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SUBMITTED ELECTRONICALLY

July 16, 2018

Hon. Alex M. Azar II, Secretary
Department of Health and Human Services,
200 Independence Ave. SW, Room 600E
Washington, DC 20201

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

Dear Secretary Azar:

Express Scripts appreciates the opportunity to submit our comments on RIN 0991–ZA49, the proposed HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint). Express Scripts (ESI) is a pharmacy benefit manager (PBM) that provides integrated PBM services including network-pharmacy claims processing, home delivery services, specialty benefit management, benefit-design consultation, drug-utilization review, formulary management, and medical and drug-data analysis services for more than 80 million Americans for commercial clients and public programs.

Towards furthering HHS' goals of improving competition, ending regulatory gamesmanship, increasing negotiation, lowering drug prices, and reducing patient out of pocket costs, we respectfully submit the following comments for your review and consideration.

Because of the wide array of clients and programs we service, ESI has perspectives on many of the questions, ideas, and proposals included in the Blueprint based on our experience with managed Medicaid plans, Medicare Advantage plans, Medicare Part D plans, exchanges and the commercial market generally.

1. **Directing CMS to Develop Demonstration Projects to Test Innovative Ways to Encourage Value-based Care and Lower Drug Prices [p.22694 - §II. B, 1st Bullet]**:

   Generally speaking, ESI agrees that using the demonstration program authority may indeed help drive development and testing of innovative models of value-based-care (VBC) in federal programs. We urge HHS allow plan participants sufficient flexibility however to design benefits that enable them to draw upon their substantial experience operating such approaches in commercial markets. ESI, for example, has already begun down this path of providing VBC products for commercial clients through a variety of offerings that will be described further throughout this letter. These programs include outcomes based reimbursement and indication based pricing for prescription drugs.

   We have long encouraged the development of demonstration projects to test innovative ways to introduce value-based care approaches that can also lower drug prices. ESI urges a broad approach that allows states flexibility to test tools that our commercial clients employ to reduce the cost of the benefits provided to their employees that are not currently permitted in Medicaid.

   In the managed Medicaid space, we are encouraged by the Administration's current 1115 demonstration waiver process that permits states to gain such authority. While we are disappointed that CMS recently rejected a frequently-used commercial tool in closed formularies within the Massachusetts waiver application, ESI remains hopeful a subsequent waiver request seeking

similar authority will eventually be approved. The Medicaid program—and states in particular—desperately need access to proven tools that help drive value and reduce drug spend, without sacrificing access to necessary medications.

Further, the current Medicaid Drug Rebate Program (MDRP), in which Medicaid covers all drugs from a manufacturer if they agree to the federal rebate, hampers competition and thereby leads to higher drug costs not only in this program, but for all healthcare payers/patients. The mandated federal Medicaid rebate levels encourage manufacturers to build these rebates *into* their initial drug price knowing that future drug price increases will likely result in additional rebate requirements. Serious consideration must be paid towards revamping this current approach, even if such changes would likely require legislation to do so. We will discuss this topic in greater detail in the appropriate sections later in this letter.

Setting aside—for now—discussions on the impact of MDRP on drug costs generally, any efforts to successfully foster adoption of value-based care in Medicaid and other federal programs will require modifications to the calculation of Medicaid best price (MBP) and the anti-kickback statute safe harbors. One obstacle to offering true VBC benefits involving the drug space cited by drug manufacturers is the potentially negative impact they would suffer if any discounts/rebates render an effective drug "price" lower than the MBP, and the consequences that non-compliance with the statute could entail (i.e. Medicaid exclusion, etc.). Another obstacle is the need for clarity in the anti-kickback safe harbors and civil monetary penalties (CMP) regulations that value-based or outcome-based benefit designs would be protected.

The potential inclusion of monies refunded for ineffective or incomplete drug treatment in the total cost of a drug for MBP purposes may discourage manufacturers from entering into value-based arrangements in which refunds exist for ineffective or incomplete drug regimens. Modifications to MBP is not the only impediment to value-based care, in federally funded programs like Medicare and Medicaid, refunds for incomplete or ineffective treatment need to be clarified in the anti-kickback safe harbors. With concerns about violations of these laws, Medicare and Medicaid beneficiaries are often not able to use such value-based or outcomes-based reimbursement models.

In the PDP space, ESI believes there are several potential ideas to explore through pilot demonstration programs that could positively impact value and spending for the beneficiaries and Medicare. These include:

- Providing member-focused incentives to promote medication adherence such as incentives for achieving or maintaining controlled blood sugar or blood pressure, etc.;
- Introducing drug manufacturer financial risk for lack of promised clinical performance when there is documented adherence, and, similarly, rewards for reduced health service utilization accordingly (e.g. fewer ER visits, etc.);
- Testing physician risk models that also include drug utilization performance measures.

We remain eager to engage HHS/CMS in further discussions to develop these ideas further, and welcome the opportunity to do so.

2. <u>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</u> [p.22694 - §II. B, 2nd Bullet]:

We share HHS' concerns regarding some price increases for sole source generic drugs. ESI cautions, however that setting a price control will give manufacturers a clear runway for price increases that are permissible *before* hitting an arbitrarily designated formulary impact threshold.

Without sacrificing the role clinical effectiveness plays in coverage decisions, a market-events type of program could be constructed that triggers the movement of a sole-source generic drug experiencing a pricing spike up-tier, or, even off formulary. We would support providing a transition period for active members already stabilized on the drug, followed by a "going-forward" change for the remainder of the benefit year. Any such notable price increases should be evaluated against clinical standards which could be addressed by plan P&T committees.

3. **Provide plans flexibility to manage high cost drugs that do not provide rebates or negotiated fixed prices, including in the protected classes [p.22695 - §II. B, 1st Bullet]:**

ESI strongly supports the concept of allowing plans flexibility to manage high cost drugs that do not provide rebates or negotiated fixed prices generally, but that leeway must extend to drugs in the protected classes. Such tools could include authority to up-tier, add Utilization Management (UM) and/or authority to remove a drug from formulary, even within protected classes—all with appropriate prior notification to CMS and beneficiaries or perhaps grandfathering for stabilized populations. As we discuss in greater detail later in this letter (see comment 25), our 2017 Drug Trend Report[1] shows that certain protected class drugs saw decreased utilization, but increased unit costs; such circumstances present significant opportunities to drive down costs through application of available UM tools without sacrificing access to needed medicines. Again, ESI is eager to engage HHS/CMS further on developing policy introducing greater plan drug benefit management and would welcome the opportunity to do so.

4. **Updating the methodology used to calculate Drug Plan Customer Service star ratings for plans that are appropriately managing utilization of high-cost drugs [p.22695 - §II. B, 2nd Bullet]:**

ESI appreciates HHS' recognition of the tension between this particular star rating and the plan sponsor's interest in more effectively managing drug utilization in general, and not just high-cost drugs in particular. This same tension plays out whenever true differences in clinical opinion occur between different stakeholders in Medicare, and we urge HHS/CMS to work with plans and other stakeholders to not penalize sponsors when clinical coverage decisions are made in good faith, using appropriate evidence and whatever information is received from the prescriber at the time the claim was submitted. All too often IRE's are provided additional information from a prescriber—which was not provided to the plan at the outset—when reviewing the coverage denial, resulting in outcomes that may unfairly harm a plan's star ratings.

Moreover, overturns at the IRE level often "cost" more to the plan via a hit to the star rating than the actual cost of the drug at issue. Accordingly, such circumstances contribute to discouraging against applying appropriate UM tools when they should, in fact, be encouraged. Therefore, in many scenarios it is more cost-effective for plans to have high-cost medications *on* formulary with UM than *off* due to the loose criteria aligned for appeals. If HHS/CMS is committed to introducing more effective UM into the Prescription Drug Benefit, then plans need to be afforded more protections regarding non-formulary reviews. Ultimately, plans must be allowed to say "no."

HHS/CMS could evaluate whether to allow members to pay the difference between the brand/generic for formulary medications if, after a tiering exception request is duly denied and any appeals upheld—he/she prefers the prescribed drug and have that "excess" payment count towards TrOOP. ESI also recommends HHS/CMS review the methodology related to Customer Service Star Rating metrics (specifically around appeals) to ensure plans are not penalized for appropriately

[1] 2017 Express Scripts Drug Trend Report. http://lab.express-scripts.com/lab/drug-trend-report/~/media/2b56ec26c9a04ec2bcca0e9bf1ea8ff1.ashx

managing their formulary not only for high-cost drugs, but also those where there is sound clinical rationale for applying UM.

5. <u>Evaluating options to allow indication-based pricing for high-cost drugs</u> [p.22695 - §II. B, 3rd Bullet]:

ESI has been an innovator in developing and implementing value based care concepts and tools in products that drive value and savings—without sacrificing quality of care—for patients and clients. We have had indication-based pricing products in the commercial market available to—and employed by—our clients for years. Accordingly, we welcome the opportunity to introduce such tools into the Medicare program. For example, one such product we offer involves indication-based pricing for oral chemo drugs.

