STATEMENT OF

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ON

"THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART III: EXAMINING FEDERAL EFFORTS TO FOSTER COMPETITION AND INCREASE AFFORDABILITY"

BEFORE THE

U.S. SENATE SPECIAL COMMITTEE ON AGING

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Chairman Collins, Ranking Member Casey, and members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS's) efforts to reduce prescription drug prices in Medicare. From day one of this Administration, President Trump has directed the Department of Health and Human Services (HHS) to make reducing drug prices a top priority, and CMS plays a critical role in these efforts.

Drugs are an important part of healthcare. Patients with diseases that scarcely a decade ago had no treatment potentially have access to cures that allow them to lead their best lives. However, patient opportunities to access these drugs are restrained by numerous distortions by a variety of factors, which can drive the price of these drugs beyond the reach of the patients who need them most. This Administration has been diligently working to root out these distortions in the interest of ensuring that patients have access to drugs at competitive prices.

Earlier this year, the President's Fiscal Year (FY) 2020 Budget laid out a range of proposals for lowering drug prices, including through reforms to Medicare. These proposals are consistent with the four key strategies for addressing challenges in the American drug market outlined in the "American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," released in May 2018 including improved competition, better negotiation, incentives for lower list prices, and lower out-of-pocket costs.[1] This blueprint constitutes the most aggressive plan of action for decreasing drug prices released by any administration ever. It, along with the FY 2020 Budget, appropriately promotes the objective of decreasing prices while maintaining our position as the world's leader in biopharmaceutical innovation and lays out dozens of possible ways that HHS—including CMS—and Congress can address this vital issue. HHS is executing on that strategy, and we are already seeing real results. Within the first 100 days since the blueprint was released, 15 drug companies reduced list prices, rolled back planned price increases, or committed to price freezes for the rest of 2018. In addition, there were 60 percent fewer brand-

[1] "American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

drug price increases and 54 percent more generic and brand-drug price decreases than the same period in 2017.[2]

However, we know there is more work to be done, and CMS is committed to doing our part to lower prescription drug prices. As the largest payer for health care in the U.S., Medicare policies can have a wide-reaching impact on health care spending, including prescription drug costs. That is why we are taking steps to reduce prescription drug prices by unleashing innovation and empowering patients through increased transparency across the program.

Unleashing Innovation

Modernizing Medicare Part D and Medicare Advantage

Last month, CMS finalized improvements to Medicare Advantage and Part D, which provide seniors with medical and prescription drug coverage through competing private insurance plans, in the "Modernizing Part D And Medicare Advantage To Lower Drug Prices and Out-of-Pocket Expenses" final rule.[3] The policies we finalized will enhance transparency by giving patients greater information on the cost of prescription drugs so they can compare options and demand value from pharmaceutical companies. Part D plans are the primary source of outpatient prescription drug coverage for 43.9 million Medicare beneficiaries.

In an effort to promote greater innovation in Part D, our final rule requires Part D plans, by January 1, 2021, to implement one or more real time benefit tools that are capable of providing prescribers with information through the prescriber's electronic health record or e-prescribing system so they can discuss out-of-pocket costs for prescription drugs with patients at the time a prescription is written. By empowering patients with more information on the cost of their prescription drugs at the point of prescribing, the rule will increase the likelihood that patients will fill their prescriptions and help ensure that pharmaceutical companies have to compete on the basis of price. After an implementation period, Part D plans would be required to provide

[2] HHS, 100 Days of Action on the President's American Patients First Blueprint, https://www.hhs.gov/about/news/2018/08/20/100-days-of-action-on-the-presidents-american-patients-first-blueprint.html

[3] CMS, Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, Final Rule, 84 Fed. Reg. 23832 (May 23, 2019), available at https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf.

access to at least one real time benefit tool that is capable of integrating with at least one prescriber's electronic prescribing (eRx) or electronic health record (EHR) system. CMS is encouraged that some plans are already offering these tools, but our policy will require all plans to provide prescribers with access to price information for different prescription drugs through this tool by 2021. Getting more information on out-of-pocket costs for prescription drugs to patients and their clinicians early in the process is critical, as there should be no surprises at the pharmacy counter.

