Member and Partner Newsletter
September 2022

Government Negotiation of Rx Prices Enacted

Budget Reconciliation Passes

Perhaps the most impactful Medicare reform legislation in decades, the Inflation Reduction Act (IRA) was signed into law August 16 by President Biden. Under this legislation, Medicare will begin the process of price negotiation with pharmaceutical manufacturers for certain high-cost, older brand name drugs that lack a generic or biosimilar. The most costly biologicals in Part B that lack a biosimilar and have been on the market for at least 13 years will be impacted in 2028. In each subsequent year, 20 additional drugs in Part D and Part B will be added to the price negotiation scheme. Biologicals will be subject to a minimum 35 percent ASP reduction. But cuts could be much more significant for certain products, depending on the actual terms of the "negotiation," which is compelled by a potential 95 percent excise tax on manufacturers who refuse to accept the terms and conditions of the "Manufacturer's Fair Price."

Medicare's ASP reimbursement and associated add-on payment will be dramatically reduced for impacted products -- Avalere estimates a 44 percent cut to providers' add-on reimbursement. These Medicare ASP reductions could eventually cascade into the commercial market for impacted products, as most insurance plans tie their reimbursement to ASP.

Over the past year, IPA has been advocating that providers be taken out of the middle of these pricing reforms and rather than cut providers' reimbursement, simply collect a rebate from the manufacturer for the same amount. IPA facilitated dozens of meetings, phone calls and letters with key legislators and their staff on the issue, explaining that our facilities save the Medicare program fifty cents on the dollar compared to the same service at hospitals, and with better outcomes. Patient access to that care should not be threatened by short-sighted policies that undermine the financial ability to service these patients. Virtually all the Democratic offices we spoke with were supportive or neutral on our suggested solution, but the Finance Committee was committed to keeping the bill intact without change.

Barrasso Amendment to Protect Providers

During August Senate floor consideration, IPA worked closely with Senator John Barrasso (R-WY) on a Senate floor amendment that would protect ASP reimbursement to infusion providers, and instead collect a manufacturer rebate for drugs that would be subject to "negotiation." However, after late night redrafting of the amendment with CMS technical staff, the Congressional Budget Office announced that it did not have time to review the amendment in time for floor consideration. All other Republican health amendments were defeated on party line votes. On the House side, Rep. Michael Burgess, MD (R-TX), a senior member of the Energy & Commerce Committee, made similar valiant efforts to offer the same amendment, but hit similar parliamentary roadblocks.

Sen. Barrasso nonetheless is committed to introduce his proposal this Fall as a free-standing bill. We will work with his office to try to secure bipartisan co-sponsors of that bill. While action on such a bill is unlikely this year it could see some movement next year, particularly if the Republicans take back control of the Senate and/or the House after this year's midterm elections in October. We have some time before Part B products are impacted to work with Congress to make this sensible change.

Part B drugs likely to be impacted in 2028 would be Eylea and Prolia and then in subsequent years (in order of costs and lacking a biosimilar) Stelara, Orencia, Ocrevus, Soliris, Cimzia, Entyvio, Xolair, Simponi Aria, Actemra and Tysabri. An important caveat is that this is a broad snapshot of the drugs as of today; the list is likely to change over time subject to numerous factors.

End of Year Health Package

As for prospects for healthcare legislation the rest of the year, the most prominent "must pass" bill will be reauthorization of the FDA's agreements to collect user fees from prescription drug, generic drug, biosimilar, and medical device developers. IPA is working in coordination with the physician and provider community to secure legislation that would block pending cuts to the physician fee schedule effective January 1 due to the expiration of temporary funding provided last year.

IPA Pushes Back on Downcoding

Much has happened since we first reported on this in our July newsletter. At that time, only four Medicare Administrative Contractors (MACs) had imposed "code corrections" of several complex biologicals from the "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration Current Procedural Terminology (CPT) Codes" (CPT 96401-96549) to the less complex "Therapeutic Prophylactic, and Diagnostic Injections and Infusions codes" (CPT 96360-96379). As of June 6 of this year, now all MACs are on board.

In an effort to stave that off, IPA has engaged at multiple fronts, including two separate meetings with top-level CMS staff, an hour-long call with the MAC Correct Coding for Administration of Complex Drugs Workgroup, formal comments to CMS, interviews with reporters and soliciting co-signers of an IPA-led stakeholder letter. Our goal is to use this letter as a means to show that a broad base of providers believes this decision was made on an arbitrary basis inconsistent with the realities of patient care. Moreover, the change in reimbursement methodology under-values the patient care resources needed to provide these complex drug administrations to beneficiaries and may endanger patient care by failing to compensate providers for the many steps that must be taken to ensure these drugs are provided in a safe manner.

Our meetings with CMS were productive and they clearly appreciated our concerns. Likewise, the MACs were cordial and interactive. When asked on what basis the coding correction was made, the MAC representatives said they:

- looked at pharmaceutical package inserts;
- read peer-reviewed literature, but did not disclose what studies or research and acknowledged there is not much out there;
- looked at the CMS self-administered drug list;
- observed hospital-based infusions;
- observed low volume of reactions to monoclonal antibodies;
- concluded that some monoclonal antibodies did not meet criteria for the higher codes (e.g., subcutaneous).

