AAM's Study on Generic Substitution is Contrary to the Evidence and Ignores Statutory Requirements and Manufacturer Workarounds that Limit Generics

A January 2020 white paper from the Association for Accessible Medicines (AAM) examines generic substitution in Medicare Part D.[i] Importantly, AAM's analysis does not account for the significant barriers to generic substitution posed by dispense-as-written laws, the Part D low-income subsidy, manufacturer Patient Assistance Programs, and manufacturer payments to prescribers.

Part D plan sponsors and PBMs have consistently promoted generic substitution since the beginning of the program and have achieved a nearly 90% generic substitution rate.[ii]

PBMs promote clinically appropriate generic drug utilization, including by:

- Implementing favorable formulary placement with lower cost sharing;
- Using prospective drug utilization review (DUR), which evaluates a patient's planned drug therapy before a medication is dispensed. This process allows for a generic substitution when a generic is available;
- Applying other utilization management tools like prior authorization and step therapy to brand drugs in order to incent generic substitution; and
- Paying performance bonuses or incentives to contracted pharmacies that increase their generic dispensing rate (GDR).

These tools are working! At the launch of Medicare Part D in 2006, generics represented 56% of prescriptions filled. For 2018, the Medicare Board of Trustees found generic utilization had risen to 88%: "There has been a substantial increase in the proportion of prescriptions filled with low-cost generic drugs that has helped constrain cost growth[.]"

Regulatory loopholes and regulations limiting PBM tools often are exploited by brand drug manufacturers, which effectively limits generic utilization.

- **Dispense as written laws:** Several states have "dispense as written" laws that require a pharmacist to dispense a specific brand name drug if the prescriber expressly indicates there should be no drug substitution. Brand drug manufacturers educate prescribers on how to use these laws to promote brand utilization.[iii]
- **Part D low-income subsidy (LIS) limits generic incentives:** LIS Medicare beneficiaries have slightly more than a $5 differential between brand and generic out-of-pocket costs; in some years, the differential has been as small as $3.[iv] MedPAC has demonstrated that LIS beneficiaries consistently have a 3% to 5% lower generic utilization compared to non-LIS beneficiaries.[v] MedPAC has recommended that LIS copays be modified to better incentivize use of generics.[vi]
- **Manufacturer Patient Assistance Programs (PAPs) promote brands over generics:** Pharmaceutical manufacturers may sponsor PAPs that provide financial assistance or free product (through in-kind product donations) if they operate "outside the Part D benefit" to ensure separateness of Part D benefits and the PAP. However, the brand manufacturer can misuse the CMS access protection policies, which favor continuation of brands once a beneficiary starts on the therapy.

- **Manufacturer payments to prescribers are associated with lower generic utilization:** Loopholes in government regulations allow manufacturers to pay doctors. According to CMS, in 2018 alone, approximately 627,000 doctors received more than $3.5 billion in payments from manufacturers.[vii] Several independent studies have found these payments are associated with higher prescribing of brands over generics.[viii] For example, one study found that doctors receiving more than $500 of industry payments prescribed generics 6.2% less often than those not receiving any payments.[ix]

AAM advocates for the placement of all new generics – not just first generics – onto Part D formularies without exceptions for appropriateness or price. Coverage guarantees lead to higher launch prices and unchecked price increases, the opposite of what generics promise. This has played out with many generic drugs in the CMS protected classes. Automatic formulary placement would allow generic manufacturers to price their new generics however they wanted and force beneficiaries, the federal government, and taxpayers to bear the costs.

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[i] Association for Accessible Medicines. Sidelined: How Seniors Miss Out On Savings Through Generic Substitution. January 2020. https://accessiblemeds.org/resources/reports/AAM-white-paper-seniors-sidelined-generic-substitution

[ii] Medicare Payment Advisory Commission (MedPAC), Report to Congress, "Chapter 14: The Medicare prescription drug program (Part D): Status report." March 2019. http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0

[iii] Takeda, What are your your state or territory's "Dispense as Written (DAW)" requirements? May 2019. https://www.firazyr.com/Resources/docs/hcp/Takeda_FIRAZYR_HCP_DAW_State_By_State_Requirement_Card.pdf

[iv] MedPAC, Report to Congress, "Chapter 14: The Medicare prescription drug program (Part D): Status report," Table 14-1 on Page 390. March 2019. http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0

[v] MedPAC, Report to Congress, "Chapter 14: Status report on the Medicare prescription drug program (Part D)." March 2017. http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf

[vi] MedPAC, Report to Congress, "Chapter 6: Improving Medicare Part D." June 2016. http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf

[vii] Centers for Medicare & Medicaid Services (CMS), The Facts About Open Payments Data. January 17, 2020. https://openpaymentsdata.cms.gov/summary

[viii] See, for example, https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf; https://www.researchgate.net/profile/Grace_Lin23/publication/304192465_Pharmaceutical_Industry-Sponsored_Meals_and_Physician_Prescribing_Patterns_for_Medicare_Beneficiaries/links/5a53b0dbaca2725638c85dd2/Pharmaceutical-Industry-Sponsored-Meals-and-Physician-Prescribing-Patterns-for-Medicare-Beneficiaries.pdf.

[ix] Jingjing Qian et al. Disclosure of Industry Payments to Prescribers: Industry Payments Might be a Factor Impacting Generic Drug Prescribing. Pharmaceoepidemiol Drug Saf. July 2017, 26(7): 819-826. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5856251/