It's commonplace for a drug to come to market to treat a type of cancer and subsequently seek FDA-approval for additional types of cancer. In one such case, a drug was approved for non-small cell lung cancer and, on average, patients experienced an additional five months of life. When the drug was subsequently approved for pancreatic cancer, plans and patients paid the same amount of money for the drug, but it only provided patients an additional 12 days of life. In this case, and others, Express Scripts has negotiated different reimbursement amounts based on the type of cancer being treated, instead of a flat reimbursement for all uses of a particular drug.

We respectfully point out, however, that there are aspects of the Medicare program that would need to be thoughtfully addressed prior to adopting such approaches. One potential obstacle—though certainly not unique—involves solving for any conflict such arrangements may have with CMS' uniformity of benefits requirements, despite the recent issuance of a HPMS Memorandum "reinterpreting" these requirements. Further clarification from CMS that allows plans to effectively charge beneficiaries different amounts for the same drug based on their diagnosis without running afoul of even the current—more permissive—interpretation of uniformity requirements will be needed to assure plans will not be penalized for participating.

Also, because the entire construct of the formulary as it exists today would be changed via introduction of indication-based pricing, member communications would also need to be carefully considered given the risk of confusion involved with having a formulary that would be based not only on the drug's copay by *tier*, but also by copay based on *drug + indication*. Other member materials—such as EOBs, ANOCs, Medicare Plan Finder, etc.—would also be similarly impacted.

6. <u>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</u> [p.22695 - §II. B, 4th Bullet]:

ESI is interested in exploring the possibility for achieving savings in the Part B program, and we think there are genuine opportunities to do so whether through this idea, or the other—introducing Part D tools/features into Pt. B—raised later in the Blueprint. Because of the complexity involved with identifying the "candidate" drugs for moving into Pt. D, along with assessing the consequences and impacts of doing so for both programs, we strongly recommend HHS/CMS engage stakeholders through a work group-type process where sample, de-identified data could be shared for mutual evaluation, or—at a minimum—via separate NPRM.

Within the Part B space, some of the drugs we believe have potential for shifting into Part D—but meriting rigorous analysis and modeling first—could include:

- Certain vaccines;
- Oral chemotherapies with a direct IV counterpart;
- Diabetic supplies;

- Steroids;
- Nebulized medications;
- Immunosuppressants;
- Hospice drugs; and
- ESRD medications.

7. <u>Taking steps to leverage the authority created by the Competitive Acquisition Program (CAP) for Part B Drugs & Biologicals</u> [p.22695 - §II. B, 5th Bullet]:

There are several possible ways Part B drugs and biologicals could be leveraged using PBM tools to help control drug costs. First, assuming Part B drugs end up not being moved into Part D, HHS/CMS could institute a regional (if not national) bid process—similar to Part D—that would allow interested parties to competitively bid for contracts to process claims involving these Part B drugs. Second, in the absence of introducing a competitive bid process, HHS/CMS could authorize limited UM use to test the effectiveness of employing these tools within the benefit. A third approach would combine formulary management *and* application of UM tools to B drugs on both the FFS and managed care benefits. Again, such concepts could be tested initially via pilot demonstrations.

One possible CAP alternative model design is explained later in comment 20.

8. <u>Direct the Centers for Medicare & Medicaid Services to make Medicare and Medicaid prices more transparent</u> [p.22695 - §II. C, 2nd Bullet]:

As a threshold matter, ESI believes that it is important to draw attention to several important facets of pricing "transparency" that have not been adequately accounted for in the current policy debate surrounding its potential role in reducing drug costs in Medicare, Medicaid, and private healthcare. Depending on the program stakeholder asked, drug pricing transparency means different things, and while differing meanings may well be pro-competitive, others are—in fact—substantially anti-competitive and potentially very harmful to patients and payors to the benefit of other stakeholders.

For example, depending on which stakeholder provides what kind of transparency, others may then be able to conduct tacit—or even overt—price fixing. Alternatively, tools like Medicare Planfinder that allow consumers to compare drug prices when selecting a plan, or the numerous other web- or app-based tools—often offered by plan sponsors such as ESI—allowing members to compare them from pharmacy to pharmacy. This feature introduces pro-competitive price transparency to every stakeholder's benefit.

In the Medicare prescription drug program, a member will only see the full cost of his/her medication within the deductible stage of the benefit. Accordingly, it is unclear where increased pricing transparency could actually accomplish any real positive results without the existence of lower cost alternatives available in the market. Price transparency also does not solve for the root cause of the manufacturer increases; it only raises awareness of the situation—which can be helpful, but does not curb the practice. In addition, providing prices without any background on the clinical efficacy of the prescribed drug or alternatives will not give members what would be needed to make informed purchasing decisions. Perhaps allowing plans to offer a limited application of such pricing and clinical information for therapeutically equivalent medications would be a good place to test such a transparency concept. Still, it should be noted that even the provision of this data would fail to explain the 'why' around pricing changes to members.

Further, while increasing price transparency appears to be a means towards controlling drug prices, there are already a number of different pricing mechanisms that exist within the drug benefit market today that effectively drive competition, lower costs, and already feature full transparency

reporting to CMS. Moreover, without a carefully considered alternative, those tools would be rendered useless—and worse, catastrophically increase costs to the federal government—if plan sponsors were to be forced to expose them to any other stakeholder. For example, the use of Maximum Allowable Cost (MAC) lists and spread pricing are commonly cited as "opaque" pricing mechanisms that allegedly lead to underpayment of providers and/or significant profits for payers. Both these mechanisms, however, have their origins in, and remain heavily utilized by, State Medicaid agencies to control drug spending—due in large part to the notion that each approach encourages competition among providers to set reasonable prices for covered drugs and dispensing services. It is worth noting that the PBM's client—the *payor*—elects which mechanism to employ for negotiating drug costs.

Spread pricing encourages active and aggressive rate negotiations to a contract by harnessing market forces to achieve the lowest drug prices through negotiation, rather than via legislative/regulatory fiat. PBMs can achieve this by leveraging access to patients and increasing market share through preferred formulary placement over comparable branded drugs. Drug manufacturers are often willing—especially in competitive markets—to offer steeper discounts accordingly to seize those benefits but, understandably, are reluctant to extend them widely and/or publicly.

It also encourages pricing based on the *whole* of a contract rather than a single claim, which is no different than contracts written with medical providers that use utilization data to determine appropriate per diem, case, or episode rates. Put more simply, spread pricing allows PBMs to offer client plan sponsors the lowest possible negotiated price as compared to "pass-through" or "cost-plus" arrangements. That said, not all clients prefer—or are permitted to enter into—such arrangements and elect pass-through instead due to the transparency it provides.

While highlighting drug price increases and creating a drug-pricing dashboard seems like a good idea in context, the reality is that some price points are already publicly available, and there is currently no real evidence that either measure has had any impact on slowing drug price increases. Strategies that are more effective may include modifications to MBP, such as including the discounts given through copay discount cards to individuals, often regardless of their ability to pay for a medication. Also worth considering is whether introducing additional price transparency in Medicare and Medicaid is moot given Medical Loss Ratio (MLR) reporting provisions and STAR ratings. If a plan is not performing adequately either financially or qualitatively, MLR and STAR rating provisions serve to penalize those that do not meet minimum standards.

So again, while "transparency" sounds universally appealing it is essential that careful consideration be given by policymakers with regard to *who* should be obligated to disclose *what* information *to whom*. Some useful questions whose answers could help guide the decision-making process include:

- Which price needs to be made transparent? "List" price? AMP, WAC, ASP, etc.? Other? Price after rebate/reconciliation? Commonly understood rules are necessary to ensure clear discussion and, eventually, reporting.
- Also, how will any kind of price transparency/reporting impact *paid* vs. *billed* claim encounters?
- Would price transparency reporting be limited strictly to drugs, or extended to medical services and/or supplies?
- While a common scorecard could be a great idea, how will such information be communicated to patients? Given the complexities of pricing in healthcare generally, how

can valuable information be clearly conveyed to a diverse body of patients within all the federal programs?

- What steps could be taken to ensure prescribers, patients and other stakeholders who may be granted access to 'transparent' pricing have all the information they need to compare safety and clinical efficacy as well?

9. <u>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</u> [p.22695 - §II. D, 1st Bullet]:

ESI does not employ such terms in our contracts and pharmacies, and while we are wholeheartedly opposed to such arrangements, we respectfully note the practice has already been prohibited by CMS and myriad state legislatures.

To the extent we have any concerns regarding the recent memorandum issued by Administrator Verma clarifying existing regulations barring gag clauses, they involve the implication that pharmacists should make beneficiaries aware of the availability of their medications outside of the benefit where a cash price may be lower. The risks to beneficiaries in obtaining their prescriptions outside of their benefit can impact adherence and drug utilization review (DUR) efforts.

ESI recommends CMS address this ambiguity accordingly as soon as reasonably possible. In the alternative, CMS might consider encouraging prescribers and pharmacists to inform patients/beneficiaries of switching their maintenance drug prescriptions to 90-day fills at retail or mail—either of which typically reduces copays for beneficiaries significantly.

10. <u>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</u> [p.22695 - §II. D, 2nd Bullet]:

We agree with the premise that finding additional ways to provide information to beneficiaries around lower cost alternatives is beneficial for members, plan sponsors, and the federal government.

