relationships between grantees and subrecipients. With this data, the contractor, to inform ASPE and ACF, will build a social/organizational network to depict how grantee and subrecipient organizations collaborate with one another through TVAP to better understand the existing network and identify potential opportunities for improving the efficiency of the network. ASPE anticipates completion of all data collection activities by October 2018.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
TVAP grantees	3	1	45/60	2.25
TVAP Subrecipients	253	1	45/60	189.75
Total	256	1	45/60	192

Terry Clark,

Asst. Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

RIN 0991–ZA49

HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

AGENCY: Department of Health and Human Services.

ACTION: Policy Statement; Request for information.

SUMMARY: Through this request for information, HHS seeks comment from interested parties to help shape future policy development and agency action.

DATES: Comments must be submitted on or before July 16, 2018.

ADDRESSES: You may submit comments in one of three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Department of Health and Human Services, 200 Independence Ave. SW, Room 600E, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Department of Health and Human Services, 200 Independence Ave. SW, Room 600E, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: John O'Brien, (202) 690–7886.

SUPPLEMENTARY INFORMATION: The United States is the world's leader in biopharmaceutical innovation. American innovation has improved health and quality of life for billions of people, and was made possible by our intellectual property system, decades of government and privately-funded research, strong capital markets, and the world's largest scientific research base. By rewarding innovation through patent and data protection, American companies hold the intellectual property rights for most new, and potentially life changing, medicines. Our regulatory system is the most rigorous in the world, ensuring the safety and efficacy of drugs for American patients. Medicare, Medicaid, other Federal health programs, and private payers ensure Americans have access to medicines, from innovative new cures, to generic versions of medications that have markedly lowered costs for consumers.

As part of President Trump's bold plan to put American patients first, the Department of Health and Human Services has developed a comprehensive blueprint that addresses many of the challenges and opportunities impacting American patients and consumers. The blueprint covers multiple areas including, but not limited to:

- Improving competition and ending the gaming of the regulatory process,
- supporting better negotiation of drug discounts in government-funded insurance programs,
- creating incentives for pharmaceutical companies to lower list prices, and,
- reducing out-of-pocket spending for patients at the pharmacy and other sites of care.

HHS also recognizes that achieving the goal of putting American patients first will require interagency collaboration on pharmaceutical trade policies that promote innovation, and are transparent, nondiscriminatory, and increase fair market access for American innovators. Furthermore, HHS seeks to identify when developed nations are paying less for drugs than the prices paid by Federal health programs, and correct these inequities through better negotiation.

HHS has already acted to increase the affordability of medicines for millions of our citizens, but is also going much further in response to President Trump's call to action. Through the work of the Food and Drug Administration and the Centers for Medicare & Medicaid Services, HHS has tremendous ability to change how drugs are developed and paid for in the United States.

The status quo is no longer acceptable. Millions of Americans face soaring drug prices and higher out-of-pocket costs, while manufacturers and middlemen such as pharmacy benefit managers (PBMs) and distributors benefit from rising list prices and their resulting higher rebates and administrative fees. An unprecedented re-examination of the whole system and opportunities for reform is long overdue. We believe a national focus on lowering list prices and out-of-pocket costs has the potential to create new and disruptive alternatives to the current system, while maintaining its many virtues. It is time to realign the system in a way that promotes the development of affordable innovations that improve health outcomes and lower both out-of-pocket cost and the total cost of care.

Through this request for information, HHS seeks comment from interested parties to help shape future policy development and agency action.

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I. Previous Actions by the Trump Administration

The President has consistently emphasized the need to reduce the price of prescription drugs. The Trump Administration has already taken a number of significant administrative steps, and proposed in the President's FY2019 Budget, to improve competition and end the gaming of regulatory processes, support better negotiation of drug discounts through government insurance programs, create incentives for pharmaceutical companies to lower list prices, and reduce consumer out-of-pocket spending at the pharmacy and other care settings.

A. Increasing Competition

Since the beginning of the Trump Administration, HHS has taken a number of actions to increase competition and end the gaming of regulatory processes that may keep drug prices artificially inflated or hinder generic, branded, or biosimilar competition. These efforts include:

