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July 6, 2018

Department of Health and Human Services
Office of the Secretary
200 Independence Avenue, SW
Room 600E
Washington, D.C. 20201

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

Submitted electronically via www.regulations.gov

To Whom It May Concern:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

The Alliance appreciates your commitment to reducing the cost of drugs. The United States leads the world in biopharmaceutical innovation, and many diseases that were once debilitating or even fatal are now manageable with the appropriate medications. However, patients, particularly those in need of expensive specialty biologics, are bearing an ever-increasing financial burden that may put their needed treatments out of reach. We have limited our comments on "American Patients First" to the items that directly affect Alliance physicians and the patients we serve. These are:

- I. Moving drugs from Part B to Part D: For the reasons explained below, the Alliance opposes moving products from Part B into Part D in its current form.
- II. Part B Competitive Acquisition Program (CAP): Any CAP must: (1) provide physicians with the option to remain in the current direct buy-and-bill system, (2) ensure a minimum of three vendor choices per physician, (3) allow physicians to easily switch among vendors or move back to direct buy-and-bill, and (4) prohibit CAP vendors and carriers from engaging in any utilization management or medical review work.
- III. Site neutrality: Any change in payment policy must carefully consider patient access. As such, this may be a good topic to finetune through a demonstration project. We are eager to assist CMS in development of such a trial.
- IV. Copay discount cards: Any policy limiting use of cards must have an exception for products without a generic or biosimilar alternative.
- V. Pharmacy Benefit Managers (PBMs) and list prices: We support a prohibition on rebates, but oppose leveraging the protected classes to bring down list prices. Additionally, we support creating a fiduciary duty for PBMs to hold them accountable to patients.
- VI. Biosimilars: We are eager to assist FDA in further education efforts for prescribers.

We hope you will find our feedback useful.

I. Moving drugs from Part B to Part D

In the blueprint, HHS requests information on what drugs or classes of drugs would be good candidates for moving from Part B to Part D. In 2011, Acumen, at the behest of CMS, modeled out such a move for six categories of products: oral anticancer and antiemetic drugs, vaccines, insulin, inhalants, immunosuppressant drugs, and parenteral nutrition. These six categories include drugs for which coverage may be made under Part B or Part D depending on the specific diagnosis, site of administration and other factors. Acumen’s analysis specifically excluded drugs that are administered in a physician office. Notably, Acumen stated that, “Drugs that are routinely administered in a physician’s office would not be good candidates for consolidation.”¹ We agree with this from a clinical perspective. Many drugs prescribed by our members must be transported and kept under specific temperature and other storage requirements and, when ready for administration, are injected or infused intravenously. It would not be safe to administer these products at home without medical supervision **and the Alliance urges HHS to maintain coverage for physician administered drugs and biologics under Medicare Part B.**

In addition, drugs that are administered during surgery should not be moved from Part B to D, for the same reasons mentioned above. These products are administered at the discretion of the surgeon during the procedure and are currently bundled into the hospital outpatient or ambulatory surgery center facility fee. Not only do these drugs often require particular storage and handling, it would be logistically challenging for patients to acquire and pay for these drugs separately prior to the procedure. Drugs that are currently supplied during a surgical procedure should remain under Part B.

From the perspective of a beneficiary in need of expensive medicines, Part B can be a financial “safe place.” Only 14% of beneficiaries in Medicare have no form of supplemental coverage.² Most beneficiaries in traditional Medicare have a type of or a combination of wraparound coverage in the form of Medicaid, employer-provided coverage, or Medigap. Part D does not allow for supplemental coverage. Thus, the beneficiary is responsible for the coinsurance and other cost-sharing requirements. A 25% coinsurance on a monthly fill of a drug with a list price of \$10,000 renders the product unaffordable for most Medicare beneficiaries. Unless we achieve a meaningful reduction in list prices or a significant pass-through of price concessions, CMS must take extreme caution in moving products over to Part D. We are concerned that program “savings” would come from a simple cost shift to beneficiaries.

