical society clinical practice guidelines be recognized as an accepted evidence base for prior authorization determinations.

We also must stress the importance of Part D plan formulary stability throughout a plan year and express concern about proposals to allow Part D plans to adjust formulary or benefit design during the benefit year. The stability of drug formularies during a plan year is important to patients with diabetes, so that they will continue to have access to the insulin product that best helps them manage their disease on a daily basis. There are many factors that patients and their physicians consider when choosing a medication, including efficacy, risk of low blood sugar, pre-existing cardiovascular diseases, impact on weight, potential side effects, costs and patient preferences. Non-medical switching of medications that occurs when a medication is removed from a formulary or moved to a higher tier in a formulary can disrupt a successful care plan, jeopardize patient health and quality of live and expose patients to burdens of increased cost-sharing

AACE opposes the Administration's proposal to restrict coverage of Part D drugs by requiring plans to include only one drug in each therapeutic class on their formularies, allow greater use of restrictive drug utilization management policies for drugs in the protected classes, and allow plans to adjust formularies and/or benefit designs during a benefit year. It is hard to see how such proposals would increase patient access to medically necessary drugs and lower patient out-of-pocket costs.

3. Create Incentives to Lower List Prices

The supply chain for insulin is very complicated and poorly understood. It is unclear, at least to most physicians and patients, what factors contribute to establishing a list price for a drug and how the list price is changed throughout the supply chain by discounts, rebates, coupon cards, etc. It appears that some of these factors only increase the list price to offset their costs. Understanding these issues and improving price and cost transparency will help create solutions to skyrocketing insulin costs. This will in turn help both physicians and patients develop optimal treatment plans and help patients with affordability issues at the point of sale. It seems, however, that the list price is an artificial price that the majority of patients do not pay, so it is unclear what the benefit would be of placing list price information in direct to consumer advertising. Such information may actually dissuade a patient from taking a medication they need or discussing a health issue and related treatment options with their physician.

AACE strongly supports legislative and regulatory initiatives that will facilitate greater drug price and cost transparency throughout the complex supply chain; however, because of the abstruse relationship between list price and patient out-of-pocket costs, we do not support placing list prices for medications in direct to consumer advertising.

4. Reduce Patient Out of Pocket Costs

    a. Information/Tools to Inform Medicare beneficiaries about cost-sharing and lower cost alternatives

The Administration has proposed providing patients with a list of "lower cost alternatives" in the Part D explanation of benefits (EOB). If the "alternatives" are drugs for the same disease, but from a different class, and therefore with different Mechanisms of Action (MOA), different on-target effects, different beneficial effects that are off-target, different adverse effects, etc., then some of these "alternatives" may not be appropriate for certain patients. Because some drugs actually do have alternatives that may result in cost-savings, we urge that that expert physician specialists in the therapeutic area in question be involved in creating these lists of "lower cost alternatives" in order for this concept to be safe for the patient and helpful for the physician.

It is suggested in the Blueprint that plans and pharmacy benefit managers have found new ways to inform prescribers about the formulary options, expected cost-sharing and lower-cost alternatives specific to individual patients. This has not generally been our experience and we would urge the Administration to take additional steps to promote drug cost and price transparency. Patients and physicians *should* have access to complete price information when determining treatment options. AACE applauds the Administration for proposing to eliminate gag clauses that prohibit Part D plan contracts from telling patients when they could pay less out-of-pocket by not using their insurance. We also urge CMS to work with electronic medical record (EMR) vendors and insurance companies by incentivizing the integration of current formularies and price information into all EMR systems, so physicians and their patients can make shared informed decisions on medications to reduce the cost burden on patients.

b. Remove Insulin from Deductibles and Cost-Sharing Like Other Preventive Benefits

Medications that are life-sustaining such as insulin, without which could lead to death, should be placed on preventive drug lists and covered without patient cost-sharing. We urge the U.S. Preventive Services Task Force to review insulin for consideration as a preventive benefit to improve access and adherence that will result in better long-term health outcomes.

AACE commends you for taking on the challenge of high prescription drug costs and engaging all stakeholders in pursuit of solutions to this issue. We note that the Administration's efforts are already facilitating voluntary actions by pharmaceutical companies to limit or forgo scheduled price increases and take additional steps to make life-sustaining medications more affordable. We must continue to strive to assist patients who require medications to live and manage their chronic disease, so they can access the drugs that they need.

Once again, thank you for the opportunity to comment on *American Patients First*. AACE looks forward to working with you to increase the affordability of prescription drugs and to improve patient outcomes. If you have any questions or if we can be of assistance, please contact Sara Milo, Director of Legislation & Governmental Affairs, at smilo@aace.com.

Sincerely,

Daniel L. Hurley, MD, FACE
President