- Accelerating Food and Drug Administration (FDA) approval of generic drugs. Studies show that greater generic competition is associated with lower prices. FDA is publishing the names of drugs that have no competitors in order to spur new entrants and bring prices down. Over 1,000 generic drugs were approved in 2017, which is the most in FDA's history in a calendar year by over 200 drugs. These generic approvals saved American consumers and taxpayers nearly $9 billion in 2017.
- Drug Competition Action Plan. In 2017, President Trump's FDA established a Drug Competition Action Plan to enable patients to access more affordable medications by focusing the Agency's efforts in three key areas: (1) Improving the efficiency of the generic drug development, review, and approval process; (2) maximizing scientific and regulatory clarity with respect to complex generic drugs; and (3) closing loopholes that allow brand-name drug companies to ''game'' FDA rules in ways that forestall the generic competition Congress intended. The Agency also has taken steps to prioritize its review of generic drug applications; issued guidance to improve efficiencies in the development, review, and approval processes for generic drugs, including complex generic drugs; and issued guidance to further streamline the submission and review process for shared system REMS, and to allow collective submissions to streamline the review of shared Risk Evaluation and Mitigation Strategies (REMS).
- FDA also announced it will facilitate opportunities for enhanced information sharing between manufacturers, doctors, patients and insurers to improve patient access to medical products, including through value-based insurance.
- Speeding Access to More Affordable Generics by Spurring Competition. Today, a generic manufacturer that has been awarded 180-day exclusivity for being the first generic to file can ''park'' their application with FDA, preventing additional generic manufacturers from entering the market. The President's FY2019 Budget proposes to prevent companies from using their 180-day exclusivity to indefinitely delay real competition and savings for consumers by seeking a legislative change to start a company's 180-day exclusivity clock in certain instances when another generic application is ready for approval, but is blocked solely by such a first applicant's 180-day exclusivity.
- Finalizing a policy in which each biosimilar for a given biologic gets its own billing and payment code under Medicare Part B, to incentivize development of additional lower-cost biosimilars. Prior approaches to biosimilar coding and payment would have created a race to the bottom of biosimilar pricing, while leaving the branded product untouched, making it an unviable market that few would want to enter.

B. Better Negotiation

Medicare Part D has been very successful since it launched in 2006. However, prescription drug markets are different than they were 12 years ago, and in some cases Part D plan sponsors may be prohibited from doing what private payers outside the Medicare program do to negotiate effectively and keep costs low. More can also be done across the Medicare program to provide beneficiaries with the lower costs and greater price transparency resulting from better negotiation.

Since the beginning of the Trump Administration, HHS has taken a number of actions to support better negotiation. These efforts include:

- Finalizing changes to the Medicare Prescription Drug Program in the 2019 Part C and Part D regulation allowing for faster mid-year substitution of generic drugs onto formularies.
- Proposing in the President's FY2019 Budget [1] a 5-part plan to modernize the Medicare Part D program, a portion of which includes enhancing Part D plans' negotiating power with manufacturers by changing Part D plan formulary standards to require a minimum of one drug per category or class rather than two. We note that the 5-part plan is intended to be implemented together, as eliminating even one piece of the package significantly changes the proposal's impacts.
- Proposing in the President's FY2019 Budget to address abusive drug pricing by manufacturers by: establishing an inflation limit for reimbursement of Medicare Part B drugs; reducing Wholesale Acquisition Cost (WAC)-Based Payment when Average Sales Price (ASP) isn't available; and improving manufacturers' reporting of Average Sales Prices to set accurate payment rates.
- Increasing the integrity of the Medicaid Drug Rebate Program, so that manufacturers pay their fair share in rebates, by proposing in the President's FY2019 Budget to remove ambiguity regarding how drugs should be reported under the program. HHS is also manually reviewing each new drug that has been reported in the Medicaid rebate system on a quarterly basis to make sure classifications are correct, and the United States took legal action against Mylan for their misclassification of EpiPen, resulting in an agreement for Mylan to pay back $465 million in rebate payments.
- Proposing in the President's FY2019 Budget to further clarify the Medicaid definition of brand drugs, which would address inappropriate interpretations leading some manufacturers to classify certain brand and over-the-counter drugs as generics for Medicaid rebate purposes, reducing the rebates they owe.
- Proposing in the President's FY2019 Budget to call for 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, coupled with an appeals process to protect beneficiary access to non-covered drugs based on medical need, and negotiate drug prices directly

[1] *https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf.*

with manufacturers. HHS and participating states would rigorously evaluate these demonstrations, which would provide states with new tools to control drug costs and tailor drug coverage decisions to state needs.

• Proposing in the President's FY2019 Budget to authorize the HHS Secretary to leverage Medicare Part D plans' negotiating power for certain drugs covered under Part B.

• Addressing price disparities in the international market. The Administration is updating a number of historical studies to analyze drug prices paid in countries that are a part of the Organisation for Economic Co-operation and Development (OECD).

C. Creating Incentives to Lower List Prices

The list price of a drug does not reflect the discounts or price concessions paid to a PBM, insurer, health plan, or government program. Obscuring these discounts can shift costs to consumers in commercial health plans and Medicare beneficiaries. Many incentives in the current system reward higher list prices, and HHS is interested in creating new incentives to reward drug manufacturers that lower list prices or do not increase them.

Since the beginning of the Trump Administration, HHS has taken a number of actions to create incentives to lower list prices. These efforts include:

• Proposing in the President's FY2019 budget a 5-part plan to modernize the Medicare Part D program, a portion of which includes the exclusion of manufacturer discounts from the calculation of beneficiary out-of-pocket costs in the Medicare Part D coverage gap, and the establishment of a beneficiary out-of-pocket maximum in the Medicare Part D catastrophic phase to reduce out-of-pocket spending for beneficiaries who spend the most on drugs. The changes in the catastrophic phase would shift more responsibility onto plans, creating incentives for plans to negotiate with manufacturers to lower prices for high-cost drugs. We note that the 5-part plan is intended to be implemented together, as eliminating even one piece of the package significantly changes the proposal's impacts.

