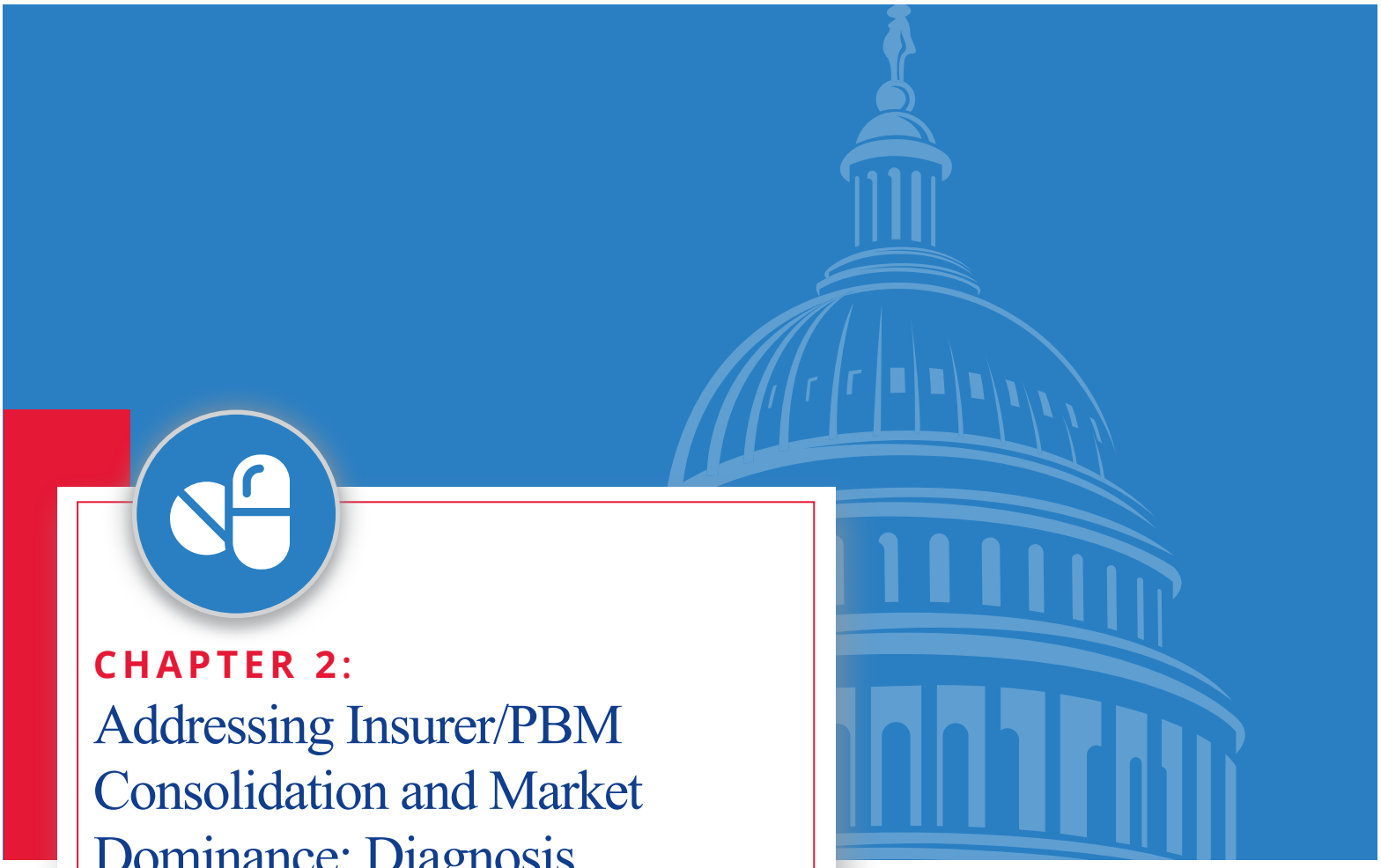


CHAPTER 2:

Addressing Insurer/PBM Consolidation and Market Dominance: Diagnosis, Prescription, and Treatment