In addition, based on guidance CMS issued in August, beginning this year, Medicare Advantage plans may use step therapy for Part B drugs as part of a patient centered care coordination program.[4] Step therapy can only be applied to new prescriptions or new administrations of Part B drugs and provides plans with the opportunity to encourage the utilization of a more affordable biosimilars before a patient progresses to a more costly biologic. Enrollees are entitled to request an exception from the plan's step therapy requirement in order to access a covered Part B drug. Medicare Advantage plans are now allowed to use consolidated step therapy programs for drugs covered under Parts B and D.

In our final rule, CMS issued a policy that further facilitates a Medicare Advantage plan's ability to negotiate prices for Part B physician-administered medicines by allowing the plan to institute step therapy when beneficiaries first start on the medicines.[5] By strengthening a plan's ability to negotiate with prescription drug companies, plans can deliver better value for a patient's medical needs. Many physician-administered medicines are biologics, which are some of the most expensive therapies in use today. Lower-cost biosimilars are coming to market to compete with biologics, and this policy is part of the Administration's broader strategy to foster innovation in biosimilars and to drive competition in the market for physician-administered drugs.

[4] https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf
[5] https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf

Beginning in plan year 2020, CMS is also providing plans with the power to use indication-based formulary design and management as a new negotiation tool.[6] Currently, when a plan covers a drug for one FDA-approved indication, it has to cover all indications. This can mean that a more appropriate or more affordable drug may not be covered because the plan has already been required to cover a therapeutic alternative. Allowing indication-based management will mean more tailored choices for patients and more power for Part D plans to bring down drug prices.

Biosimilars

In 2018, an HHS report found that Medicare Part D plans spend $9 billion on brand-name drugs that have a generic alternative.[7] Choosing generics in these situations would mean $3 billion in total savings for Part D, including $1.1 billion in out-of-pocket savings for patients. In response to this report, CMS issued a memo to Part D plans reminding them of the tools they have available and the expectation CMS has to ensure that beneficiaries get the best deal.[8]

Similar to encouraging the uptake of generics, CMS is also looking to increase the availability of biosimilars to encourage competition with biologics. Many of the highest-cost medicines that Medicare pays for are biologics. Biosimilars have the potential to introduce competition and drive down costs for patients. However, right now, there are only a few biosimilars available in the U.S. To encourage growth, CMS finalized a policy in the CY 2018 Physician fee Schedule Final Rule that established separate Part B billing codes for each biosimilar product for a given biologic.[9] This change was designed to encourage companies to invest in bringing more biosimilars to market and would increase competition to reduce costs.

Reducing Out-of-Pocket Costs

The President's Proposed Budget request for FY 2020 includes a comprehensive Medicare Part D structural reform package that gives plan sponsors more incentives to manage benefits,

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[6] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf
[7] https://aspe.hhs.gov/system/files/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf
[8] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-July-24th.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=ascending
[9] https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf

provides beneficiaries with better protection against catastrophic costs, and encourages use of lower-cost drug alternatives.[10] A portion of this package would provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap. Currently, the Part D benefit creates a perverse incentive structure for plans, wherein plans are incentivized to speed beneficiaries through the donut hole and into the catastrophic phase, where Medicare pays 80 percent of costs. Beneficiaries who reach the catastrophic phase continue to be responsible for five percent of their drug costs, which can be a substantial financial burden for those using high cost specialty drugs, such as those used to treat Hepatitis C. This proposal would: (1) increase Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over four years from 15 percent to 80 percent; (2) decrease Medicare's reinsurance liability from 80 to 20 percent; and, (3) eliminate beneficiary coinsurance, creating a true out-of-pocket maximum in Part D for the first time in the program's history.

In addition, last year CMS issued a final Medicare Advantage and Medicare Part D rule to establish a lower copay for biosimilars that is equivalent to the lower copay required for generic drugs for low-income subsidy beneficiaries in Part D.[11] This will lower out-of-pocket costs for biosimilars for low-income beneficiaries, thereby incentivizing biosimilar use. President Trump's FY 2020 Budget goes even further, with a proposal to eliminate cost sharing altogether for generics and biosimilars for low-income beneficiaries.