Generally, plan call centers have access to cost-saving information and may suggest a savings opportunity to members calling about lowering their cost burdens. The best opportunity to steer members towards lower cost, clinically appropriate options is when the prescriber is writing the prescription. Once a member is at the pharmacy the disruption to the patient, pharmacy and physician increase though the opportunity is still not completely lost. Moreover, it is important to encourage members to consider obtaining maintenance fills through options other than 30-day fills at retail. For example, 90-day fills at retail or by mail for maintenance medications can significantly reduce their copays (often by around half vs. refilling month-to-month for generics).

ESI also has concerns that while such information could be helpful to members if provided in written form, it could get lost within the generally dense content of an EOB. Another alternative method for communicating such information could be through use of electronic formats (i.e. e-mail, text, web), depending on the level of detail this proposed additional information would entail. We would also encourage HHS/CMS to review the current EOB template for opportunities to simplify information to beneficiaries generally. ESI has received feedback from members that the level of information contained within the EOB document is already hard for beneficiaries to follow; and we believe there is demand that it be provided to them in a more clear and concise manner.

11. <u>Improving competition in the pharmaceutical and insurance markets through HHS regulatory reform</u> [p.22695 - §III]:

ESI broadly supports efforts that provide plan sponsors greater flexibility to introduce benefit management tools that are otherwise prohibited in federal programs, as well as regulatory reforms that address regulatory gaming by drug manufacturers that otherwise hampers the introduction of competitor products into the market without contributing to patient safety or efficacy. Moreover, such efforts comport with our general support for regulations that foster competition—among plans, PBMs, drug manufacturers, and pharmacies—to provide the best value to patients and payors without sacrificing safe access to necessary medications.

Although ESI is not a drug manufacturer, we have observed the impacts on payors of regulatory "gaming" by manufacturers that utilize existing FDA rules to delay the entry of competitors—whether via "pay-for-delay," patent extension/ever-greening, gaining orphan status, etc. While ESI recognizes the importance of protecting intellectual property and balancing the incentive to profit from invention and subsidizing additional research and development is a tricky one, we nevertheless appreciate and encourage the efforts led by Secretary Azar and Commissioner Gottlieb to address abuses by manufacturers seeking to inhibit competition at the expense of patients and payors. ESI supports the continuing reduction of the generic application backlog, along with the initial steps taken by FDA to curb REMS abuses hindering the development of high-cost specialty (including biosimilar) drugs.

In addition to lending our support for passage of the "CREATES" Act in Congress, we believe other changes to the drug approval process may require further legislative authorization. For example, ESI has long criticized the frequent extension of sole-source patent protection for products achieved through minor changes to the drug's formulation—such as creating an extended release formula—as it only delays the entry of competitor drugs and hinders the ability of payors to help their patients gain affordable access to these medications for an additional time period. Perhaps—subject to FDA review and approval—rather than extending such a drug's full patent protection status, any such extension would be limited to a shorter specified time period (e.g. one additional year).

In the Medicaid context, while we note that it may be very difficult to further reduce a member's cost share much lower in most cases, ESI believes broader structural changes to the MDRP could achieve significant savings—even if such modifications may require new statutory authority. For example, removing the MDRP requirement that states cover all drugs for which a federal rebate has been negotiated prevents significant opportunities for them to individually negotiate drug prices lower still. Instead, states should be allowed to exclude drugs that are not clinically comparable to other drugs in its class and/or for which the total net cost of the drug is more expensive than other drugs in that class. We would encourage legislative modifications that allow a managed care organization (MCO) to "earn" an exemption from the mandate to cover all MDRP drugs provided it can negotiate a lower total net cost for the State Medicaid Program and federal government than the standard rebate already provides.

Further changes could require including in the AMP and MBP calculations the discounts afforded to the Medicare Part D program along with the "savings" achieved through copay discount cards provided to patients outside of public programs. Currently, the exclusion of these price points from the AMP and MBP calculations allows manufacturers to further game the system by offering patients discounts "post-fill" that are not made available to all consumers and/or lower the overall cost of the drug for the consumer. Doing so could help mitigate somewhat the negative effects such discount cards have for payors in that they see no reduction in their total cost for co-pay card-discounted drugs, but also watch utilization trends for these expensive drugs—which may have

cheaper therapeutically equivalent brands preferred on their benefit tiers or even better, a much less expensive generic substitute—increase, leading to greater drug spending.

Within the Medicare Part D space, we note at the outset the ability of plan sponsors to harness market forces to drive down drug prices has delivered a benefit that costs beneficiaries and Medicare much less than what had been anticipated. Program costs could have been driven down even further if the same principles applied to all classes of drugs, and rules requiring covering all or substantially all drugs in a class did not exist and prevent harnessing of those same market forces to improve affordability for all.

As ESI has noted many times previously, this coverage mandate—along with the "protected classes" of drugs—effectively removes any incentives for affected drug manufacturers to offer price discounts in exchange for preferred formulary placement, even when equally effective alternatives exist. These mandates continue despite the fact that the appeals and exception processes in place since the program's inception allow members who need a specific non-formulary or up-tiered medication to generally overturn plan coverage determinations and gain both access and coverage through their benefit.

Also, reducing consumer out-of-pocket costs shifts the burden away from the member and to other parties that are assuming a greater proportion of the cost, effectively shielding the member from the consequences of rising prices. Therefore, given existing patient protections and the distortive pricing effects of current Part D drug coverage and protected class mandates, ESI reiterates our recommendation that HHS/CMS reconsider continuing these policies.

12. <u>Underpricing or Cost-Shifting: Do HHS programs contain the correct incentives to obtain affordable prices on safe and effective drugs?</u> [p.22695 - §III. A, (1)]:

The Part D program *does* contain the right incentives to drive toward affordable prices; by its very nature, the program tested the ability of a competitive market, operating under appropriate conditions can—and continues to—deliver a wildly popular benefit that has come *under* projected costs to the federal government since inception. That said, we believe many of the best features of Part D could be applied to other HHS programs for similar effect.

For example, while the MDRP rebates are an attempt to control costs and incent manufacturers to provide drugs at competitive prices, ultimately, the exclusions to MBP have created a system—as discussed previously—whereby manufacturers can still charge high prices and encourage consumers to use these expensive drugs by helping to subsidize their OOP costs. Research[2] has shown the MDRP rebates also incentivize State Medicaid programs to continue utilizing high-cost brand drugs in an effort to secure additional rebates under the guise of lowering total cost of care.

Lack of transparency into the rebates gained per drug under these federal programs obscures the total net cost of a drug, making it more difficult to determine whether State Medicaid programs are truly purchasing drugs at the lowest total net cost when employing brand-preferred, state-mandated formulary strategies in both their FFS and Managed Medicaid markets.

MBP reporting does also pose some barriers to price negotiation and creative value- or outcomes-based pricing arrangements; though it is not the only obstacle to rolling out such programs. Certainly, MBP affects the desire of manufacturers to offer creative pricing for non-regulated lines of business because it creates a threshold that manufacturers are not willing to breach for fear of paying additional Medicaid rebates.

[2] "The Effect of Florida Medicaid's State-Mandated Formulary Provision on Prescription Drug Use and Health Plan Costs in a Medicaid Managed Care Plan," Munshi KD, Mager D, Ward KM, Mischel B, Henderson RR; J Managed Care Spec Pharm, 2018 Feb;24(2):124-131. doi: 10.18553/jmcp.2018.24.2.124. https://www.ncbi.nlm.nih.gov/pubmed/29384030

Also noted previously in our comments is the presence of another significant impediment to devising and applying VBC pricing arrangements to government-regulated lines of business is the need for clarity in anti-kickback statute safe harbor(s) and CMP regulations. Manufacturers are concerned about entering into these arrangements in the presence of ambiguity with regard to whether payments based on a drug's "performance" constitutes a violation. Under cover of a separate NPRM/information collection, we urge HHS/CMS to engage stakeholders for input on how best to protect good faith value-, indication-, and outcome-based arrangements within the anti-kickback safe harbors and CMP regulations.

13. Distribution Restrictions [p.22695 - §III. A, (3)]:

ESI fully supports and encourages passage of the CREATES Act legislation (H.R.2212 in the House, S.974 in the Senate) currently awaiting action in Congress.

14. Samples for Biosimilars and Interchangeables [p.22696 - §III. A, (4)]:

Again, ESI fully supports and encourages passage of the CREATES Act legislation (H.R.2212 in the House, S.974 in the Senate) currently awaiting action in Congress.

15. Educating Providers and Patients on biosimilar and interchangeable products [p.22696 - §III. A, (7)]:

Currently, six state pharmacy practice acts do not allow even interchangeable—despite there being none approved in the U.S. as of this writing—biosimilar products to be substituted without physician notification requirements, unlike generic oral solid medications that face no similar restrictions or requirements. Once formal FDA biosimilar interchangeability guidance is issued, the aforementioned state requirements will represent the greatest obstacle to widespread public acceptance of biosimilars on the scale traditional generic oral solids currently enjoy. Information to consumers should generally follow suit with what they are accustomed to receiving when a small molecule brand name drug is substituted for generic. We would urge against preparing and disseminating extensive and wordy materials on these products as it could only serve to impose a burden on prescribers and pharmacists, and may even cause undue alarm in patients.

