AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

July 11, 2018
The Hon. Secretary Alex M. Azar II
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
[Submitted electronically via http://www.regulations.gov]

Re: [83 FR 22692; RIN 0991-ZA49; Document Number: 2018-10435]
HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), and the specialty societies that agreed to weigh-in and sign-on to these comments, we would like to share input on the Administration's Blueprint on lowering drug prices. The AAOS appreciates the initiatives undertaken by The White House and your Agency in this regard and for prioritizing lowering the prices of prescription drugs for all Americans. In our comments below, we have responded to some of the questions included in this Request for Information (RFI) that was published in the Federal Register on May 16, 2018.

Increasing Competition

We appreciate the Food and Drug Administration's (FDA) efforts to speed up the approval of generic drugs. By your own analysis,[1] currently, about 10 percent of branded drugs with expired patents have no competition from generics. Further, in 2016 generic drugs accounted for 89 percent of prescriptions written and 26 percent of total prescription expenditures.[2] As you have correctly noted, generics bring greater competition into the market. Thus, publicizing drugs that currently do not have generic counterparts can spur further competition and lower prices.

[1] U.S. Department of Health and Human Services (2017). Understanding Recent Trends in Generic Drug Prices. Available: https://aspe.hhs.gov/system/files/pdf/175071/GenericsDrugpaperr.pdf
[2] Association for Accessible Medicines (2017). Generic Drug Access and Savings in the U.S. Available: http://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report

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Related to this, biosimilars can reduce the patients' out-of-pocket expenditure as well as payer cost of treatment by offering a highly similar, lower priced alternative. However, physicians should be reimbursed the same amount for each biosimilar product as for their reference drug under Medicare Part B. This will ensure that Medicare beneficiaries have equal access to biosimilar products. As this area evolves, the Centers for Medicare and Medicaid Services (CMS) should revisit its reimbursement policies to ensure adequate access to biosimilars and encourage innovation. Also, the Department of Health and Human Services (HHS) should work closely with the FDA and CMS to make it easier for biosimilars to be included and preferred on formularies.

Given your emphasis on encouraging innovation, AAOS believes that biologics are the future of musculoskeletal care. Your Agency should start thinking about ways to accurately encourage and pay for these technologies. However, at this time the evidence-based literature has just begun to study the efficacy and effectiveness of such treatment. Thus, initially we support the FDA's decision to take a more conservative and watchful approach such as on stem cells, irrespective of the harvest site.

Recently, the prices of many older generic drugs, including numerous antibiotics, have increased substantially. These antibiotics are essential for treating musculoskeletal and other infections. According to an estimate[3] of pricing and availability of antibiotics, between 2013 and 2016, 11 (14 percent) formulations increased in price by 90 percent or more, and 13 (16percent) had 2 or fewer manufacturers during the period of analysis. Antibiotic prices were negatively correlated with the number of available manufacturers. Thus, greater manufacturer competition is needed to keep essential antibiotic prices affordable.

There is a great need for information dissemination on availability and pricing of prescription drugs for patients and providers. Often patients do not have access to the actual price of a drug and the availability of cheaper alternatives because of non-disclosure terms on price negotiations between insurance plans and pharmacy benefit managers (PBMs). Sometimes, co-pay amounts may be greater than out of pocket prices for a medication. In 2013, one in four Part D medications were overpaid for by patient beneficiaries, who had higher copayments than the drug's list cash prices. For 12 of the 20 most commonly prescribed drugs, patients

[3] Alpern, J. D., Zhang, L., Stauffer, W. M., & Kesselheim, A. S. (2017). Trends in pricing and generic competition within the oral antibiotic drug market in the United States. *Clinical Infectious Diseases, 65*(11), 1848-1852.

overpaid by more than 33 percent.[4] Under such circumstances, pharmacists should be able to openly discuss the alternatives with patients and help them choose the best medication. This will require a change in the current pharmacy-gag requirements in plan-PBM contracts. Even providers are, sometimes, unaware of actual prices and cheaper alternatives. Providers often must prescribe multiple medications before knowing what is on a formulary. In addition, the HHS Office of Inspector General (OIG) notes that there are 386 "unique" formularies used by the more than three thousand Medicare Part D plans operating in 2018. Payers are not forthright with that information. Although health plans and PBMs have developed ways to better share this information with physicians, in practice, this often does not happen. The CMS should be able to write regulation that requires payers and PBMs to share such information without electronic health record (EHR) vendors charging additional fees for such information. Related to this, actual cost of Part D medication to patients is often unclear because of discounts and rebates. The CMS should consider undiscounted drug prices when determining catastrophic level thresholds. Also, the public should be made aware of the net price rather than the list price of a prescription drug.