Increasing Competition and Reducing Opportunities for Gaming

The President's FY 2020 Proposed Budget request also includes a provision that would increase competition by reducing average sales price-based payments when a drug manufacturer takes anti-competitive action. Currently, the majority of Part B drugs are paid at Average Sales Price (ASP) plus 6 percent. When an innovator product is under patent, the ASP is based on that drug's ASP alone, meaning that the manufacturer has complete power to set the price. Often,

[10] Putting American Patients First: Lowering List Prices, Reducing Out-of-Pocket Costs, and Improving Negotiation and Competition, https://www.whitehouse.gov/wp-content/uploads/2019/03/FY20-Fact-Sheet_Lowering-Drug-Pricing-and-Payment_FINAL.pdf.

[11] CMS, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, Final Rule, 83 FR 16440 (April 16, 2018) available at: https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf

when a drug is about to go off patent, manufacturers will make an agreement with generic or biosimilar competitors to delay the launch of their product in exchange for some sort of payment, extending the time period during which the innovator product is available without competition. These agreements are known as "pay-for-delay" deals. Actions like the filing of pay-for-delay agreements slow the entry of generic competitors and keep drug prices higher for longer.

The proposal would reduce payment for innovator drugs from average sales price (ASP) plus 6 percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action. Once a competitor to the innovator product is commercially available, CMS would provide payment for both the innovator and competitor product at ASP plus 6 percent.

Part D Models at the Center for Medicare and Medicaid Innovation

On January 18, 2019, CMS's Center for Medicare and Medicaid Innovation ("Innovation Center"), which tests innovative payment and service delivery models to reduce expenditures and preserve or enhance the quality of care, announced a new payment model to enable Part D plans to better serve patients and help them achieve good health. The Part D Payment Modernization model will test the impact of a revised Part D program design and incentive alignment on overall Part D prescription drug spending and beneficiary out-of-pocket costs.[12] The model is open to eligible standalone Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs) that are approved to participate. Under the new model, which takes effect for the 2020 plan year, participating plans will take on greater risk for spending in the catastrophic phase of Part D, creating new incentives for plans, patients, and providers to choose drugs with lower list prices. Based on plan year performance, CMS will calculate a spending target for what governmental spending would have been without plans taking on this additional risk. Participating Part D plans will share in savings if they stay below the target but will be accountable for losses if they exceed the target.

The Innovation Center is also testing ways to improve Part D Medication Therapy Management (MTM) activities under the Enhanced MTM Model, which began on January 1, 2017, with a

[12] https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/

five-year performance period. CMS is testing the model across five Part D regions with 22 participating plans administered by six Part D sponsors. Under this model, participating basic stand-alone Part D Prescription Drug Plans (PDPs) adopt innovative approaches to administering MTM activities in lieu of the standard Part D MTM program. The objectives for this model are for stand-alone PDP sponsors to identify and implement innovative strategies to optimize medication use and therapeutic outcomes, improve care coordination, strengthen system linkages, and maximize the effectiveness of Part D MTM expenditures. The Enhanced MTM Model offers a performance-based payment to participating prescription drug plans in a Part D region if their enrolled members' medical (Part A and B) expenses are reduced by at least 2 percent in a given plan year compared to a benchmark that simulated their performance if they were not in the model. For performance year 2017, the first performance year of the model, participants in the model spent approximately $325 million less than the anticipated spending benchmark across the 1.7 million beneficiaries enrolled in participating plans.[13]

Through the Innovation Center, CMS is examining still other ways to lower drug prices, including last year's advance notice of proposed rulemaking that solicited comments on a new way of paying for Part B drugs under an International Pricing Index (IPI) model.

Empowering Patients Through Increased Transparency

The "American Patients First Blueprint" described a new, more transparent drug pricing system that would lower high prescription drug prices and bring down out-of-pocket costs. At CMS, we are constantly looking for better ways to serve our beneficiaries and empower them with information they need to make the best health care decisions for themselves and their families. We have several complementary efforts underway to increase transparency on drug prices.