16. Better Negotiation improving price transparency to help foster a Value-based transformation of healthcare [p.22696 - §III. B, (1)]:

ESI respectfully reiterates our comments on "pro-competitive" vs. "anti-competitive" pricing transparency per comment 8 above; transparency for its own sake can potentially cause catastrophic disruptions to patients, especially among the most vulnerable who are enrolled in Medicare and Medicaid.

Moreover, while low co-pays in Medicare and Medicaid are perhaps among the most laudable aims and features of both programs, they work—unfortunately—against any intention to introduce price sensitivity for these populations. In fact, this is a systemic challenge inherent to third-party health insurance product design. As such, the American consumer is not sensitive to the price of a medication unless they take an expensive medication for which they must pay part of the cost through a higher copay/coinsurance or under a high-deductible plan. We note here—for clarification purposes—that ESI does not take a position on preferring co-pay vs. co-insurance or high-deductible plan designs; we work to provide what our clients request.

In Medicaid, the costs are further masked because of limited cost-sharing options for consumers as mandated by the program. Even initiatives that could drive generic utilization in the program—

such as $0 copays where applicable—do not necessarily incentivize a patient paying a $3 or even $5 co-pay for a branded drug. Complicating matters in this program is the greater frequency of costly conditions to treat that are found in the Medicaid population, appearing disproportionally when compared to other patient populations. For example, the Medicaid population has a higher prevalence of HIV and Hepatitis C, two conditions that require the more expensive drug regimens to successfully treat. Failure to maintain strict patient adherence to those drug regimens can also substantially increase costs because an incomplete course of therapy may necessitate use of a more costly drug in the future to treat a more aggressive or mutated form of these conditions. Hence, we respectfully urge HHS/CMS consider the importance of factors other than lack of price transparency that contribute to high-cost drug spending.

In Medicare, it remains unclear how introducing new transparency in drug pricing would impact member drug spending behaviors as well. By way of a recent example, if beneficiaries had been made aware of the sky-high costs of the new treatments for Hepatitis-C, we are unsure this knowledge could/would have influenced their demand for the medication. Lending weight to that uncertainty is the question of whether the copay amount for those drugs would be so far removed from the plan cost that it obviates any concern the beneficiary would have about plan cost, since his/her OOP copay would in no way be comparable. Moreover, as we noted previously in these comments, drug price transparency without the clinical (e.g. efficacy, side effects) information to accompany it may result in poor/incomplete beneficiary choices that may even ultimately result in greater long-term costs to themselves and the program. Again, ESI urges HHS/CMS exercise caution when considering the risks of promoting cost transparency taking a larger role in affecting treatment choices.

Notably, the new Hepatitis C drugs in particular forced plans to change how they approach the prospect of absorbing the potentially staggering costs of break-through therapies. One significant change plans made was to close formularies, which created—minimally—an initial stop-gap to any/all prescriptions, valid or not. Closed formularies can help drive down price but also cause a plan to forego added rebates when non-formulary requests go through the highly generous formulary exception process, creating operating losses. Two more ways to help mitigate these impacts involve granting Medicare plans authority to add UM to multiple drugs as soon as they hit the market, and also allow UM be applied for non-formulary exception use of these products.

17. <u>Value-Based Arrangements and Price Reporting</u> [p.22696 - §III. B, (2)]:

Simply changing the statutory provisions related to these VBC arrangements is not enough to encourage their use in Medicare and Medicaid. More key to spurring use is clarification of the anti-kickback statute to address protections for such programs in the safe harbors. Without this clarification, VBC arrangements will not proliferate in Medicare and Medicaid as manufacturers maintain anti-kickback statute and CMP concerns.

The conflict between MDRP requirements and incentives for engaging in VBC arrangements only highlights further the absurdity of MBP as a construct that serves to control drug price increases. As we have previously argued in this letter and elsewhere, MDRP requirements and other price controls serve only to impose obstacles to allowing true market-based price negotiations to occur between issuers/PBMs and manufacturers. Accordingly, the prospect of adopting VBC arrangements in public programs finally forces HHS/CMS and other policymakers to choose between antiquated price controls and the prospect for true VBC transformation in healthcare.

That said, assuming anti-kickback and CMP regulations ultimately address VBC arrangements in Medicare and Medicaid, excluding these types of discounts and pricing arrangements from MBP reporting and AMP calculations could spur increased prices occurring in both metrics. We note however, that the full effects of such increases remain unknown at this time, as we do not yet know

the scale to which these programs could be used within these populations. Excluding these discounts from MBP and AMP would eliminate a potentially low price point, which, in theory, would raise MBP and AMP accordingly.

Raising MBP could cause Medicaid to pay a little more for these drugs—when not paid for under value-based or outcomes-based arrangements—although the difference between MBP now and in the future remains to be seen. Consequently, AMP would also increase, potentially leading to an increase in Medicaid rebates under available under the MDRP. Still, how much the effects of increases in MBP and AMP affect overall Medicaid pricing—especially with the offset in pricing due to these creative arrangements—also remains to be seen. At this time excluding value-based arrangements has an unknown effect on ASP and 340B ceiling prices. In the latter's case, because 340B ceiling prices are confidential there is no way to assess the market impact.

Given that VBP arrangements largely do not exist in either the Medicare or Medicaid pharmacy benefit at present, ESI suggests that it is not necessary to extend the timeframe for manufacturers to restate financials regarding AMP and BP. In addition, we respectfully direct attention to our previous comments about modification to best price related to discount cards and exclusions for VBP arrangements, though we continue our assertion that clarity within the anti-kickback statute and CMP regulations are also necessary.

18. <u>Indication-Based Payments – how could indication-based pricing support value-based purchasing?</u> [p.22696 - §III. B, (3)]:

Aligning the payment incentives between the pharmacy, the plan, the manufacturer, and the patient would be essential in all working toward a common outcome (adherence, member satisfaction, lowest net cost, and improved clinical outcomes). A challenge in drug pricing is that price can be determined by actual cost, perceived value, or competition.

ESI approaches indication-based pricing as a form of VBC. When creating pricing arrangements to promote extracting the most value from each claim payment, clients have the option of basing them on outcomes or the manner in which the patient's conditions are treated (i.e. indication-based pricing). In the latter example, clients pay the manufacturer and/or prescriber for the ultimate outcome achieved and doing so may result in paying less for drugs that evidence shows will have less optimal outcomes for patients. Such an approach is heavily dependent on the proper application of substantial amounts of clinical and claims data.

ESI has been a pioneer and leader in designing and implementing VBC into the drug benefit space, primarily in the commercial market. Through our SafeGuardRx Solutions, we have leveraged tools such as value-based contracting to take on some of the most challenging therapy classes, including hepatitis C, high cholesterol, cancer, inflammatory conditions, diabetes, pulmonary, and multiple sclerosis. Accordingly, we have been able to negotiate value-based purchasing contracts that include some of the following components:

- Refunds for early discontinuation of therapy for lack of efficacy or adverse side effects;
- Capping cost of treatment; for example, with PCSK9 inhibitors, we offer plan sponsors who use this solution a guaranteed PMPY cost.
- Management at the Indication level; our solution also offers clients the ability to manage inflammatory conditions and cancer medications at the *indication* level to extract the most value out of treatment costs as our data analytics have determined these categories best allow this form of utilization management.

Clients enrolled in our value-based programs have seen significant improvements in both patient adherence and decreased spending in 2017 concerning inflammatory diseases, cancer, diabetes and high cholesterol. Notably:

- One quarter of enrolled clients saw decreased specialty medication spending for patients with inflammatory conditions—*despite increased utilization* of drugs in these classes. Early discontinuation of therapy rates were 15 percent lower in 2017 as compared to 2016 data.
- In just one year, per-patient spend for diabetes members declined and greater compliance with recommended treatment guidelines was achieved. Addressing common co-morbidities among this population, specialist clinicians at our Diabetes Therapeutic Resource Center[SM] started an additional 15% of enrolled patients at risk for heart attack and stroke on statin therapy. Taking this broader approach could, if ultimately adopted by all our clients, result in preventing nearly 13,000 heart attacks over the next ten years.

Introduction of ICD-10 has brought increased granularity in coding. We note however that the appropriate utilization of diagnosis codes and their availability for each form of a condition requires further research to better assess how it is best used in this context. In Hepatitis C treatments for example, it may be necessary to know the genotype for the specific medication—and ICD-10 diagnosis codes may not yet exist for every genotype or mutation needing a particular, or more appropriate, treatment. Using UM, payers obtain the information needed to make appropriate indication-based payments.

In addition to engaging in value based contracting with manufacturers, ESI has created quality pharmacy networks to ensure retail pharmacies are aligned with plan sponsors' efforts to improve patient care while driving down treatment costs.

We do note that systems designed to show pricing information—i.e. Medicare Plan Finder—would require significant changes to incorporate and portray indication based pricing. Specifically, published pricing would no longer have a 1:1 relationship to the chemical entity and would now have potentially *many* prices based on various approved indications.

In sum, as noted in other parts of this letter, ESI held the overall rate of growth in prescription drug spending in 2017 to 1.5 percent, the lowest growth rate we have measured since we started tracking this metric in the early 1990s. Fully 44% of our clients saw negative trend in 2017 and we remain eager to work with CMS to explore opportunities to apply these same approaches to the Medicare program.