Indeed, in its 2011 simulation, Acumen noted that, “The increase in beneficiary out-of-pocket costs is an important concern in examining the effects of the proposed consolidation, as it could impede beneficiary access to needed medication. Beneficiaries taking pumped insulin experience the largest increase in out-of-pocket costs (\$426), followed by beneficiaries taking immunosuppressants (\$418) and anticancer/antiemetic drugs (\$391).”³ The only category where

¹ “Estimating the Effects of Consolidating Drugs under Part D or Part B,” Acumen LLC (September 2011), available: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf.

² <https://www.kff.org/report-section/a-primer-on-medicare-what-types-of-supplemental-insurance-do-beneficiaries-have/>.

³ “Estimating the Effects of Consolidating Drugs under Part D or Part B,” Acumen LLC (September 2011), available: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf.

beneficiaries saw a financial benefit from a move from Part B to Part D was vaccines and, even so, it was “a relatively small decrease[.]”⁴ Across all six categories modeled by Acumen, “decreases of approximately \$230 for Medicare and \$100 for Medicaid are partially offset by an increase of \$200 for beneficiaries.” This illustrates the fact that moving drugs from Part B to Part D is nothing more than a shift of cost responsibility from the program to beneficiaries. True reform will require meaningful changes to bring down prices.

A recent Avalere analysis of a consolidation of all Medicare drug coverage under Medicare Part D includes Part B drugs administered in the physician office. Results from this analysis are consistent with Acumen’s earlier analysis. Savings accrued to the Medicare program would simply represent a shift in costs to Medicare beneficiaries. The Avalere analysis also identified potential unintended consequences of a consolidation, such as an increase in Part D premiums with no corresponding offset in Medicare Part B programs.⁵

A cost increase for beneficiaries has downstream effects that will, in the long run, result in higher costs to Medicare. The biggest risk of a cost increase for beneficiaries is always the effect such an increase might have on medication adherence. When chronic illnesses are poorly managed or not managed at all, a fast escalation of the condition is inevitable. This may result in a greater financial burden to the program in the form of increased hospitalizations or other, high-cost interventions that may have been avoided with full adherence to appropriate medications.

Additionally, at this stage, the RFI’s concept of moving Part B drugs into Part D does not account for the 27% of beneficiaries without Medicare prescription drug coverage. We urge the Administration to study this population at a granular level to determine whether they have alternative, comprehensive drug coverage, some limited coverage, or no drug coverage at all. Any proposal to move Part B drugs over into the Part D benefit must ensure that these individuals do not lose access to needed medicines.

Finally, we would be remiss not to highlight the fact that several paragraphs of the RFI are dedicated to reining in the practices of pharmacy benefit managers, yet this proposal would bring more products within the purview of these entities. Again, unless we achieve meaningful reform of the current Part D environment, moving drugs from Part B to Part D would result in a simple cost shift to patients. As we explain below, list prices in Part D have risen much faster than those in Part B, which we believe is due to the perverse incentives in Part D. As such, **we should not move additional products into Part D in its current form.**

II. **Part B Competitive Acquisition Program**

The blueprint requests information about the concept of moving Part B drug acquisition into a Competitive Acquisition Program (CAP), noting that physicians could choose between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the current average sales price (ASP) methodology.

⁴ Estimating the Effects of Consolidating Drugs under Part D or Part B,” Acumen LLC (September 2011), available: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf.

⁵ http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1526912651_Avalere_B_to_D_Analysis.pdf

As the blueprint acknowledges, this is not the first time that HHS has considered a CAP for Part B drugs. As of December 31, 2008, CMS indefinitely postponed its rollout of the previous CAP due to various implementation challenges. One of these challenges related to the fact that only one vendor signed a contract to become an approved CAP vendor. As CMS noted, this suggested that “the business model conforming most to the legislated program design, specialty pharmacy, is a highly concentrated industry with relatively few firms capable of fulfilling the requirements of the CAP.”⁶ In the years since implementation of the initial CAP was suspended, the specialty pharmacy market has not become any less consolidated. While estimates vary, there are still only a few large distributors who cover a large share of the market – one estimate suggests that only three distributors own 90% of the market share.⁷ While the lucrative nature of specialty products encourages new market entrants, thus far we have only seen more consolidation rather than standalone, new players in the market. This market does not seem to get more participants; it just seems to get bigger ones. We are concerned that this lack of competition in the specialty drug supply chain will result in the same issues that led to suspension of program implementation in 2008.