• In addition, the President's FY2019 Budget proposes reforms to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations.

D. Reducing Patient Out-of-Pocket Spending

American patients have the right to know what their prescription drugs will really cost before they get to the pharmacy or get the drug. Too many people abandon their prescriptions at the pharmacy when they discover the price is too high, and too many patients are never informed of lower cost options.

Since the beginning of the Trump Administration, HHS has taken a number of steps to lower consumer out-of-pocket spending and improve transparency. These efforts include:

• Finalizing Medicare Outpatient Prospective Payment System (OPPS) rules to reduce beneficiary out-of-pocket spending for 340B drugs administered in certain hospitals by an estimated $320 million in 2018, which would equal $3.2 billion when multiplied over ten years.

• Seeking information about changes in the Medicare Prescription Drug Program regulations for contract year 2019 that would increase transparency for people with Medicare prescription drug coverage. The proposed rule included a Request for Information soliciting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale.

• Finalizing changes to the Medicare Prescription Drug Program in the 2019 Part C and Part D regulation allowing Medicare beneficiaries receiving low-income subsidies to access biosimilars at a lower cost.

• Proposing in the President's FY2019 Budget a 5-part plan to modernize the Medicare Part D program, a portion of which includes eliminating cost-sharing on generic drugs for low-income beneficiaries and requiring Medicare Part D plans to apply a substantial portion of rebates at the point of sale. We note that the 5-part plan is intended to be implemented together, as eliminating even one piece of the package significantly changes the proposal's impacts. We also note that in the months following this Part D proposed rule and the President's budget proposal that included this policy change explicitly, several major insurers and pharmacy benefit managers announced they would pass along a portion of rebates to individual members in their fully-insured populations or when otherwise requested by employers.

II. Responding to President Trump's Call to Action

President Trump recently reaffirmed his commitment to reducing the price of prescription drugs, and called on the Administration to propose new strategies and take bold actions to improve competition and end the gaming of regulatory processes, support better negotiation of drug discounts through government insurance programs, create incentives for pharmaceutical companies to lower list prices, and reduce consumer out-of-pocket spending at the pharmacy and other care settings. HHS may undertake these and other actions, to the extent permitted by law, in response to President Trump's call to action.

A. Improve Competition

In response to President Trump's call to action, HHS may support improved competition by:

• *Taking steps to prevent gaming of regulatory processes:* FDA will issue guidance to address some of the ways in which manufacturers may seek to use shared system REMS to delay or block competition from generic products entering the market.

• *Promoting innovation and competition for biologics.* FDA will issue new policies to improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics. FDA will also continue to educate clinicians, patients, and payors about biosimilar and interchangeable products as we seek to increase awareness about these important new treatments.

B. Better Negotiation

In response to President Trump's call to action, HHS may support better negotiation by:

• Directing CMS to develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices. These models should hold manufacturers accountable for outcomes, align with CMS's priorities of value over volume and site-neutral payments, and provide Medicare providers, payers, and states with additional tools to manage spending for high-cost therapies.

• Allowing Part D plans to adjust formulary or benefit design during the benefit year if necessary to address a price increase for a sole source generic drug. Presently, Part D plans do not contract with generic drug manufacturers for the purchase of generic drugs, and generally are not permitted to change their formulary or benefit design without CMS approval in

response to a price increase. This change could ensure Part D plans can respond to a price increase by the only manufacturer of a generic drug.

- Providing plans full flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices, including in the protected classes. Presently, Part D plans are unable to negotiate lower prices for high-cost drugs without competition. This change could allow Part D plans to use the tools available to private payers outside of the Medicare program to better negotiate for these drugs.
- Updating the methodology used to calculate Drug Plan Customer Service star ratings for plans that are appropriately managing utilization of high-cost drugs. Presently, if a Part D plan issues an adverse redetermination decision, the enrollee, the enrollee's representative or the enrollee's prescriber may appeal the decision to the Independent Review Entity (IRE). This process may discourage Part D plan sponsors from appropriately managing utilization of high-cost drugs. This change could provide Part D plan sponsors with the ability to appropriately manage high-cost changes, while holding sponsors accountable primarily using other successful enforcement mechanisms.
- Evaluating options to allow high-cost drugs to be priced or covered differently based on their indication. Presently, Part D plans must cover and pay the same price for a drug regardless of the indication for which it was prescribed. This change could permit Part D plans to choose to cover or pay a different price for a drug, based on the indication.
- Sending the President a report identifying particular drugs or classes of drugs in Part B where there are savings to be gained by moving them to Part D.
- Taking steps to leverage the authority created by the Competitive Acquisition Program (CAP) for Part B Drugs & Biologicals. This program will generally provide physicians a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the current average sales price (ASP) methodology. The CAP, or a model building on CAP authority, may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP, and provides opportunities for physicians who do not wish to bear the financial burdens and risk associated with being in the business of drug acquisition.
- Working in conjunction with the Department of Commerce the U.S. Trade Representative, and the U.S. Intellectual Property Enforcement Coordinator to develop the knowledge base necessary to address the unfair disparity between the drug prices in America and other developed countries. The Trump Administration is committed to making the appropriate regulatory changes and seeking legislative solutions to put American patients first.