ADDRESSING INSURER/PBM CONSOLIDATION AND MARKET DOMINANCE: DIAGNOSIS

Trend: PBMs have become extremely powerful intermediaries in the health care system. The PBM industry is highly concentrated and vertically integrated. Integration in the insurance/PBM industry has resulted in the top three PBMs effectively controlling 80 percent of the prescription drug market.[24] Not only have PBMs merged, and continue to do so, but they are also part of insurance corporations that have in turn merged to increase their market dominance and leverage over patients, employers, and pharmaceutical manufacturers. As a result, insurance markets have grown increasingly concentrated, limiting patient choice and inflating costs.[25] [26] The modern PBM business model incentivizes PBMs to promote those drugs—often the most expensive drugs—that maximize their profits.[27] In the process, this has fueled an arms race between mega hospital systems and insurers/PBMs, each vying for greater market leverage by consolidating.[28] Patients and independent medical practices are left to shoulder escalating costs and complex administrative burdens, while the "corporate practice of medicine" increasingly becomes the norm, denying physician and patient treatment choices.

Patient Impact: Increasingly, insurers/PBMs are prioritizing their profits over appropriate clinical decisions and patient wellbeing, dictating what treatment will be given and how and where it will be administered, and causing delays in treatment.[29] [30] This is particularly detrimental in cancer care, where the opportunity for effective intervention is narrow. Delays in treatment can lead to disease progression, diminished treatment efficacy, and ultimately, worse patient outcomes, even death. Treatment options are increasingly dictated by insurer/PBM profit incentives, not by what is clinically best for the patient.

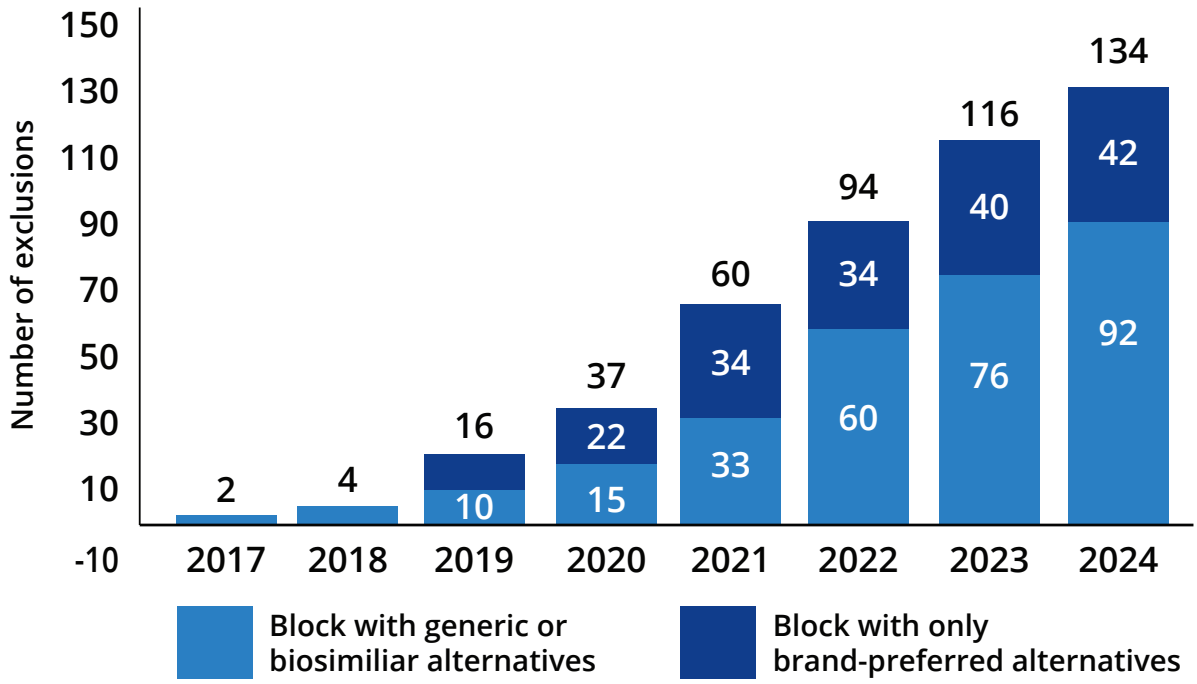
PBM administrative layers have also increased patients' out-of-pocket costs, creating significant financial burdens that make it difficult for patients to afford essential treatments.[31] [32] Despite negotiating rebates and discounts with drug manufacturers, PBMs rarely pass these savings on to patients and employers, leaving them with inflated costs. Utilization management practices, such as prior authorization, "fail-first" step therapy, and restrictive formularies, limit access to optimal, affordable medications and delay or deny critical patient care.[33] Consolidation among PBMs and their market leverage to dictate drug reimbursement has pressured independent pharmacies, creating "pharmacy deserts" across the country, especially in rural areas.[34] Access to needed medication to maintain health or address acute problems becomes impeded by the proximity to the nearest pharmacy.