The FDA has a great variety of informational materials, public service announcements, infographics and articles on brand name vs. generic drugs as well as alternative biosimilars. All these materials should be widely available at doctors' offices and at pharmacies.

Thus, price transparency is the first step toward better competition and information-sharing in the prescription drug markets. Further, effective policies are needed to promote competition. One cautionary note here is that some medications simply do not have a lower-priced alternative. In those cases, lowering drug prices is not a straightforward solution. We discuss additional issues on creating value-based payments for prescription drugs below.

Better Negotiation

A recent report[5] from the HHS OIG found that total reimbursement for all Part D brand-name drugs increased 77 percent from 2011 to 2015, despite a 17-percent decrease in the number of prescriptions for these drugs. During the same period, Part D beneficiaries who did not receive

[4] Jaffe, S. (2018). To Lower Your Medicare Drug Costs, Ask Your Pharmacist For The Cash Price. National Public Radio. Available: https://www.npr.org/sections/health-shots/2018/05/29/614556060/to-lower-your-medicare-drug-costs-ask-your-pharmacist-for-the-cash-price

[5] HHS Office of Inspector General (2018). Data Brief. June 2018. OEI-03-15-00080 Available: https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf

third-party assistance had $29 billion in out-of-pocket costs (which include copayments and coinsurance amounts) for all brand-name drugs. This is a substantial increase in financial burden for Medicare beneficiaries. Presently, Part D plans and PBMs negotiate rebates with drug manufacturers in exchange for favorable placement on drug plan formularies. However, as indicated above these negotiation details and rebate amounts are not public. HHS should take actions to make these details and amounts publicly available.

As you are aware and have acknowledged in this blueprint, the Secretary of HHS is prohibited from negotiating directly with drug manufacturers on behalf of Medicare Part D enrollees. The Congressional Budget Office (CBO) estimated that allowing such negotiation for Medicare alone will not have a sizeable impact on federal expenditure on drugs.[6] On the other hand, 92 percent of the public support allowing the federal government to negotiate drug prices for Medicare beneficiaries.[7] Interestingly, CBO has analyzed that we can get some savings if the Secretary had authority to negotiate prices for unique drugs that lack competitor products or therapeutic alternatives. Of course, this change in authority will require Congressional action in changing the current law. Among several policy options that have been proposed, per the CBO, extending the Medicaid drug price rebate to low-income Medicare Part D enrollees would achieve $145 billion in savings to Medicare over a ten-year period (2017-2026).[8] The Veterans Health Administration (VHA) and TRICARE do have negotiating authorization and clearly obtain pricing not presently available to CMS. Consideration of an all federally-funded health care negotiation for drugs used by Medicare, Medicaid, VA, Military, Indian, Public Health and federal employee health care should be pursued.

It is very important for you to consider the financial burden on beneficiaries and the impact on access of moving drugs from Medicare Part B to Part D. Both programs do not have an out-of-pocket limit. While Part D drugs require a degree of patient out-of-pocket spending for those not qualifying for low-income cost-sharing subsidies (LIS), under Part B fee-for-service, beneficiaries pay a 20 percent coinsurance on drugs. Most patients have supplemental medical insurance (e.g., Medigap) to cover this coinsurance amount. Per an analysis from Avalere

[6] Letter from CBO Director Douglas Holtz-Eakin to U.S. Senator Bill Frist. Available: https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/fristletter.pdf

[7] Kaiser Health Tracking Poll (2017). Available: https://www.kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/

[8] CBO (2016). Options for Reducing The Deficit: 2017 To 2026. Available: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/52142-breakout-chapter5.pdf

Health,[9] if new cancer therapies and other high-cost drug therapies are switched from Part B to Part D, Medicare beneficiaries who do not qualify for LIS would pay more out-of-pocket. On the other hand, Medicare beneficiaries that do not buy Medigap or other supplemental coverage would pay less out-of-pocket, especially if they were eligible for LIS. Thus, as in all policy choices there will be winners and losers and we urge HHS to weigh pros and cons very closely before deciding on such a switch.

From the clinician perspective, such a switch will have implications for their Merit-based Incentive Payment System (MIPS) scores. Expensive drugs that are administered under Part B in physician offices when counted in the MIPS resource use/cost category unfairly disadvantage specialties that administer such drugs. Thus, switching drugs from Medicare Part B to Part D may create access issues for patients who depend on such physician administered drugs (e.g., insulin, oncology medicines, vaccines, etc.).