Prohibition on Gag Clauses in Pharmacy Contracts

In the "Modernizing Part D And Medicare Advantage To Lower Drug Prices and Out-of-Pocket Expenses" final rule issued last month, CMS implemented a provision in the Know the Lowest Price Act of 2018 (P.L. 115-262) to codify our existing prohibition of "gag clauses." Gag clauses

[13] CMS, Part D Enhanced Medication Therapy Management Model First year Performance Based Payment Results Fact Sheet, https://innovation.cms.gov/files/x/mtm-firstyrresults-fs.pdf.

are provisions in drug plan pharmacy contracts that restrict the ability of pharmacies to discuss with enrollees the availability of prescriptions at a cash price that is less than the amount the enrollee would be charged when obtaining the prescription through their insurance. Under the rule, Part D sponsors may not prohibit or penalize a pharmacy from disclosing a lower cash price to an enrollee. Ultimately, informing Medicare beneficiaries about lower cost alternatives will help Medicare beneficiaries save money on their prescription drugs costs.

Drug Spending Dashboards

CMS has also advanced price transparency through the release of interactive, web-based dashboards that present spending on prescription drugs for the Medicare Part B and Part D programs as well as Medicaid.[14] The dashboards reflect CMS' effort to support innovative data driven insights to improve quality, accessibility, and affordability of prescription drugs as well as empower patients and prescribers with information to take ownership of their health and ensure that patients have the flexibility and information to make choices as they seek care.

The dashboards focus on average spending per dosage unit and change in average spending per dosage unit over time in order to allow the public to understand trends in drug spending. The tools also display information for manufacturer(s) of the drugs as well consumer-friendly information of drug uses and clinical indications so patients and physicians can compare program spending for different medications for a given condition. This tool allows the public to see both spending and spending increases in Medicare and Medicaid on prescription drugs.

Plan Finder

As part of CMS's eMedicare multi-year initiative to improve Medicare service across its customer support channels, CMS is undertaking a comprehensive redesign of the Medicare Plan Finder this year. CMS is working to improve usability of the Plan Finder based on feedback we have been collecting from stakeholders and we look forward to continuing our collaborations as we move forward with our efforts to modernize this important tool.

[14] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/information-on-prescription-drugs/index.html

The updated Plan Finder will combine and update several tools on the current site to provide a comprehensive experience that offers additional decision support and clarity around prescription drug costs. The redesigned Plan Finder tool will be an important source for Medicare plan information and provide an updated platform and experience for Medicare beneficiaries, family members, caregivers, advocates, and healthcare providers with one central place to view, compare, and select Medicare Part D prescription drug and Medicare Advantage plans. The redesigned Plan Finder tool is expected to be released before the upcoming Medicare Open Enrollment Period.

Requiring Manufacturers to Disclose Drug Prices in Television Ads

To create better incentives for lower list prices, the blueprint considered requiring the inclusion of list prices in direct-to-consumer advertising. Less than a year later, CMS published a final rule to implement this policy.[15]

Price transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information. However, for consumers of prescription drugs or biological products, including those whose drugs are covered through Medicare, the list price remains hard to find.

Our final rule, effective July 9, 2019, requires direct-to-consumer television advertisements for prescription pharmaceuticals covered by Medicare or Medicaid to include the list price, if that price is equal to or greater than $35 for a month's supply or the usual course of therapy. This final rule will provide consumers with more information to better position them as active and well-informed participants in their health care decision-making.

Moving Forward

While CMS has taken actions consistent with the President's "American Patient First Blueprint" to combat drastically rising prescription drug prices, we know we have more to do. As we continue our important work in this area, we remain committed to finding ways to promote innovation and patient empowerment in our programs by facilitating transparency and

[15] https://www.govinfo.gov/content/pkg/FR-2019-05-10/pdf/2019-09655.pdf

competition. We look forward to working with Congress and our Federal partners as well as providers, beneficiaries, plans, pharmaceutical companies, and other stakeholders as we continue to evaluate the most effective ways to approach these issues.