C. Lowering List Prices

In response to President Trump's call to action, HHS may:

- Call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising.
- Direct the Centers for Medicare & Medicaid Services to make Medicare and Medicaid prices more transparent, hold drug makers accountable for their price increases, highlight drugs that have not taken price increases, and recognize when competition is working with an updated drug pricing dashboard. This tool will also provide patients, families, and caregivers with additional information to make informed decisions and predict their cost sharing.
- Develop proposals related to the Affordable Care Act's Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of the Average Manufacturer Price.

D. Reduce Patient Out-of-Pocket Spending

In response to President Trump's call for action, HHS may:

- Prohibit Part D plan contracts from preventing pharmacists from telling patients when they could pay less out-of-pocket by not using their insurance—also known as pharmacy gag clauses.
- Require Part D Plan sponsors to provide additional information about drug price increases and lower-cost alternatives in the Explanation of Benefits they currently provide their members.

III. Solicitation of Comments

Building on the ideas already proposed, HHS is considering even bolder actions to bring down prices for patients and taxpayers. These include new measures to increase transparency; fix the incentives that may be increasing prices for patients; and reduce the costs of drug development. HHS is interested in public comments about how the Department can take action to improve competition and end the gaming of regulatory processes, support better negotiation of drug discounts through government insurance programs, create incentives for pharmaceutical companies to lower list prices, and reduce consumer out-of-pocket spending at the pharmacy and other care settings. HHS is also interested in public comments about the general structure and function of the pharmaceutical market, to inform these actions. Proposals described in this section are for administrative action, when within agency authority, and legislative proposals as necessary.

In this Request for Information, HHS is soliciting comments on these and other policies under active consideration.

A. Increasing competition

Underpricing or Cost-Shifting. Do HHS programs contain the correct incentives to obtain affordable prices on safe and effective drugs? Does the Best Price reporting requirement of the Medicaid Drug Rebate Program pose a barrier to price negotiation and certain value-based agreements in other markets, or otherwise shift costs to other markets? Are government programs causing underpricing of generic drugs, and thereby reducing long-term generic competition?

Affordable Care Act Taxes and Rebates. The Affordable Care Act imposed tens of billions of dollars in new taxes and costs on drugs sold in government programs through a new excise tax, an increase in the Medicaid drug rebate amounts, and an extension of these higher rebates to commercially-run Medicaid Managed Care Organizations. How have these changes impacted manufacturer list pricing practices? Are government programs being cross-subsidized by higher list prices and excess costs paid by individuals and employers in the commercial market? If cross-subsidization exists, are the taxes and artificially-depressed prices causing higher overall drug costs or other negative effects?

Access to Reference Product Samples

Distribution restrictions. Certain prescription drugs are subject to limitations on distribution. Some of these distribution limitations are imposed by the manufacturer, while others may be imposed in connection with an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS). Some manufacturers may be gaming these distribution limitations to prevent generic developers from accessing their drugs to conduct the tests that are legally required for a generic drug to be brought to market, thereby limiting

opportunities for competition that could place downward pressure on drug prices. In some instances, for products that are subject to REMS that impact distribution, manufacturers continue to restrict access to generic developers even after the FDA issues a letter stating that it has favorably evaluated the developer's proposed safety protections for testing and would not consider the provision of drug samples to this developer for generic development to violate the applicable REMS. Should additional steps be taken to review existing REMS to determine whether distribution restrictions are appropriate? Are there terms that could be included in REMS, or provided in addition to REMS, that could expand access to products necessary for generic development? Are there other steps that could be taken to facilitate access to products that are under distribution limitations imposed by the manufacturer?

Samples for biosimilars and interchangeables. Like some generic drug developers, companies engaged in biosimilar and interchangeable product development may encounter difficulties obtaining sufficient samples of the reference product for testing. What actions should be considered to facilitate access to reference product samples by these companies?

Biosimilar Development, Approval, Education, and Access

Resources and tools from FDA: FDA prioritizes ongoing efforts to improve the efficiency of the biosimilar and interchangeable product development and approval process. For example, FDA is working to identify areas in which additional information resources or development tools may facilitate the development of high quality biosimilar and interchangeable products. What specific types of information resources or development tools would be most effective in reducing the development costs for biosimilar and interchangeable products?

Improving the Purple Book. In the Purple Book, FDA publishes information about biological products licensed under section 351 of the Public Health Service Act, including reference products, biosimilars, and interchangeable products. The Purple Book provides information about these products that is useful to prescribers, pharmacists, patients, and other stakeholders. FDA is committed to the timely publication of certain information about reference product exclusivity in the Purple Book. How could the Purple Book be more useful to health care professionals, patients, manufacturers, and other stakeholders? What additional information could be added to increase the utility of the Purple Book?

Educating providers and patients. Physician and patient confidence in biosimilar and interchangeable products is critical to the increased market acceptance of these products. FDA intends to build on the momentum of past education efforts, such as the launch of its Biosimilars Education and Outreach Campaign in 2017, by developing additional resources for health care professionals and patients. What types of information and educational resources on biosimilar and interchangeable products would be most useful to heath care professionals and patients to promote understanding of these products? What role could state pharmacy practice acts play in advancing the utilization of biosimilar products?