19. <u>Long-term Financing Models to help pay for high-cost treatments by spreading payments over multiple years</u> [p.22697 - §III. B, (4)]:

For a payment model involving long-term financing to work, a number of practical, operational considerations would need to be addressed that have never been contemplated by current billing and claims adjudications systems. For example, our current system of paying for drugs and services assumes payment is to be made up front rather than over a period of time, necessitating substantial software coding and engineering to accommodate a long-term financing concept. Modifications for reporting these drug prices to the MDRP will also be necessary to account for a portion of the drug cost/ potential rebates, or it would otherwise need to be carved out of MBP and AMP.

Given the high rate of churn for Medicaid beneficiaries (and dual-eligibles) moving into and out of the program, along with annual enrollment switching enjoyed by Medicare beneficiaries, the implications of tracking long-term financing arrangements between programs and plans becomes

exceptionally complex. There would need to be interoperability and massive data sharing to track patients over time.

First, would it be necessary that a minimum (high) cost threshold be set to limit the universe of drugs eligible for long-term financing, and if so, what should that be? Would setting a threshold encourage drug manufacturers to target pricing drugs to reach that minimum price floor? Could long-term financing therefore de-sensitize consumers to the high cost of such drugs?

Next, how would that threshold adjust over time? Simply pegging an initial price to the rate of annual inflation may prove unrealistic given manufacturers do not seem able to keep year-over-year price increases limited to such a rate, especially for high-cost, specialty drugs. How would a plan place such drugs within a formulary; would a new tier be necessary? What/how should the plan apply UM criteria to such drugs, and would the current, generous appeals process negate the efficacy of those tools, or would a unique—stricter—coverage appeals process be put into place sole for these extreme high cost drugs? Further, as these high-cost specialty drugs would likely require strict adherence to work, should a member stop taking it or otherwise interrupts therapy, how could plans mitigate the expenses incurred, and future additional expenses for restarting treatment?

Third, HHS/CMS needs to thoroughly consider the long-term implications of a plan making the initial decision to cover a patient's first fill of this kind of drug, in that it necessarily binds any and all subsequent plans the beneficiary may ultimately enroll in during their entire experience in Medicare. Presumably, each payer that touches such members would pay for a portion of the drug regardless of their regulated status. What happens when a subsequent plan is forced to take up patients financing their drugs over time when, under their own criteria, they would have denied coverage of the drug? How would "inheritor" plans taking in members with financing obligations manage the risk—and would actuaries be able to properly anticipate impacts on future plan bids? Would mechanisms such as risk corridors akin to those in the Exchanges be necessary to help compensate plans that incur a disproportionate number of enrollees with financing arrangements?

Given that the one common entity beneficiaries engaged in financing arrangements consistently over their entire experience in Medicare is CMS, it may follow that the agency itself may be in the best position to mitigate these difficulties plans would otherwise have to solve for by independently incurring and managing such arrangements apart from the plan?

With regards to how Medicare or Medicaid should account for the cost of disease averted by a curative therapy paid for by another payer, ESI has long considered this argument proffered by manufacturers as a justification for charging extremely high prices for their products to be dependent on a number of shaky assumptions and faulty applications of logic. A simple analogy to this argument that debunks its premise can be found in the example of a fixing a pothole found on a road. Running over a pothole can cause hundreds or thousands of dollars to a vehicle; multiplied by the number of vehicles potentially damaged by the pothole over a day, week, or month before it is repaired yields potentially millions of dollars of cumulative damages for a road condition that requires on average $25 dollars' worth of material to repair. Given the tens of thousands of "unspent" dollars that would be "saved" by fixing the pothole, should it follow that a contracted paver be paid a significant percentage (30%, 50%, more?) of what *could* have been spent to repair all the damage that had been avoided by the repair?

Granted, the batch of asphalt used for repairing the pothole did not require hundreds of millions of dollars to research and develop—or acquire from another company—before gaining approval for that purpose, but in the case of at least the recent Hepatitis C cures introduced in recent years, the actual manufacturing cost of the product represents the merest fraction of its exceptionally high list price in lieu of a specious estimation of the number of avoided liver transplants to payors. At

least for those particular drugs, pending competitor drugs entering into the market not long after the first drug's approval limited the long-term application of the excessive pricing practices initially imposed by that manufacturer. In the end, manufacturer competition via free markets is—in addition to allowing plan sponsors maximum flexibility to manage drug utilization—the least fraught means of placing "checks" on unfettered drug pricing.

20. <u>Part B Competitive Acquisition Program: 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?</u> [p.22697 - §III. B, (5)]:

We agree that the previous Competitive Acquisition Program for Part B drugs was not successful in bringing choice or value to the market. Additional vendors and providers would likely be interested in participating in a revised initiative, though we urge the approval process be simplified, with clear terms describing—or letting bidders suggest—program controls to prevent fraud, waste or abuse.

We believe there is an opportunity for Medicare Part B to offer providers a voluntary alternative to buying and billing. In a CAP 2.0, Medicare and taxpayers could save money without changing treatment settings for patients. Key features of a redesigned CAP should include:

- The CAP vendor should be a wholesale distributor and not a specialty pharmacy. The distributor should have sufficient capability for just in time distribution, but also support a replenishment model when necessary.
- While participation is voluntary, providers should commit to participation for a defined period of time (e.g. one year).
- Provider reimbursement for administering Part B drugs should be a flat fee that is stratified based on the clinical requirements of administration.
- The CAP vendor could also administer value-based programs (e.g. indication based, outcomes based, reference based pricing) for participants.

Another idea worth considering would allow PBMs to manage a regional 'formulary' with the MACs through a process akin to that used in making Local Coverage Determinations (LCDs) and allow suppliers to bid on 'formulary' preference and positioning much like they do in the Part D benefit. Such an idea—if constructed with stakeholder input—likely would yield similar savings enjoyed in the Part D benefit.

21. <u>Moving Medicare Part B drugs to Part D</u>? [p.22697 - §III. B, (6)]:

ESI respectfully reiterates our comments on moving Part B drugs into Part D drugs submitted under question 6 above.

Administering a neutral payment policy for drug administration procedures will have an impact on the location for practice of medicine; however, it could also have an adverse impact to patients. Provider agreements would need to ensure that patients could not be balanced-billed for the difference between the payment and the site of care costs. In addition, there may be an access issue if providers start to deny care to patients of payers who use a neutral drug administration pricing strategy.

22. <u>Accuracy of National Spending Data: what innovation is needed to maximize price transparency without disclosing proprietary information or data protected by confidentiality provisions?</u> [p.22697 - §III. B, (10)]:

ESI contends that there are too many prescription drug pricing reports produced on a frequent basis to suggest broad "national healthcare spending" reports are obscuring rising drug costs from gaining public attention. We, along with others in the PBM industry produce annual drug trend reports detailing spending across numerous healthcare sectors; this in addition to the various academic publications released on a regular basis within any given year. Regarding the value of encouraging better understanding of the gross to net difference in drug prices, ESI asks again, respectfully: what constitutes the gross and net cost of a drug, and, given that different payors pay different amounts for the same drug depending on their ability to negotiate a lower price, how would reporting account for such disparities—through aggregation? At what scale should those numbers be aggregated—nationally, regionally, intrastate?—and should they be grouped by insurance product category (e.g. Medicare, Medicaid, Exchange, Group, etc.)?

Moreover, we again raise our concern that placing so high an emphasis on cost tacitly suggests price alone should motivate patient/consumer behavior. Plan sponsors and PBMs do not simply drive utilization to the lowest "priced" drug, given the various clinical factors—existence of co-morbidities, side-effects, interactions with other treatments, etc.—that may, when given proper medical evaluation prove that the "cheapest" medication may in fact prove to be the most expensive option if it has a strongly likelihood of being ineffective or potentially harmful. Respectfully, ESI is compelled to point out that "lowest" net drug price is not equivalent to "value" in the pharmaceutical care space.

We encourage HHS/CMS to further consider the nuances involved in formulary placement of drugs, and more importantly, the indispensable role that a plan sponsor or PBM's Pharmacy and Therapeutics (P&T) Committee plays in ensuring patients have safe and affordable access to their needed medications. ESI has, over the course of many comment letters submitted over time, extolled the performance of our own P&T Committee—and processes—while urging CMS to embrace an approach empowering plans to utilize this tool to help introduce greater value in making formulary and UM decisions.

Further, ESI asserts that reporting average Part D rebate amounts for covered drugs—regardless of categorization—carries potentially catastrophic implications for the drug space, inclusive of commercial health insurance markets and federally funded programs. Putting aside the current statutory prohibition against sharing rebate information outside CMS, should HHS gain and exercise such authority the effect of doing so creates the most anti-competitive conditions possible for negotiating lower drug prices.

Building on our previous comments on pro-competitive vs. anti-competitive transparency, disclosing only proprietary, trade-secret rebate information negotiated with manufacturers for Part D drugs would completely undermine plan/PBM negotiating positions for the program. Providing manufacturers access to this information—without also providing issuers access to equivalent manufacturer pricing data—creates a completely asymmetric negotiation scenario that effectively prevents the extracting of any price concessions from drug makers. This asymmetry would in essence foster tacit—or even explicit—price collusion among manufacturers. Moreover, given the influence Medicare and Medicaid exerts on drug pricing generally, the damage of harming issuers' ability to negotiate lower prices would spread to negotiations in the commercial/private health insurance markets over time since manufacturers could glean from the reported rebate data negotiated prices in these other insurance settings with reasonable accuracy.