The Facts: Insurers/PBMs Create Patient Access Challenges in Cancer Care

Formulary Exclusions Are Increasingly Common in Oncology

As new oncology treatments come to market, formulary exclusions and other access barriers have become more common in oncology.[i] A 2024 IQVIA analysis found that across the top national commercial formularies, there were 134 formulary decisions to exclude oncology products in 2024 (Figure 2). Within Medicare, the "six protected class" requirements provide some guardrails for oncology treatment coverage in the pharmacy benefit, but access challenges through utilization management remain.

Figure 2: Number of National Formulary Exclusions by Year, Top National Payers, Oncology Products, Commercial, 2017-2024[i]



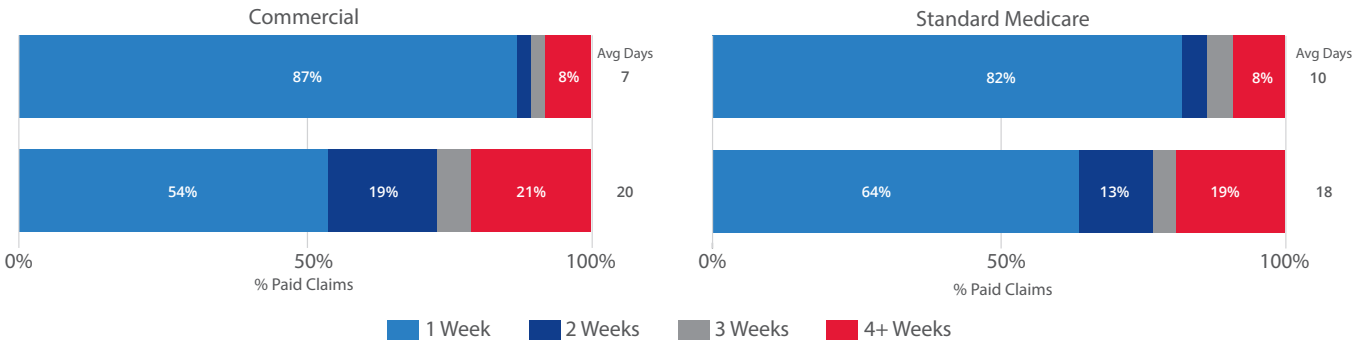
The Facts: Insurers/PBMs Create Patient Access Challenges in Cancer Care (continued)

The Burden of Prior Authorization Impacts People with Cancer, Caregivers, Doctors, and Staff, and Can Lead to Delayed or Denied Treatment

In addition to formulary exclusions, insurers/PBMs use prior authorization, step therapy, or other formulary requirements to control access. The number of diagnostic and therapeutic procedures requiring prior authorization has increased in recent years in staggering numbers. In 2023, 93 percent of physicians surveyed by the AMA found that prior authorization had a "somewhat or significant negative impact" on patient clinical outcomes. Nearly one in four physicians (24 percent) reported that prior authorization led to a serious adverse event for a patient in their care.[ii]

Among commercial and traditional Medicare patients, those with an initially rejected claim status had an average of 20-day delay and 18-day delay in accessing treatment, respectively. Around one in five patients had to wait over four weeks for their insurer to approve their prescription (Figure 3).[i]

Figure 3: Time to Treatment by Initial Claim Status, Branded Oral Oncology Therapy, 2020-2023[i]



The time spent and personnel required to adjudicate and be rightly reimbursed for these "authorized" claims is increasingly a financial and staffing drain on practice resources.[iii] For the patients who are denied prior authorization approval, access to immediate treatment is delayed and/or denied, and the physician typically begins an opaque and cumbersome process that can go on for several weeks as the medication or treatment plan is continually denied. This often leaves patients confused, frustrated, and hopeless at a time when they are particularly vulnerable. Furthermore, it is unclear what purpose prior authorization serves when treatments are prescribed following recognized pathways or clinical care guidelines.