Interchangeability. How could the interchangeability of biosimilars be improved, and what effects would it have on the prescribing, dispensing, and coverage of biosimilar and interchangeable products?

B. Better Negotiation

The American pharmaceutical marketplace is built on innovation and competition. However, regulations governing how Medicare and Medicaid pay for prescription drugs have not kept pace with the availability of new types of drugs, particularly higher-cost curative therapies intended for use by fewer patients. Drug companies, commercial insurers, and states have proposed creative approaches to financing these new treatments, including indication-based pricing, outcomes-based contracts, long-term financing models, and others. Value-based transformation of our entire healthcare system is a top HHS priority. Improving price transparency is an important part of achieving this aim. What steps can be taken to improve price transparency in Medicare, Medicaid, and other forms of health coverage, so that consumers can seek value when choosing and using their benefits?

Value-Based Arrangements and Price Reporting. What benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value-based arrangements? How would excluding these approaches from Average Manufacturer Price (AMP) and Best Price (BP) calculations impact the Medicaid Drug Rebate program and supplemental rebate revenue? How would these exclusions affect Average Sales Price (ASP) and 340B Ceiling Prices? What benefits would accrue to Medicare and Medicaid beneficiaries by extending the time for manufacturers to report restatements of AMP and/or BP reporting, as outlined in 42 CFR 447.510, to accommodate adjustments because of possible extended VBP evaluation timeframes? Is there a timeframe CMS should consider that will allow manufacturers to restate AMP and BP without negative impact on state rebate revenue? What modifications could be made to the following regulatory definitions in the current Medicaid Drug Rebate Program that could facilitate the development of VBP arrangements: (1) Bundled sale; (2) free good; (3) unit; or (4) best price? Would providing specific AMP/BP exclusions for VBP pricing used for orphan drugs help manufacturers that cannot adopt a bundled sale approach? What regulatory changes would Medicaid Managed Care organizations find helpful in negotiating VBP supplemental rebates with manufacturers? How would these changes affect Medicare or the 340B program? Are there particular sections of the Social Security Act (*e.g.,* the anti-kickback statute), or other statutes and regulations that can be revised to assist with manufacturers' and states' adoption of value-based arrangements? Please provide specific citations and an explanation of how these changes would assist states and manufacturers in participating in VBP arrangements.

Indication-Based Payments. Prescription drugs have varying degrees of effectiveness when used to treat different types of disease. Though drugs may be approved by the FDA to treat specific indications, or used off-label by prescribers to treat others, they are typically subject to the same price. Should Medicare or Medicaid pay the same price for a drug regardless of the diagnosis for which it is being used? How could indication-based pricing support value-based purchasing? What lessons could be learned from private health plans? Are there unintended consequences of current low-cost drugs increasing in price due to their identification as high value? How and by whom should value be determined?? Is there enough granularity in coding and reimbursement systems to support indication-based pricing? Are changes necessary to CMS's price reporting program definitions or how the FDA's National Drug Code numbers are used in CMS price reporting programs? Do physicians, pharmacists, and insurers have access to all the information they

need to support indication-based payments?

Long-term Financing Models. States and other payers typically establish budgets or premium rates for a given benefit year. As such, their budgets may be challenged when a new high-cost drug unexpectedly becomes available in the benefit year. Long-term financing models are being proposed to help states, insurers, and consumers pay for high-cost treatments by spreading payments over multiple years. Should the state, insurer, drug manufacturer, or other entity bear the risk of receiving future payments? How should Medicare or Medicaid account for the cost of disease averted by a curative therapy paid for by another payer? What regulations should CMS consider revising to allow manufacturers and states more flexibility to participate in novel value-based pricing arrangements? What effects would these solutions have on manufacturer development decisions? What current barriers limit the applicability of these arrangements in the private sector? What assurances would parties need to participate in more of these arrangements, particularly with regard to public programs?

Part B Competitive Acquisition Program. HHS has the authority to operate a Competitive Acquisition Program for Part B drugs. What changes would vendors and providers need to see relative to the 2007–2008 implementation of this program in order to successfully participate in the program? Has the marketplace evolved such that there would be more vendors capable of successfully participating in this program? Are there a sufficient number of providers interested in having a vendor selected through a competitive bidding process obtain these drugs on their behalf, and bear the financial risk and carrying costs? How could this program be implemented in a way that ensures a competitive market among multiple vendors? Is it necessary that the vendors also hold title to the drugs and provide a distribution channel or are there other ways they can provide value? What other approaches could lower Part B drug spending for patients of providers choosing not to participate, without restricting their access to care?

Part B to D. The President's Budget requested the authority to move some Medicare Part B drugs to Medicare Part D. Which drugs or classes of drugs would be good candidates for moving from Part B to Part D? How could this proposal be implemented to help reduce out-of-pocket costs for the 27% of beneficiaries who do not have Medicare prescription drug coverage, or those who have Medicare supplemental benefits in Part B? What additional information would inform how this proposal could be implemented and operated?