Site neutral payments

It is important for CMS to clarify and develop a conceptual model for "site-neutral payments" in the Medicare and Medicaid programs. The term "site-neutral payments" can be easily misinterpreted and mis-conceptualized in various ways and can differ among stakeholders and the legislative and regulatory arms of the government. Historically, as you are aware, Medicare uses different payment systems depending on the location where a beneficiary receives services (e.g., inpatient, outpatient, ambulatory surgical center, emergency department, physician office). Having payments that vary by facility site derives from the idea of payment based on total resources used in provision of healthcare services, something that has long been a part of Medicare and Medicaid payments, and remains the central part of payment systems like the Physician Fee Schedule. Even for prospective payment systems like the Outpatient Prospective Payment System and the Ambulatory Surgical Center (ASC) Payment System, there is payment variation by site due to the overall calculations and conversion factors. This variation in the Medicare payment system has resulted in inefficient care, increased consolidation of physician practices into hospital systems (because the office for an employed physician can be deemed as a hospital outpatient department when the physician is paid staff for a hospital system), and increased costs to Medicare patients who face higher co-pays for hospital-based outpatient (HOPD) services compared to services provided in an ASC.

[9] Avalere Health (May 21, 2018). Transitioning Medicare Part B Drugs into Part D.

AAOS is generally supportive of efforts to reduce or eliminate payment differentials by site for the same surgical cases and has consistently commented to CMS and Congress. As technology improves and more orthopaedic surgical cases can be safely completed in an outpatient setting, we ask for equalized payments for services furnished in the ASC and HOPD settings. Moreover, we have consistently recommended seeking this equilibrium not by bluntly reducing the outpatient payments to equal ASC but by also increasing payments in the ASC toward a middle ground. Similarly, in-office physician services, including drug administration, should be equalized between the physician's office and the HOPD.

Value-based Arrangements

Value-based pricing of a drug refers to pricing based on evidence/data demonstrating its outcomes, i.e., benefits and harms. European regulators and policy makers use advanced procedures — called health technology assessments — to measure the value of new treatment protocols, drugs, and devices. However, this is a new idea in the US. The nonprofit Institute for Clinical and Economic Review conducts regular health technology assessments on approved drugs and devices. Indication-based pricing, mortgage pricing and outcomes-based pricing are often adopted by payers and pharmacies to develop value-based payments for drugs.[10] The problem here is that it is extremely difficult, if not impossible, to measure the value of a drug and treatment. The source of data, correct pricing information, change in outcomes-based evidence, changes in competitive structure of the prescription drug market and how expensive a drug is can all influence health technology assessment.[11] Some researchers argue that models used to conduct these assessments should be widely available on open source platforms. There are issues of information sharing about assessments, and the methods often do not adequately consider the physician's expert opinion. Moreover, the coding system may not be built to include such novel payment arrangements.

The AAOS supports value-based arrangements for drug payments if these payment models are voluntary, include the surgeon's expert opinion in value assessment methodology and provide adequate access to necessary care for patients. Moreover, drug research and development is a very expensive process and must be publicly funded to a large extent via the US National

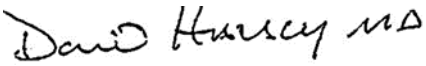
[10] Kaltenboeck, A. & Bach, P.B. (2018). Value-Based Pricing for Drugs: Theme and Variations. *JAMA, 319*(21):2165–2166. doi:10.1001/jama.2018.4871

[11] Goldman, D. & Jena, A. (2017). Value-based drug pricing makes sense, but is difficult to pull off. First Opinion, STAT News. Available: https://www.statnews.com/2017/06/08/value-based-drug-pricing/

Institutes of Health. If we are a society that values innovation and market-based competition, then innovators should be adequately rewarded.

The AAOS thanks you for this opportunity to comment. Also, we hope that based on this Blueprint and our comments on the accompanying RFI, you will be able to develop policy which will empower our patients by reducing their financial burden. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,



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The following orthopaedic specialty societies agreed to sign-on:

American Association for Hand Surgery (AAHS)

American Association of Hip and Knee Surgeons (AAHKS)

American Orthopaedic Foot and Ankle Society (AOFAS)

American Orthopaedic Society for Sports Medicine (AOSSM)

American Shoulder and Elbow Surgeons (ASES)

American Society for Surgery of the Hand (ASSH)

Arthroscopy Association of North America (AANA)

Cervical Spine Research Society (CSRS)

Limb Lengthening and Reconstruction Society (LLRS)

Musculoskeletal Infection Society (MSIS)

Musculoskeletal Tumor Society (MSTS)

Orthopaedic Trauma Association (OTA)

Pediatric Orthopaedic Society of North America (POSNA)

Ruth Jackson Orthopaedic Society (RJOS)

Scoliosis Research Society (SRS)