Of particular concern to specialty physicians who prescribe Part B medicines is the fact that, as CMS noted, “Because only one bidder signed a contract to provide drugs under the CAP, the risk to the CAP program was increased because of potentially poor vendor performance. Were the vendor to have performance problems, physicians and beneficiaries might have associated the problems with CMS rather than the vendor. In addition, the participation of a single vendor eliminated choice within the CAP program. **If physicians were unhappy with the vendor, they could not switch vendors.**”⁸ (Emphasis added.) Any CAP must ensure that physicians and patients have alternative options in the event that a vendor underperforms.

What is critical from the Alliance’s perspective is that a CAP vendor or specialized carrier associated with this new program should not become involved in medical reviews or any utilization management. In its review of the first CAP, CMS noted that a specialized Medicare carrier would process CAP vendor claims and have “other responsibilities,” which would include medical review, among other things.⁹ This is extremely concerning to physicians. In Medicare Part D and the commercial world, prescribers must overcome formulary requirements, “medical” reviews by individuals with no relevant medical background, prior authorizations, and other utilization management tactics. In 2016, to quantify this issue, the Alliance conducted a survey of 1,000 practicing physician members on the topic of prior authorization. A full 63% of respondents answered that they have staff members who must work exclusively on prior authorizations. Even so, over 64% had, at least once in the previous year, received denial of payment for services that actually were prior authorized – for almost 21% of respondents, this happened as many as twenty times or more in that year. Not surprisingly, 94% of respondents stated that increased administrative burdens by insurers influenced their ability to practice medicine. In light of these results, we are not eager to extend these experiences to Part B. **A**

⁶ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.

⁷ <https://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2017/assembly-2017/specialty-pharmacy-where-are-we-now-and-where-are-we-headed>.

⁸ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.

⁹ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.

vendor or specialized carrier selected for CAP must not, under any circumstances, be empowered by CMS to conduct any utilization management or medical reviews.

In sum, should CMS move forward with CAP, we urge the agency to: (1) allow physicians to remain in the current direct buy-and-bill system should they choose to do so, (2) ensure a minimum of three vendor choices per physician, (3) allow physicians to easily switch among vendors or move back to direct buy-and-bill, should they be dissatisfied with vendor performance, and (4) prohibit CAP vendors and carriers from engaging in any utilization management or medical review work.

III. Site neutrality for physician-administered drugs

As the RFI notes, facility fees at hospitals and hospital-owned outpatient departments are higher than those at physician offices, making the physician's office a more cost effective setting for infused drugs and other physician-administered products. While the Alliance supports the concept of Medicare paying for the highest quality, least expensive setting, we do urge CMS to consider the impact on patient access of any change in payment policy. If a hospital finds that these products are no longer profitable to administer, hospital-based infusion centers may close and not all of the patients affected by such a development would have access to infusion in a physician's office. This may be a good topic to finetune through a demonstration project and we are eager to assist CMS in development of such a trial.

IV. Copay discount cards

In the RFI, CMS asks whether copay cards provided by manufacturers lower consumer cost or drive up list prices. For the individual patient, there is no question that these cards can make the difference between being able to access the medicine, or not. However, when viewed cumulatively across programs, there is data indicating that these cards drive brand adherence, increasing prescription drug costs. One study estimates that coupons increase branded sales by over 60%.¹⁰

The concept of copay cards and their effect on spending is more related to the small molecule drug world, where the cards can drive brand utilization to the detriment of the less expensive, equally effective generic. For large molecule biologics, these cards are not driving brand adherence since there are not many biosimilar alternatives yet. The cards are just helping patients afford these very expensive medicines. For biologic autoimmune drugs in particular, the treatments are mostly brand products and, where there are biosimilars, the price differential has not been what we have seen with traditional generics. **Any policy limiting the use of copay cards should include an exception for products for which there is no generic or biosimilar alternative.**

In any event, these cards are only band-aids to fix a symptom of the greater problem: a broken system with an incentive for high list prices. The only way to truly address this problem is to reform the current system where manufacturers set ever-higher list prices as they factor in ever-growing price concessions – which are not shared with patients. If the system is reformed, the discussion of how to control copay cards becomes less pressing.