Part B drugs are reportedly available to OECD nations at lower prices than those paid by Medicare Part B providers. HHS is interested in receiving data describing the differences between the list prices and net prices paid by Medicare Part B providers, and the prices paid for these same drugs by OECD nations. Though these national health systems may be demanding lower prices by restricting access or delaying entry, should Part B drugs sold by manufacturers offering lower prices to OECD nations be subject to negotiation by Part D plans? Would this lead to lower out-of-pocket costs on behalf of people with Medicare? How could this affect access to medicines for people with Medicare?

Fixing Global Freeloading. U.S. consumers and taxpayers generally pay more for brand drugs than do consumers and taxpayers in other OECD countries, which often have reimbursements set by their central government. In effect, other countries are not paying an appropriate share of the necessary research and development to bring innovative drugs to the market and are instead freeriding off U.S. consumers and taxpayers. What can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equally between the U.S. and other developed countries? What policies should the U.S. government pursue in order to protect IP rights and address concerns around compulsory licensing in this area.

Site neutrality for physician-administered drugs. Currently under Medicare Part B and often in Medicaid, hospitals and physicians are reimbursed comparable amounts for drugs they administer to patients, but the facility fees when drugs are administered at hospitals and hospital-owned outpatient departments are many times higher than the fees charged by physician offices. What effect would a site neutral payment policy for drug administration procedures have on the location of the practice of medicine? How would this change affect the organization of health care systems? How would this change affect competition for health care services, particularly for cancer care?

Site neutrality between inpatient and outpatient setting. Medicare payment rules pay for prescription drugs differently when provided during inpatient care (Part A) or administered by an outpatient physician (Part B). Beneficiaries also have different cost-sharing requirements in Part A and Part B. Some drugs can be administered in either the inpatient or outpatient setting, while others are currently limited to inpatient use because of safety concerns. Do the differences between Medicare's Part A and Part B drug payment policies create affordability and access challenges for beneficiaries? What policies should CMS consider to ensure inpatient and outpatient providers are neither underpaid nor overpaid for a drug, regardless of where it was administered? Which elements of the inpatient or outpatient setting lead to naturally differential payments, and why? If a drug can be used safely in the outpatient setting, and achieve the same outcomes at a lower cost, how should Medicare encourage the shift to outpatient settings? In what instances would inpatient administration actually be less costly?

Accuracy of national spending data. Are annual reports of health spending obscuring the true cost of prescription drugs? What is the value of better understanding the difference between gross and net drug prices? How could the Medicare Trustees Report, annual National Health Expenditure publications, Uniform Rate Review Template, and other publications more accurately collect and report gross and net drug spending in medical and pharmacy benefits? Should average Part D rebate amounts be reported separately for small molecule drugs, biologics, and high-cost drugs? What innovation is needed to maximize price transparency without disclosing proprietary information or data protected by confidentiality provisions?

C. Create Incentives To Lower List Prices

Government programs, commercial insurers, and individual consumers pay for drugs differently. The price paid at the pharmacy counter or reimbursed to a physician or hospital is the result of many different complex financial transactions between drug makers, distributors, insurers, pharmacy benefits managers, pharmacies and others. Public programs are also subject to state and Federal regulations governing what drugs are covered, who can be paid for them, and how much will be paid. Too often, these negotiations do not result in the lowest out-of-pocket costs for consumers, and may actually be causing higher list prices.

Fiduciary duty for Pharmacy Benefit Managers. Pharmacy Benefit Managers (PBMs) and benefits consultants help buyers (insurers, large employers) seek rebates intended to lower net drug prices, and help sellers (drug

manufacturers) pay rebates to secure placement on health plan formularies. Most current PBM contracts may allow them to retain a percentage of the rebate collected and other administrative or service fees.

Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices? Do higher rebates encourage benefits consultants who represent payers to focus on high rebates instead of low net cost? Do payers manage formularies favoring benefit designs that yield higher rebates rather than lower net drug costs? How are beneficiaries negatively impacted by incentives across the benefits landscape (manufacturer, wholesaler, retailer, PBM, consultants and insurers) that favor higher list prices? How can these incentives be reset to prioritize lower out of pocket costs for consumers, better adherence and improved outcomes for patients? What data would support or refute the premise described above?

Should PBMs be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits? Should PBMs be forbidden from receiving any payment or remuneration from manufacturers, and should PBM contracts be forbidden from including rebates or fees calculated as a percentage of list prices? What effect would imposing this fiduciary duty on PBMs on behalf of the ultimate payer (*i.e.,* consumers) have on PBMs' ability to negotiate drug prices? How could this affect manufacturer pricing behavior, insurance, and benefit design? What unintended consequences for beneficiary out-of-pocket spending and Federal health program spending could result from these changes?

Reducing the impact of rebates. Increasingly higher rebates in Federal health care programs may be causing higher list prices in public programs, and increasing the prices paid by consumers, employers, and commercial insurers. What should CMS consider doing to restrict or reduce the use of rebates? Should Medicare Part D prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and require these contracts to be based only on a fixed price for a drug over the contract term? What incentives or regulatory changes (*e.g.,* removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices? How would this affect the behavior of drug manufacturers, PBMs, and insurers? How could it change formulary design, premium rates, or the overall structure of the Part D benefit?