Reporting rebates, in addition to the aforementioned effects on markets, fails to properly account for how those amounts are utilized by issuers to lower premiums for all beneficiaries in Part D. Not all Part D drugs provide rebates for their products, but total amounts collected from those who do are used by plan sponsors to maintain premium costs at or below annual inflation rates year over year. Therefore, despite the best intentions of introducing such transparency, the end result of doing would be to increase drug prices over time for all patients and payors.

23. <u>Fiduciary Duty for Pharmacy Benefit Managers</u> [p.22697 - §III. C, (1)]:

The portrayal of the role rebates play in negotiations as described in this question stems from the misperception that they flow solely—and in perfect secrecy—to PBMs, and/or that all manufacturers offer rebates for all their products. While all rebates collected within Part D are reported to CMS through the annual end-of-year reconciliation process, in the commercial market clients alone similarly elect how to account for and apply drug rebate arrangements within their contracts with their PBM. Again, PBM clients elect whether to use a pass-through or spread pricing arrangement, and they are highly sophisticated entities who negotiate—with or without the assistance of expert drug benefit consultants—competitively with multiple PBMs through bid processes to select the arrangement that best suits their needs.

ESI has gone on record[3] favoring lower list prices from manufacturers over higher rebate amounts, and reject the implication that we purposely seek higher list prices accordingly. The notion that rebate arrangements drive higher list prices given the percentages of any increases that can possibly be collected by PBMs or clients more accurately describes the market dynamics currently operating in the Part B market. In fact, fierce competition exists in the PBM market to drive down Rx costs in order to gain clients and their patients' prescription volume; ESI's *profit margins* are driven through these means, not from rebates.

By contrast, the fixed ASP+6 compensation rate for prescribers mandated in the Part B benefit introduces no price sensitivity in terms of incentivizing providers to acquire medications from the lowest cost supplier. This fixed pricing system does encourage prescribers to prescribe more expensive medications, regardless of acquisition cost, because of the built-in 6% profit margin. Hence, given the choice between 6% of a $80 per dose drug vs. a $90/dose drug—all other things being equal—the prescriber stands to profit more from dispensing the more expensive drug.

While spread arrangements typically offer lower net drug costs for clients, pass-through arrangements represent the option selected in the vast majority of our commercial contracts. As illustrated by these choices, lowest net cost is not the sole—or even determinative—consideration for clients when selecting a PBM and reimbursement structure. Other measures of value factor into such decisions such as generic utilization and medication adherence rates, the quality of clinical support services provided, the availability of VBC options, etc. Accordingly, the benefit consultant market is considerably more nuanced and sophisticated in taking in numerous client considerations over simply securing greater rebates when advising which PBM to contract with. Consultants who only drive lowest cost as the only consideration when counseling clients fill a very narrow market niche, given the demand for *value* that has been trending in the market for years.

ESI's annual Drug Trend Report[4] shows that our efforts on their behalf helped employers hold the rate of growth in per-person prescription drug spending to 1.5% in 2017—belying the notion that we seek higher prices for drugs. Further, our >95% client retention rate suggests satisfaction with

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[3] "<u>The healthcare industry is starting to turn on itself as pressure over drug prices heats up;</u>" Lydia Ramsey, Business Insider, 3/7/17. http://www.businessinsider.com/express-scripts-responds-to-gilead-drug-pricing-comments-2017-3

[4] 2017 Express Scripts Drug Trend Report. http://lab.express-scripts.com/lab/drug-trend-report/~/media/2b56ec26c9a04ec2bcca0e9bf1ea8ff1.ashx

our performance and confirmation of the value we bring to efforts seeking to lower the cost of prescription drug benefits. Clients are not compelled to hire us; they choose to because of the value we bring in providing safe and affordable drug benefits for their employees.

With regard to how beneficiaries are ". . . negatively impacted by incentives across the benefits landscape (manufacturer, wholesaler, retailer, PBM, consultants and insurers) that favor higher list prices," ESI again—respectfully—rejects the false assumption underlying the question. The *only stakeholders* listed who actually are incentivized to raise list prices are drug manufacturers; more importantly, they *alone* can raise or lower drug prices.

The best mechanisms available to lower drug costs generally—including OOP for consumers—while also improving adherence and outcomes exist already in the commercial market, and are readily deployable for federal programs if plans/PBMs are allowed to use their full suites of UM tools and capabilities as employed in the private space. Further, authorizing plan flexibility to innovate and employ new concepts—e.g. VBC—in cooperation with HHS/CMS will further help mitigate the effects of increasing drug prices.

With specific regard to the concept of imposing a fiduciary duty on PBMs, we are compelled to point out as a threshold matter that doing so would require a remaking of the well-established definition of an ERISA fiduciary, one that has been consistently upheld through litigation since the statute's inception. Namely, that PBMs serve only in administrative and advisory capacities for client health plans, and do not have discretionary authority over such plan sponsors' assets—arguably among the most critical elements of the definition—accordingly. Moreover, the health plan sponsor occupies the role of ERISA fiduciary. While HHS could attempt to restrict application of the new definition to PBMs only, future litigation would likely seek to challenge such limitations and risk upending decades of previously settled law, to the detriment of millions of retirees. ESI therefore urges HHS not to impose a fiduciary duty on PBMs for the aforementioned, and following reasons.

As an industry predicated on providing the best drug benefit management services to our clients, we operate on the principle that our clients are entitled to enter into any kind of business relationship they choose. Those relationships should be dictated by private contract terms, not via mandate. Because the plan sponsor is the ERISA fiduciary to its beneficiaries, it alone determines the formulary, cost-sharing, and other discretionary aspects of the drug benefit to be offered and administrated by the PBM.

Moreover, plans can and do define the terms of their PBM contracts. The PBM marketplace is highly competitive and PBM-clients have considerable leverage to dictate favorable terms through bid and contract negotiations. This leverage enables payors to seek out and secure PBM agreements that meet their unique needs; thus, if a payor wants full transparency, complete pass through of all rebates, or even if they want to assign a limited fiduciary role to their PBM—such terms can be made part of a bid requirement and any contract negotiations. Payors typically do not seek to impose fiduciary status on their PBM however because their primary concern is obtaining guarantees for the lowest possible price. Demanding PBMs assume a fiduciary role undermines their ability to use all available tools to achieve the lowest possible drug spend for clients.

Fiduciary status would make the proven PBM business model unworkable by imposing bureaucratic reporting requirements that would lead to disclosure of sensitive business information and trade secrets to competitors and government entities. Such disclosures would drastically undermine the negotiating leverage of PBMs and lead to increasing drug costs for health plans and their enrollees. Also, because beneficiaries already have access to ample grievance procedures to address plan disputes under ERISA—which already regulates retiree health plans—consumers would derive no additional benefits from making PBMs fiduciaries.

Imposing fiduciary status would also add substantial procedural and administrative costs on PBMs and employer sponsored plans that would ultimately be borne by beneficiaries in the form of higher premiums and copays. Defending against the inevitable frivolous lawsuits ERISA plan fiduciaries frequently encounter would also contribute significantly to increased costs to beneficiaries and sponsors as well. Again, ESI respectfully urges HHS not to proceed with any efforts to designate PBMs as fiduciaries.

25. Reducing the Impact of Rebates: Are increasingly higher rebates in Federal health care programs causing higher list prices in public programs, and increasing the prices paid by consumers, employers, and commercial insurers? [p.22698 - §III. C, (2)]:

Conceptually speaking, it is difficult, if not impossible, under existing rules to accommodate a wish to eliminate or otherwise lessen the role of rebates—or some form of reconcilable, post-claim adjudication payment process—with reducing the price of drugs or introducing VBC arrangements into federal programs. Any assessment of the quality or effectiveness of a given drug therapy is necessarily from a historical, not real-time or predictive perspective. Further, any attempt to incentivize a drug manufacturer to provide additional discounts to payors for their products based on utilization/market-share also necessitates a reconciliation process by which to compare what a contract's terms achieved vs. what was promised. Therefore, by any other name a "rebate" or reconciliation payment plays a critical part in achieving any discounts currently enjoyed by payors, including through VBC arrangements.

We note that the premise that rebates drive increased drug prices is a false one for several reasons, but mainly because not all drugs have rebates, and many of those that don't still experience year over year increases that often outpace drugs that do. In some cases, those drugs fall within the Part D protected classes (e.g. HIV, and Oncology), thereby limiting PBMs' ability to apply additional pressure for discounts from manufacturers. For example, our 2017 Drug Trend Report[5] shows that even though utilization of oncology and HIV drugs were *down* .5% and 2.9% respectively, unit costs for both *rose* 13.3% and 12.9% each! Additionally, a recent PCMA analysis[6] noted that "[a]mong the top insulin brands, there is no correlation between rebates and price increases. In fact, several insulins with lower-than-average rebates have had greater price increases over the past five years than insulins with higher-than-average rebates. Competition—not manufacturer price increases—determine rebate levels." Ultimately—as we have noted on multiple occasions in these comments and other public forums—drug manufacturers have the only authority to set list prices.