Sources:

i. *Thiesan, Jeff, et al. "Access Challenges in the Cancer Patient Journey: How barriers to oral oncology affect patient initiation and persistency." IQVIA. August 2024.* https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-access-challenges-in-oncology-report-white-paper-2024.pdf

ii. *American Medical Association. "2023 AMA prior authorization physician survey; Care Delays Associated with PA Treatment Abandonment due to PA." 2023.* https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

iii. *Community Oncology Alliance. "Position Statement on Prior Authorization." 22 April 2021.* https://mycoa.communityoncology.org/education-publications/position-statements/coa-position-statement-prior-authorization

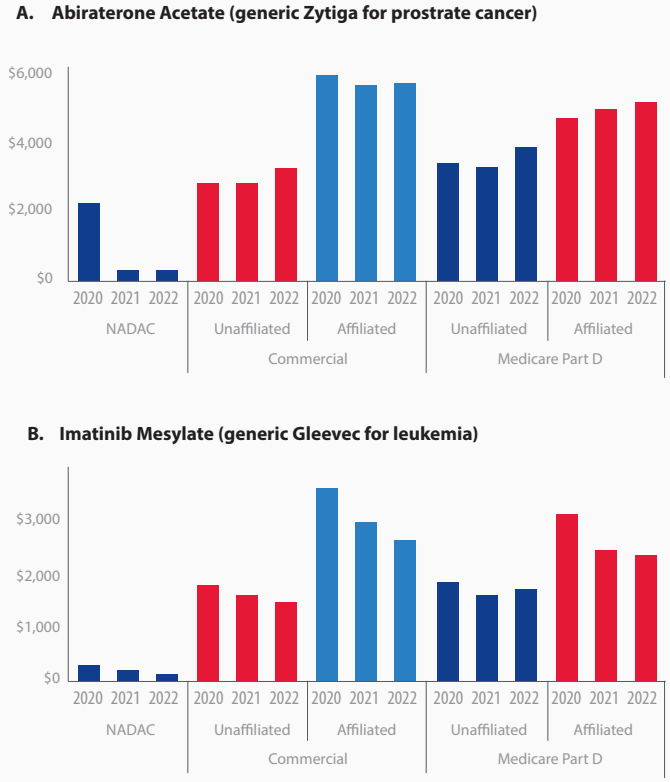
The Facts: Insurers/PBMs "Game the System" to Fuel Consolidation and Control Market Share

Lower Reimbursement and Exclusions from Insurance Networks Threatens Independent Pharmacies and Fuels Consolidation

Vertically integrated PBMs have the ability and incentive to prefer their own affiliated pharmacies, creating conflicts of interest that disadvantage unaffiliated pharmacies and increase prescription drug costs.[i ii] The PBM market has become highly concentrated in recent years, and the largest PBMs are also vertically integrated with the nation's largest health insurers and specialty and retail pharmacies. The top three PBMs—CVS Caremark, Express Scripts, and Optum Rx—processed nearly 80 percent of the approximately 6.6 billion prescriptions dispensed by U.S. pharmacies in 2023, while the top six PBMs processed more than 90 percent.[ii]

Low reimbursement rates by PBMs, as well as PBMs' exclusions of certain pharmacies from their preferred networks, affect pharmacies' profitability and lead to disparate closure rates. A Health Affairs study looked at closure rates of independent pharmacies relative to chain pharmacies from 2010 through 2021 and how the impact of those closures varied across geographic and demographic factors.[i] The research found that independent pharmacies were much more likely than chains to be in predominantly Black and Latino neighborhoods, as well as in neighborhoods with poverty rates of 20 percent or more. Independent pharmacies were nearly two times more likely than chain pharmacies to be in neighborhoods with higher uninsured rates and over twice as likely than chain pharmacies to be critical access pharmacies (the sole pharmacy in the neighborhood). Overall, the risk for closure among independent pharmacies was more than twice that of chain pharmacies.[i]