Incentives to lower or not increase list prices. Should manufacturers of drugs who have increased their prices over a particular lookback period or have not provided a discount be allowed to be included in the protected classes? Should drugs for which a price increase has not been observed over a particular lookback period be treated differently when determining the exceptions criteria for protected class drugs? What should CMS consider doing, under current authorities, to create incentives for Part D drug manufacturers committing to a price over a particular lookback period? How long should the lookback period be?

The Healthcare Common Procedure Coding System (HCPCS) codes for new Part B drugs are not typically assigned until after they are commercially available. Should they be available immediately at launch for new drugs from manufacturers committing to a price over a particular lookback period? What should CMS consider doing, under current authorities, to create incentives for Part B drugs committing to a price over a particular lookback period? How long should the lookback period be?

How could these incentives affect the behavior of manufacturers and purchasers? What are the operational concerns to implementing them? Are there other incentives that could be created to reward manufacturers of drugs that have not taken a price increase during a particular lookback period?

Inflationary rebate limits. The Department is concerned that limiting manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of calculated AMP allows for excessive price increases to be taken without manufacturers facing the full effect of the price inflationary penalty established by Congress. This policy, implemented as part of the ACA, may allow for runaway price increases and cost-shifting. When is this limitation a valid constraint upon the rebates manufacturers should pay? What impacts would removing the cap on the inflationary rebate have on list prices, price increases over time, and public and private payers?

Exclusion of certain payments, rebates, or discounts from the determination of Average Manufacturer Price and Best Price. The Department is concerned that excluding pharmacy benefit manager rebates from the determination of Best Price, implemented as part of the ACA, may allow for runaway price increases and cost-shifting. The Department is also interested in learning more about the effect of excluding payments received from, and rebates or discounts provided to pharmacy benefit managers (PBMs) from the determination of Average Manufacturer Price.

What impacts would these changes have on list prices, price increases over time, and public and private payers? What data would support or refute the premise described above?

Copay discount cards. Does the use of manufacturer copay cards help lower consumer cost or actually drive increases in manufacturer list price? Does the use of copay cards incent manufacturers and PBMs to work together in driving up list prices by limiting the transparency of the true cost of the drug to the beneficiary? What data would support or refute the premise described above?

CMS regulations presently exclude manufacturer sponsored drug discount card programs from the determination of average manufacturer price and the determination of best price. What effect would eliminating this exclusion have on drug prices?

Would there be circumstances under which allowing beneficiaries of Federal health care programs to utilize copay discount cards would advance public health benefits such as medication adherence, and outweigh the effects on list price and concerns about program integrity? What data would support or refute this?

The 340B Drug Discount Program

The 340B Drug Pricing Program was established by Congress in 1992, and requires drug manufacturers participating in the Medicaid Drug Rebate Program to provide covered outpatient drugs to eligible health care providers—also known as covered entities—at reduced prices. Covered entities include certain qualifying hospitals and Federal grantees identified in section 340B of the Public Health Service Act (PHSA). The Health Resources and Services Administration (HRSA) administers and oversees the 340B program, and the discounts provided may affect the prices paid for drugs used by Medicare beneficiaries, people with Medicaid, and those covered by commercial insurance.

Program Growth. The 340B program has grown significantly since 1992—not only in the number of covered entities and contract pharmacies, but also in the amount of money saved by covered entities. HRSA estimates that covered entities saved approximately $6 billion on approximately $12 billion in discounted purchases in Calendar Year

(CY) 2015 by participating in the 340B program.[2] It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than $16 billion in 2016—a more than 30 percent increase in 340B program purchases in just one year.[3] How has the growth of the 340B drug discount program affected list prices? Has it caused cross-subsidization by increasing list prices applicable in the commercial sector? What impact has this had on insurers and payers, including Part D plans? Does the Group Purchasing Organization (GPO) exclusion, the establishment of the Prime Vendor Program, and the current inventory models for tracking 340B drugs increase or decrease prices? What are the unintended consequences of this program? Would explicit general regulatory authority over all elements of the 340B Program materially affect the elements of the program affecting drug pricing?

Program Eligibility. Would changing the definition of ''patient'' or changing the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (*i.e.,* child sites) help refocus the program towards its intended purpose?

Duplicate Discounts. The 340B statute prohibits duplicate discounts. Manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Are the current mechanisms for identifying and preventing duplicate discounts effective? Are drug companies paying additional rebates over the statutory 340B discounts for drugs that have been dispensed to 340B patients covered by commercial insurance? What is the impact on drug pricing given that private insurers oftentimes pay commercial rates for drugs purchased at 340B discounts? Do insurers, pharmacy, PBM, or manufacturer contracts consider, address, or otherwise include language regarding drugs purchased at 340B discounts? What should be considered to improve the management and the integrity of claims for drugs provided to 340B patients in the overall insured market? What additional oversight or claims standards are necessary to prevent duplicate discounts in Medicaid and other programs?