Further, we are unclear if this concern with the drug rebate process carries over to the MDRP, and whether HHS/CMS has any intent to abolish its own rebate requirements accordingly. The market distorting effects of MDRP in the drug pricing market would only be magnified if it is the sole permissible rebate arrangement because, at a minimum, manufacturers would be further incented to make their list prices even higher as there would be no "back-end" pressure to provide further discounts to payors. There is also evidence[7] that State Medicaid agencies chase rebates more aggressively than commercial insurers without lowering drug prices for beneficiaries or otherwise passing on those additional revenues. Research[8] also shows that the introduction of a state-mandated formulary in a managed care environment *increases* overall total costs and reduces generic fill rates among those populations. If CMS favors a prohibition on rebates, then additional

[5] Id.

[6] "Insulins: Prices, Rebates, and Other Factors Influencing Costs," PCMA, May 2018. https://www.pcmanet.org/wp-content/uploads/2018/05/Insulins-Prices-Rebates-Costs.pdf

[7] "The Effect of Florida Medicaid's State-Mandated Formulary Provision on Prescription Drug Use and Health Plan Costs in a Medicaid Managed Care Plan," Munshi KD, Mager D, Ward KM, Mischel B, Henderson RR; J Managed Care Spec Pharm, 2018 Feb;24(2):124-131. doi: 10.18553/jmcp.2018.24.2.124. https://www.ncbi.nlm.nih.gov/pubmed/29384030

[8] Id.

regulation and/or oversight would be needed to ensure that drug prices do come down by at least the size of the rebate and more after the rebates program is abolished in the Medicaid program as well.

Eliminating drug rebates from the current process will have impacts beyond those just for Part D enrollees; there are 7 million members that are covered through the Part D program through the EGWP program, which also relies on the model of applying rebates to keep benefits affordable for patients and payors. Drastic changes to the rebate model may cause more employers to exit the market and stop providing retiree coverage, resulting in even more members turning to Part D and increased costs to the federal government.

As an alternative, ESI recommends HHS/CMS pursue changes that allow the free market to work without the influence of price controls that ultimately distort pricing behaviors. Of course, the entire concept of insurance relies on low utilization of the healthy to support the costs of the sick, and affordable premiums to ensure attracting a significantly large enough pool of insureds to fund the benefit. In the Part D benefit, the rebate helps to lower the premiums for *all* enrollees—and thus "rewards" non-utilizers while still offering robust, affordable benefit coverage to the utilizers. The success of this program—though always improvable—in terms of providing value to Medicare beneficiaries while reining in costs for all is beyond dispute.

26. <u>Incentives to Lower or Not Increase List Prices</u> [p.22698 - §III. C, (3)]:

ESI's concerns with the proposals offered here are several, but foremost among them is that they fixate on list drug prices vs. value or clinical efficacy/outcomes and thus represent approaches heading in a completely opposite direction away from adopting VBC arrangements—a stated priority of HHS that we enthusiastically support. The central flaw with focusing on incentivizing lower drug prices is that this concept necessarily assumes clinical efficacy of all drugs are equal across all classes and disease indications. Incentivizing payments for lower priced drugs comes at the expense of discouraging considerations of clinical effectiveness or other factors such as likelihood for adherence, then even the "cheapest" drug ends up costing Medicare significantly by failing to potentially treat the patient's condition according their needs. Of course, such failures may eventually lead to more costly medical interventions in the future, or worse—patient harm. Moreover, it should be noted that a lack of a price increase from one year to the next might be a reflection of the drug's efficacy as much as a potential change in the market—say introduction of a more effective competitor.

The desire to incentivize manufacturers to lower drug prices and reward them is admirable, but rather than creating what would effectively be a protected drug class for drugs satisfying the arbitrary price requirements as outlined, ESI instead suggests that payers be allowed to consider covering these medications as preferred medications if consistent with P&T committee guidance and client input—consistent with our long-standing opposition to use of granting protected drug class status. It is important to support the ability of plans to determine their own formulary composition because protected class drugs are otherwise exempt from utilization management, with coverage in Part D plans mandatory. Not all drugs with low to no price increases should be mandated for coverage, especially since there are often situations where such drugs neither achieve better health outcomes for patients nor clinically superior to others—which may not necessarily be much more costly.

In addition, drug manufacturers could exploit such a policy by setting an extremely high list price initially so as not to take a price increase in a subsequent year(s) and thus score placement on such a mandatory coverage list. This coverage mandate could ultimately further increase drug prices by discouraging competition among manufacturers seeking to compete with an originator, while also

potentially encouraging vastly increased use of less effective or more appropriate medications due to the prevention of plan imposition of utilization management tools for those drugs.

From a VBC perspective, an alternative to an arrangement that effectively establishes a new protected drug class involves introducing risk-based contracting between plans/PBMs and pharmaceutical manufacturers. Such an approach would align all payers—including the beneficiary—into achieving an agreed-upon clinical outcome for an agreed-upon price where possible. ESI contends this approach would provide CMS the benefit of an agreed-upon price going forward into a plan benefit year for clinically eligible indications and the medications used to treat them. The evaluation period would be a given plan year, and we believe the current HCPCS coding system is adequate for all drugs—including future Part B medications.

Injectables, along with other Part B drugs now and into the future (e.g. biosimilars) could also be engaged in a similar risk/reward program based on adherence, clinical outcomes and relative performance to their peers where applicable using the same plan year evaluation period. Data will likely come from several sources (pharmacies, members, PBMs/plans) in order for this approach to function appropriately.

Finally, we believe the Administration could encourage some drug makers to reintroduce their products as competing brand drugs, with new/different NDCs, that would allow the market to move to lower list price products. While immediate list price decreases are attractive, and something Express Scripts has asked drug makers to do, challenges in the supply chain abound: pharmacies and wholesalers have inventories of drugs at high prices that they would have to sell for less; plans have underwritten plan offerings and benefit designs for 2018 and 2019, based on existing economics; drug maker concerns are myriad. Should the Administration allow drug makers to introduce competing brands of their own drugs with lower list prices, uninsured Americans would benefit immediately. Patients who find themselves in high deductible plans would immediately have new treatment options. Plans, pharmacies and the rest of the supply chain could transition to a new pricing model over time and the drug maker could ultimately retire their high list-price product.

27. <u>Inflationary Rebate Limits</u> [p.22698 - §III. C, (4)]:

While an attractive policy option in light of the common drug manufacturer practice of increasing product prices significantly higher than the rate of annual inflation, ESI maintains concerns that attempting to develop and apply an inflationary penalty—whether in the form of additional rebates or other sanction—presents too great an opportunity for gaming by manufacturers that introduces more price control constructs that may further distort the negotiation landscape. We therefore respectfully advise HHS/CMS not pursue such approaches and instead permit full free-market negotiations between payors and manufacturers.

28. <u>Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price</u> [p.22698 - §III. C, (5)]:

A 2018 OIG report[9] "*<u>Increases in Reimbursement for Brand Name Drugs in Part D</u>*" highlighted that even after accounting for manufacturer rebates, reimbursement for brand name drugs in Part D still increased 62% from 2011 to 2015. The increase before netting the rebates was 77%, after netting rebates it was 62%. Therefore, the presence of rebates did not increase prices for drugs – instead, manufacturers raised pricings despite a decrease in the utilization of brand name drugs during the same time period and that lead to greater Part D spending and higher beneficiary costs.

[9] "<u>Increases in Reimbursement for Brand-Name Drugs in Part D</u>," U.S. Dept. Health & Human Services, Office of Inspector General; June 2018 OEI-03-15-00080; https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp

Excluding PBM rebates from MBP and AMP is unlikely to have the desired effect, specifically because they are based on the manufacturer's list price, so if PBM rebates end up excluded from AMP, costs are more likely to then increase *faster*.

29. <u>Copay Discount Cards</u> [p.22698 - §III. C, (6)]:

Manufacturer copay cards can help lower OOP copay costs for consumers; however, because these discount cards are excluded from AMP and MBP calculations, they effectively "raise" the overall cost of drugs because manufacturers do not give this pricing to Medicaid or other consumers. Again, manufacturers are solely responsible for setting a drug's list price. Copay cards do not incent the PBM to drive up prices, because we are simply not responsible for setting them but, we do base discounts and negotiate rebates on the list price because we have no alternative basis to work from.

Moreover, the premise that PBMs work with manufacturers to increase list prices via copay cards—or any other mechanism—is baseless. PBMs have no such capabilities and must competitively win opportunities to serve clients.

Although prohibited in Medicare, we cannot in fact confirm they are not utilized in the program because the claims transactions for these cards route through different payers than the member's PBM. The use of these cards in Medicaid is likely non-existent or minimal because Medicaid recipients should still receive their prescriptions regardless of their ability to pay their copays.

Today, the impact of these manufacturer copay coupons on adherence is unknown because the very process of adjudicating them prevents the study of their effects. Again, because copay discount cards route through a different payer (the drug's manufacturer) and not the member's plan/PBM, the member's full prescription history would not be available for such a study and thus positive or negative changes in adherence would therefore be unknown. Furthermore, the manufacturer copay cards are often associated with higher cost brand drugs for which less expensive preferred brand—or even generic drugs—which misses opportunities to further drive value-based approaches in these programs.