¹⁰ https://www.hbs.edu/faculty/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf.

We do believe there are circumstances in which allowing beneficiaries of federal healthcare programs to utilize copay cards could advance medication adherence, particularly for medications that have no cheaper alternatives, or no alternatives at all. Whether the benefits of improved medication adherence outweigh the potential effects on list prices is difficult to say.

V. Pharmacy Benefit Managers and list prices

- a. **Reducing the impact of manufacturer rebates** Pharmacy benefit managers (PBMs) receive a variety of fees, rebates, and other price concessions from manufacturers and pharmacies. Some of these price concessions occur after the point-of-sale, which changes the final cost of the drug for the payer or the price paid to the pharmacy, but is not reflected in the cost of the drug to the patient. While these price concessions occur in every market, within Part D, this compensation after the point-of-sale is referred to as Direct and Indirect Remuneration (DIR). DIR factors into CMS's calculation of final payments to Part D plans.

Total DIR reported by Part D sponsors has been growing significantly in recent years, in both frequency and size: according to CMS, a higher number of arrangements feature compensation after the point-of-sale and the dollar value of that compensation is growing. Since 2010, total DIR grew 22% per year while total Part D gross drug costs grew 12% per year.¹¹ There is a growing disparity between gross drug costs (calculated at the point-of-sale) and net drug costs (calculated reflecting DIR).

This is concerning from both the program's perspective and the patient's perspective. From the program's perspective, if a plan receives DIR above the projected amount factored into its bid, that DIR does not lower premiums but contributes primarily to the plan's profits. Perhaps not surprisingly in light of that fact, this overestimation trend is increasing: the DIR amounts that Part D plans and their PBMs *actually* receive has consistently exceeded bid-projected amounts in recent years, according to CMS.¹² Many stakeholders, the Alliance included, believe that the current system drives up Medicare Part D costs. According to CMS' Drug Spending Dashboard, from 2012 to 2016, of the 15 drugs with the highest total spending in Medicare Part B, only a single drug had an annual spending growth rate in excess of 10 percent. In contrast, during the same period, of the 15 drugs with the highest total spending in Medicare Part D, 10 had annual spending growth rates in excess of 10 percent and one had an annual spending growth rate in excess of 20 percent.¹³ These data suggest that the current Part D system accelerates price and spending growth, negatively impacting the Medicare program and patients. These data also suggest that the average sales price methodology used to set payments for Medicare Part B drugs may actually be better at constraining spending.

The current system also harms patients. Medicare beneficiaries face ever increasing cost-sharing obligations. The current system encourages Part D plans to drive patients toward drugs with the lowest net (i.e., after rebate) cost to the plan, but often these drugs have higher list prices than

¹¹ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>.

¹² CMS Proposed Rule, "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program."

¹³ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-05-15.html>.

alternative medications. Since coinsurance at the point-of-sale can be based on the list price, this practice increases the cost to Medicare beneficiary.

In the blueprint, HHS asks whether Part D should prohibit the use of rebates in contracts between sponsors and manufacturers and instead require these contracts to be based only on a fixed price for a drug over the contract term. There is no question that the current system harms patients and the Medicare program. **While we support other policy solutions entertained by CMS, such as increased transparency or mandatory pass-throughs of price concessions, these would be more vulnerable to gaming. An outright prohibition on use of rebates may be more effective.**

b. Incentives to lower or not increase list prices

The RFI asks whether leveraging the six protected classes in Part D might help control list prices. We have discussed at length the various problems with the current drug supply chain, which creates incentives for high list prices. However, we do not believe that limiting the protected classes in Part D accomplishes the goal of creating a better drug supply chain for patients. Such a policy would punish or reward patients based on the actions of manufacturers, which seems like yet another misaligned incentive. We urge CMS to hold manufacturers accountable for the actions of manufacturers. **Instead of leveraging the protected classes to control list prices, CMS should reform or eliminate the rebate system, as discussed above.**

VI. Biosimilar development, approval, education, and access.

Physician Education

In the years following enactment of the Biologics Price Competition and Innovation Act (BPCIA), communication about implementation was influenced heavily by both innovator and biosimilar manufacturers. Perhaps in response to this reality, in October 2017, the Food and Drug Administration (FDA) announced new educational materials for physicians related to biosimilars.¹⁴ FDA has also expressed increased interest in working with physician societies to ensure that the practicing physician knows of these resources. Wherever possible, our members prefer to rely on information directly from the agency tasked with implementing the law, rather than information from third parties. We strongly encourage FDA to continue reaching out to specialty organizations who prescribe biologics to collaborate on rolling out information to clinicians. The Alliance is a willing partner to assist the agency in these efforts.