D. Reduce Patient Out-of-Pocket Spending

Part D end-of-year statement on drug price changes and rebates collected. Part D plans presently provide their members with an explanation of benefits, which includes information about the negotiated price for each of their dispensed prescriptions, and what the plan, member, and others paid. What additional information could be added about the rate of change in those prices over the course of the benefit year? Alternatively, could pharmacists could be empowered to inform beneficiaries when prices for their drugs have changed? Would this information be best distributed by pharmacists at the point of sale, by Medicare as an annual report, or by the health plan on a more regular basis, or some combination of these approaches? Could CMS improve transparency for Medicare beneficiaries without violating the Part D program's confidentiality protections? What operational challenges or concerns about burden exist with this approach, and how could CMS measure compliance with this approach?

Federal preemption of contracted pharmacy gag clause laws. Right now, some contracts between health plans and pharmacies do not allow the pharmacy to inform a patient that the same drug or a competitor could be purchased at a lower price off-insurance. What purpose do these clauses serve other than to require beneficiaries pay higher out-of-pocket costs? What other communication barriers are in place between pharmacists and patients that could be impeding lower drug prices, out-of-pocket costs, and spending? Should pharmacists be required to ask patients in Federal programs if they'd like information about lower-cost alternatives? What other strategies might be most effective in providing price information to consumers at the point of sale?

Inform Medicare beneficiaries with Medicare Part B and Part D about cost-sharing and lower-cost alternatives. Health plans and pharmacy benefit managers have found new ways to inform prescribers and pharmacists, when prescribing or dispensing a new prescription, about the formulary options, expected cost-sharing, and lower-cost alternatives specific to individual patients. How could these tools reduce out-of-pocket spending for people with Medicare? Is this technology present in all or most electronic prescribing or pharmacy dispensing systems? Should Medicare require the use of systems that support providing this information to patients? What existing systems, tools, or third-party applications could support the creation of these tools? Does the technology exist for this approach to be quickly and inexpensively implemented? Would this increase costs for the Medicare program? Does this create unreasonable burden for prescribers or pharmacists?

E. Additional Feedback

We are interested in all suggestions to improve the affordability and accessibility of prescription drugs, including reflections and answers to questions not specifically asked above. Whenever possible, respondents are asked to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses.

What other regulations or government policies may be increasing list prices, net prices, and out-of-pocket drug spending? What other policies or legislative proposals should HHS consider to lower drug prices while encouraging innovation? What data or evidence should HHS consider when developing proposals to lower drug prices?

HHS is actively working to reduce regulatory burdens. To what extent do current regulations or government policies related to prescription drug pricing impose burden on providers, payers, or others? To what extent do the planned actions described in this document impose burden, and do these burdens outweigh the benefits?

This is a request for information only. Respondents are encouraged to provide complete but concise responses to the questions outlined above. We note that a response to every question is not required. This request for information is issued solely for information and planning purposes; it does not constitute a notice of proposed rulemaking or request for proposals, applications, proposal abstracts, or quotations. This request for information does not commit the United States Government (''Government'') to contract for any supplies or services or make a grant award. Further, HHS is not seeking proposals through this request for information and will not accept unsolicited proposals. Respondents are advised that the Government will not pay for any information or administrative costs incurred in response to this request for information; all costs associated with responding to this request for information will be solely at the interested party's expense.

[2] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 FR 1210, 1227 (Jan. 5, 2017).

[3] Aaron Vandervelde and Eleanor Blalock, Measuring the Relative Size of the 340B Program: 2012–2017, BERKELEY RESEARCH GROUP (July 2017), available at *https://www.thinkbrg.✖ Vandervelde_Measuring340Bsize-July-2017_WEB_FINAL.pdf.*

Not responding to this request for information does not preclude participation in any future rulemaking or procurement, if conducted. It is the responsibility of the potential responders to monitor this request for information announcement for additional information pertaining to this request. We also note that HHS may not respond to questions about the policy issues raised in this request for information. HHS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review request for information responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this request for information may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This request for information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become Government property and will not be returned. HHS may publicly post the comments received, or a summary thereof. While responses to this request for information do not bind HHS to any further actions related to the response, all submissions will be made publicly available on *http://www.regulations.gov.*

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. This request for information constitutes a general solicitation of comments. In accordance with the implementing regulations of the Paperwork Reduction Act (PRA) at 5 CFR 1320.3(h)(4), information subject to the PRA does not generally include ''facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment.'' Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: May 11, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–10435 Filed 5–14–18; 11:15 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the NHLBI Mentored Transition to Independence Review Committee.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Review Committee.

Date: June 7–8, 2018.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, *Pintuccig@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 10, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–10472 Filed 5–15–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 22, 2018, 10:00 a.m. to May 22, 2018, 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on May 9, 2018, 83 FR 21301.

The meeting will be held on June 13, 2018 at 11:00 a.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 10, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–10470 Filed 5–15–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC Application Review (2018/10).

Date: June 19–21, 2018.

Time: 6:00 p.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Wild Palms Hotel, 910 East Fremont Avenue, Sunnyvale, CA 94087.

Contact Person: John P. Holden, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707