Figure 4: Gross Pharmacy Reimbursement Rates for a One-Month Supply of Two Specialty Generics Paid to PBM-Affiliated and Unaffiliated Pharmacies by Commercial and Medicare Part D Plans and Members Managed by the Big Three PBMs, and NADAC, 2020-2022 [ii]



The first interim Federal Trade Commission (FTC) staff report on PBM practices took a case study of two oncology products and compared reimbursement across markets (commercial, Medicare) and PBM affiliation. The comparison in reimbursement found that PBM-affiliated pharmacies also received significantly higher gross reimbursement rates than unaffiliated pharmacies for the two case study drugs. In 2022, commercial health plans paid affiliated pharmacies roughly 80 to 90 percent more than unaffiliated pharmacies for abiraterone acetate (generic Zytiga) and imatinib mesylate (generic Gleevec), while Part D plans paid affiliated pharmacies over 30 percent more than unaffiliated pharmacies for both drugs.[ii] A second interim FTC report documented that the top three PBMs excessively mark up generic cancer drugs and other critical therapies dispensed from their affiliated pharmacies. Additionally, the FTC analysis found that the PBMs paid their pharmacies more than unaffiliated independent pharmacies. [iii]

Sources:

i. *Guadamuz, Jenny S, et al. "More US Pharmacies Closed than Opened in 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk." Health Affairs. December 2024.* https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192

ii. *Federal Trade Commission. "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies." July 2024.* https://www.ftc.gov/reports/pharmacy-benefit-managers-report

iii. *Federal Trade Commission. "Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers." January 2025.* https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers

ADDRESSING INSURER/PBM CONSOLIDATION AND MARKET DOMINANCE: PRESCRIPTION AND TREATMENT

The 119th Congress must prioritize PBM reform and stop the insurer/PBM middlemen from gaming the system, increasing costs, and hurting patients.

Require PBM Transparency

- Require PBMs to report on gross and net drug price, formulary construction, and related information including, but not limited to, drug rebates, spread pricing arrangements, formulary placement rationale, and information about benefit designs that encourage the use of pharmacies affiliated with PBMs to independent (non-corporate-affiliated) Medicare Part D plan sponsors.
- Mandate that specialty pharmacy performance or quality programs use evidence-based and relevant measures. For example, oncology practice dispensing facilities or pharmacies should not be measured on cardiovascular drug adherence.
- Mandate that the PBM drug dispensing fee must cover the cost of dispensing the medication.
- Require PBMs to publicly disclose the Maximum Allowable Cost (MAC) source used to calculate generic drug reimbursements.

Prohibit Insurers/PBMs from Owning Pharmacies

- Prohibit parent companies of insurers and/or PBMs from owning any type of pharmacy business.
  - Mandate that the Department of Health and Human Services (HHS), the FTC, and antitrust divisions of the Department of Justice (DOJ) use their authority to issue orders to violators to divest pharmacy business and relinquish revenue during the violation period.
  - Allow the FTC to distribute the funds to communities harmed by insurer/PBM ownership of pharmacies.
  - Report divestitures to the FTC and the Securities and Exchange Commission (SEC) to review all divestitures and actions to protect the financial viability, interest of the public, and competition.

Mandate PBM Rebate Reform

- Delink PBM rebates and fees as a percentage of prescription drug prices.
- Eliminate safe harbor protections for PBM rebates.
- Require that all PBMs institute "pass-through" pricing, in which (a) the amount a PBM charges a plan is equivalent to the amount the PBM pays the dispensing pharmacy, including dispensing fees; and (b) the amount paid to the PBM for a medication is passed through in its entirety to the pharmacy provider with no offset for reconciliation.

Prohibit Insurers/PBMs From Owning Physician Practices

- Prohibit insurers/PBMs from owning or controlling any type of physician practice.