30. <u>Part D End-of-Year Statement on Drug Price Changes and Rebates Collected: what additional information could be added about the rate of change in those prices over the course of the benefit year?</u> [p.22699 - §III. D, (1)]:

The Explanation of Benefits (EOB) is not a particularly effective tool for informing beneficiaries how they have utilized their Part D benefit. The benefit itself is complicated in comparison to most commercial benefits; yet this information must be portrayed in a manner most beneficiaries can understand. Using the EOB to convey pricing information may be a possibility, but we caution that this proposal account for several considerations. First, by nature the EOB reports information one month in arrears despite drug pricing changing on a daily basis. Therefore, from the outset any information provided to the member would not be timely. Second, beneficiaries are typically more sensitive to price once they are into the deductible or coverage gap phases of the benefit.

Alerting beneficiaries to the availability of a lower cost alternative drug may potentially raise the risk of disruption to his/her stabilized therapy, and again highlight the beneficiary's sensibilities when considering how to convey such complex information. We note that pharmacists and member services call centers are generally aware when cost saving opportunities appear, and often advise patients of the availability of less expensive alternatives.

To achieve optimal member decision-making while also minimizing potential care disruption, providing cost information at the point of *prescribing* through real-time benefit checks has—ESI

contends—the best of getting the beneficiary started on the most cost effective therapy without sacrificing clinical efficacy. While efforts to furnish this capability to prescribers are well underway, we note that widespread industry adoption of real-time benefit check systems will take some time still, and urge HHS/CMS allow plans to conduct the necessary outreach for brand/generic conversions or other appropriate cost saving opportunities consistent with best industry practices and per appropriate standards.

31. Federal Preemption of Contracted Pharmacy Gag Clause Laws [p.22699 - §III. D, (2)]:

We reiterate our earlier response in comment 9. Express Scripts does not use these clauses in our contracts, and supports advising the beneficiary of less costly alternatives that may be available and clinically appropriate within their benefit. In addition, we have long employed a "lessor of" logic for adjudicating our claims, meaning that the lowest price available—even if less than our reimbursement rate—is charged to the member. The health plan, who holds most of the financial risk, should ultimately be the source of truth on drug pricing to the member however. While pharmacies may not necessarily feel the same incentives to align with plan sponsors in terms of conveying what is the least expensive option to the plan or beneficiary, they may nevertheless use many plan communication tools to help members make better choices within their drug benefit.

Employing "lessor of" pricing language uniformly across Part D and including the Usual and Customary (U&C) pharmacy cash price for beneficiary encounters at the point of sale (POS) can eliminate some of these concerns, however. While gag clauses should indeed be prohibited in Part D, largely relying on individual pharmacists alone to inform members of their plan's features may not ultimately prove to be the most effective approach. Modern digital tools, such as smartphone applications for members and physicians to ascertain real-time drug pricing information, should be fully encouraged and widely adopted.

32. Inform Medicare Beneficiaries with Medicare Part B and Part D about Cost-Sharing and Lower-Cost Alternatives [p.22699 - §III. D, (3)]:

As noted earlier in our comments, Express Scripts supports providing benefit information, including cost, to the prescriber at the point of prescribing. This has been shown to lead to the most cost effective medication being selected the first time. It is also the least disruptive process for the prescriber, pharmacy, and the beneficiary. With the majority of prescriptions now coming in electronically, the limitation now is integration with the electronic health records systems in providing specific benefit information. Incentives to spur adoption by electronic health record companies could drive better overall outcomes.

33. Additional Feedback: what other policies or legislative proposals should HHS consider to lower drug prices while encouraging innovation [p.22699 - §III. E, (1)]:

ESI urges HHS/CMS consider and promulgate regulatory provisions that ban the use of state-mandated formularies in Medicaid markets where an MCO takes risk on medical and pharmacy benefits. As the State Medicaid agency ostensibly chose managed care for their Medicaid program in the interest of securing the most value available, state-mandated formularies and utilization management guidelines undermine the very commercial principles that achieve those benefits in the commercial market. We share the following research on this topic below to help HHS/CMS further assess the impacts of both the MDRP on drug pricing and state-mandated formulary usage in Medicaid:

- "*Assessment of Louisiana Medicaid's Prescription Drug Management Performance and Preferred Drug List Policy Options*" by The Menges Group, May 16, 2018.

- "*Assessment of Medicaid MCO Preferred Drug List Management Impacts*" by The Menges Group, February 2016.
- "*State Policies Regarding Medicaid MCO Preferred Drug Lists*" by The Menges Group, March 2014.
- "*The Effect of Florida Medicaid's State-Mandated Formulary Provision on Prescription Drug Use and Health Plan Costs in a Medicaid Managed Care Plan*" by the Journal of Managed Care Pharmacy (JMCP), February 2018.

We also suggest HHS consider the following additional proposals:

A. Pay-for-delay agreements hinder the introduction of generics, denying patients access to lower-cost treatments:

Regulators and lawmakers have long paid attention to settlements between brand and generic drug makers that end patent dispute litigation. In most cases, these settlements provide a specific date that a competing drug could come to market. But in some cases, these settlements also included a payment to the competing manufacturer, giving rise to concerns about an anticompetitive effect. Sometimes, these pay-for-delay agreements have hindered the introduction of generics onto the market, denying patient access to lower-cost treatments.

When Congress enacted the Medicare Modernization Act (MMA) of 2003, lawmakers included legislation that required brand and generic drug makers to file patent settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DOJ). With the information from these settlement agreements, the FTC could evaluate and decide whether to take any legal action to challenge the settlement. This requirement eventually led to the Supreme Court weighing in on the subject in the 2013 case of Federal Trade Commission (FTC) v. Actavis. The decision in that case increased FTC scrutiny of pay-for-delay agreements and the agency's ability to challenge them in federal court.

Prescription drugs in 2003, however, were mostly that—drugs. The legislation that required the disclosure of these settlements covered the vast majority of the market in 2003, but does not include biologics or biosimilars. Drug makers can enter into settlements delaying the market introduction of biosimilars without disclosing said settlement to the FTC.

Congress struck a balance in 2003 by allowing these types of settlements to occur, but requiring oversight by the FTC and DOJ to avoid anticompetitive harms. The same policy needs to be adopted and applied to biologics and biosimilars approved under the Public Health Service Act. Payers' drug spending costs increased minimally in the markets where this oversight exists, but surged more than 11.3% among specialty drugs, including biologics.

The best way to reverse this trend is to adopt policies that promote a competitive biosimilars market, which includes ensuring that drug makers aren't delaying competition themselves. Requiring patent settlements between biologic and biosimilar manufacturers to be reported to FTC and DOJ will ensure that these agencies have the information needed to challenge anticompetitive agreements in federal court.

B. Support legislation to prevent misuse of the Orphan Drug Act:

Medicines that treat small patient populations (typically 200,000 patients or fewer in the U.S.) are provided special incentives under the Orphan Drug Act (ODA). However, some drug manufacturers increasingly use ODA provisions to extend the market lives of widely

used brand drugs. In some instances, a drug or biologic is first FDA approved with a limited indication to treat an uncommon condition. Subsequent to initial approval, the manufacturer seeks additional indications that expand the population to well beyond the limits established in the ODA. In other cases, a drug maker seeks orphan drug status for an already-approved brand drug toward the end of its exclusivity period, thus attempting to delay generic competition. Potential savings from amending the ODA could be significant.

C. Support real-time electronic prior authorization:

By their own admissions, physician organizations want to change public policies to reduce the amount of time spent on administrative tasks associated with utilization management. Plan sponsors, however, have a significant interest in managing inappropriate utilization of high-cost drugs through prior authorization (PA). A consortium of prescriber and provider groups, including the American Medical Association (AMA) and the American Hospital Association (AHA), have formed a coalition to frustrate PA programs.15 Instead of discontinuing the use of this important tool, lawmakers should require the use of fully electronic PA (ePA) that minimizes administrative burdens, but maintains a plan sponsor's ability to manage utilization of high-cost drugs and services. Already mandated in four states, ePA technology has proven available, inexpensive and effective.

D. Offering coverage flexibility in high deductible plans:

Many plans desire the flexibility to offer immediate coverage of chronic care treatments (e.g. insulin) in high deductible plans, but find Internal Revenue Service (IRS) regulations prevent them from reducing their beneficiaries out of pocket costs. We encourage the IRS to redefine preventive care to permit plans such flexibility.

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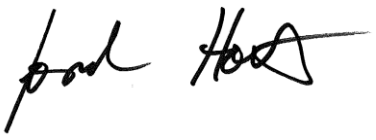
Again, Express Scripts thanks HHS for this opportunity to provide feedback on the proposed Blueprint document, RIN 0991–ZA49. We are confident the Administration will receive voluminous comments from a diverse group of stakeholders across the nation. As the Administration considers rulemaking, guidance, legislation or other next steps, we respectfully suggest that the best solutions to increase competition, increase negotiation, lower list prices, and lower out of pocket costs may be an amalgamation of simple solutions.

As always, we appreciate your consideration of our comments and look forward to continuing to work with you on ways to improve federal programs and reduce the price of drugs for all.

If you have any questions about these comments, please contact me at 202-383-7983 or jhouts@express-scripts.com.

Sincerely,



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