Interchangeability

With regard to interchangeability, we urge the agency to consider the real-world impact of a finding of biosimilarity without a finding of interchangeability. We have received reports from members that, in some cases, patients are being pushed onto biosimilars, even though these biosimilars have not yet been found interchangeable by FDA. Given the cost of these products, payers are aggressive with utilization management and may cling to FDA's finding of

¹⁴ <https://blogs.fda.gov/fdavoices/index.php/2017/10/fda-taking-new-steps-to-better-inform-physicians-about-biosimilars-through-education-about-these-potentially-cost-saving-options/>.

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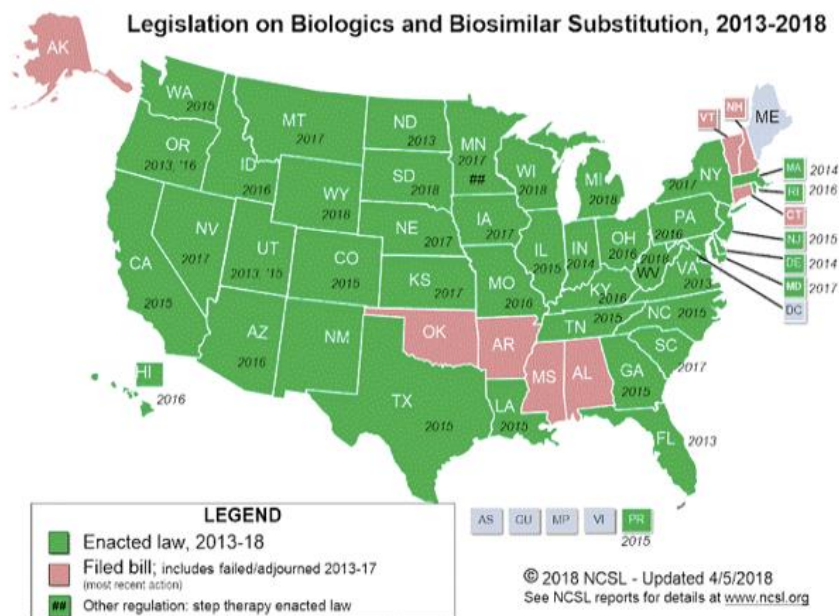
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American Society of Plastic Surgeons • American Society of Retina Specialists • American Urological Association • Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons • National Association of Spine Specialists • Society for Cardiovascular Angiography and Interventions

biosimilarity as clinical justification that mandated switches are harmless. We urge the agency to create an education campaign for payers on the statutory and regulatory differences between biosimilarity and interchangeability. Furthermore, we urge the agency to keep in mind that, in the current payer climate, a finding of biosimilarity may result in mandated non-medical switching of patients, even in the absence of studies supporting such switching.

Role of States

While FDA sets the approval standards and educates providers on a national scale, states can and do play a role, particularly in pharmacy substitution practices and educating a state's clinicians on that topic. The National Conference of State Legislatures indicates that all fifty states have now considered bills, with over forty having enacted legislation. This year alone, five states have enacted laws related to biosimilar substitution. The total is as follows:



The Alliance has been engaged with states as they consider legislation, to ensure that any substitution law incorporates the following principles: physician discretion must be protected and the prescriber must be notified of any switch within a reasonable timeframe. We are pleased to report that, thus far, most state legislation is aligned with these commonsense principles.

In closing, we thank you again for your attention to this critical issue that directly affects patients. We hope the perspective of practicing specialists is helpful to you as you explore the various policy ideas contained in the blueprint. Thank you for your consideration of our feedback. Should you have questions or require additional information, please contact Judith Gorsuch, jgorsuch@hhs.com.

Sincerely,

American Association of Neurological Surgeons
American College of Osteopathic Surgeons
American Gastroenterological Association

American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
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