Address Prior Authorization Challenges

- Ban "fail-first" step therapy and non-medical switching in cancer care if a drug is FDA approved, and a National Comprehensive Cancer Network (NCCN) Category 1 or 2A recommended cancer drug.
- Ensure a clear exception process for patients forced into "fail-first" step therapy and non-medical switching in cancer care.
- Require Medicare Part D (e.g., an oral cancer drug) and Part B (e.g., physician-administered drugs, radiation therapy) prior authorizations and appeals be reviewed by a physician of the identical specialty. For example, for medical or radiation oncology, a pediatrician cannot review an appeal of a cancer treatment.
- Mandate the timely review of all prior authorizations within 72 hours of submission.
- Require that all Part D plans establish electronic prior authorizations to expedite review and approval times.

Mandate Formulary Transparency and Accountability

- Require Medicare Part D plans to provide a continuity-of-care period following any mid-year plan drug formulary changes.
- Require Part D plan sponsors to provide transparent, comprehensive information on plan prescription drug claims.
- Prohibit Part D plan sponsors from making mid-year formulary changes that remove drugs or place drugs on more restrictive tiers unless the removed drug has been withdrawn from the market.

- Require Part D plan sponsors to provide an up-to-date, maintained, publicly accessible online link to the plan drug formulary.
- Require Part D plan sponsors to provide a plain-language, written justification when denying a prior authorization due to non-formulary rejections along with clear and meaningful recourse options.

Create Patient-Oriented Solutions

- Ban copay accumulator or maximizer programs that prevent patient assistance from counting toward out-of-pocket costs.
- Mandate coverage policies following Value-Based Insurance Design (VBID) principles that ensure access to proper screening, imaging, treatment, and long-term care options, including payment for diseases found at screening.

Curb Insurance/PBM Consolidation

- Require PBMs to provide the same reimbursements to independent pharmacies and specialty dispensing facilities as they do to their own mail order and affiliated specialty pharmacies until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.
- Prevent PBMs from steering patients toward their corporately affiliated pharmacies until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.
- Require PBMs and their mail order pharmacies to operate under the state pharmacy laws where the patient lives, not where the filling facility is located, until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.
- Require Group Purchasing Organizations (GPOs) affiliated with insurers/PBMs to completely disclose all relevant financial information regarding rebates and administrative fees.
- Prohibit PBMs from requiring the mandatory use of their mail order pharmacies and discriminatory differential patient cost sharing for independent pharmacies, until insurer/PBM pharmacies are divested to comply with the prohibition against insurer/PBM ownership of pharmacies.

Implement Medicare Guardrails

- Ensure that MA plans have clear, enforceable guardrails to protect patient access.
- Ensure that MA plans are not using "ghost networks" that delay access to care.
- Require CMS to create a centralized data hub where MA plan sponsors would load provider contact information to ensure completeness and accuracy of their networks.
- Require MA plans to cover the same benefits as fully loaded A, B, Medigap, and D Medicare FFS plans.
- Prohibit Medigap plans from using pre-existing condition exclusions.
- Ensure that the Medicare Plan Finder is kept up to date and is a valuable resource for beneficiaries, particularly those with chronic conditions and who take multiple medications.

ADDRESSING INSURER/PBM CONSOLIDATION AND MARKET DOMINANCE: ONGOING TREATMENT

The 120th Congress and beyond must ensure that physicians are able to make clinical decisions and ensure that PBMs are held accountable to Employee Retiree Income Security Act (ERISA) fiduciary duties.

Create Federal Policies That Make Physicians, not Administrators, the Decision Makers

- Legislate a Corporate Practice of Medicine Doctrine (CPOM) at the federal level to ensure clinical decisions remain with licensed physicians, not corporations.

Amend ERISA to Require PBM's to Follow ERISA Fiduciary Duties

- Require PBMs to act as fiduciaries, which would mandate that PBMs act in the best interests of plan participants. As ERISA fiduciaries, PBMs could not engage in price-inflating behavior. Requiring PBMs to act as fiduciaries would align PBM practices with the best interests of plan sponsors and beneficiaries—for example, preventing a PBM from mandating patients receive an expensive originator biologic, which through rebating is more profitable to the PBM, rather than a less expensive biosimilar.