When asked if they had conducted observations from an infusion center or physician office, they said no.

We invited them to visit an IPA facility and observe first-hand all the resources, training, pre-administration and post-administration requirements that justify the higher code. We plan on expanding our engagement with CMS and Congress over the next quarter.

On a separate track, IPA worked with the Coalition of State Rheumatology Organizations (CSRO) to successfully stop MAC downcoding of five rheumatology drugs (Cimzia, Prolia, Orencia, Simponi Aria and Stelara), at least on a temporary basis.

CMS Reverses on Tezspire Exclusion from Part B

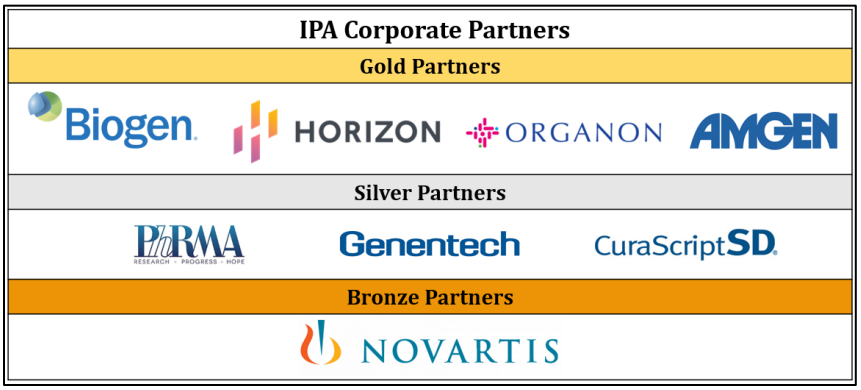
Another manner in which MACs conduct "code correction" on Medicare Part B providers is by determining whether a drug is self-administered more than 50 percent of the time, and thereby not covered under Part B. MACs make this change in the same manner they used in the downcoding initiative mentioned above: through the "Local Coverage Article" system, which does not provide for stakeholder input.

While these "self-administered drug" (SAD) list additions are often routine in nature, in the very recent case of Amgen's asthma drug Teszpire it can be arbitrary and improper. Despite the fact that the FDA-approved label for Teszpire clearly states that it "is intended for administration by a healthcare provider," seven MACs recently announced their intent to move it to the SAD list and deny Part B coverage. The IPA mobilized along with like-minded stakeholders to inform Congressional offices and HHS staff of the significant access problems that would arise, as the drug was not covered by Part D plans. As a result, the MACs reversed their decision. This means Medicare beneficiaries with severe asthma will continue to have access to Tezspire under Part B.

House Republican Healthy Futures Taskforce Adopt IPA Recommendations

The House Republican leadership established the Taskforce last year, comprised of 17 Members of various committees to develop a positive healthcare agenda in the event they re-claim control of the House. Since we last reported on this, the Taskforce has announced two additional reform packages here and here, including several which IPA recommended:

- Ensure patients pay the same lower rate for Medicare Part B medicines (like drugs for cancer care and Rheumatoid Arthritis), whether they're at their doctor's office, a freestanding infusion center or a hospital outpatient department, by capping out-of-pocket liability for Part B drugs administered in the physician office or free standing infusion center at the hospital outpatient cap.
- Provide equal drug administration reimbursement for Part B drugs in the physician office or freestanding infusion center as in the hospital.
- Reform prior authorization and step therapy practices conducted by PBMs and commercial payers.
- Provide certainty surrounding physician and provider reimbursement under the physician fee schedule in Medicare.
- Speed up and improve the FDA Accelerated Drug Approval program (specifically referencing Alzheimer's treatments).



Telehealth Virtual Supervision

The IPA will be submitting comments and data on September 6 supporting a permanent change made under telehealth Public Health Emergency waiver, which allowed virtual supervision. IPA is asking the agency to permanently change the direct supervision definition to include virtual, and we provided specific examples of how this flexibility has enhanced the ability to serve our patients.

The immunocompromised patients that receive infusions are much better off getting their treatment in settings away from hospitals, where they are less likely to contract other diseases. Making virtual direct supervision a permanent feature for Medicare would also recognize our constrained health care workforce challenges, with providers facing shortages across the country. The COVID-19 pandemic has exacerbated the U.S. health care system, and a recent study by Morning Consult found that nearly 1 in 5 health care workers have quit their jobs during the pandemic and 79% of health care professionals said the national worker shortage has affected them and their place of work. Making virtual supervision coverage permanent will continue to address these issues.

Joint Study on Hidden Costs of White-Bagging

Numerous articles have been written about the deleterious impact on patients and providers of "white bagging," wherein drugs are dispensed from a pharmacy and delivered to the provider to prepare and administer to the patient; the pharmacy bills for the drug while the provider bills for drug administration. IPA has discussed this problem with insurers, pointing to among other things the hidden costs of wastage associated with this system.

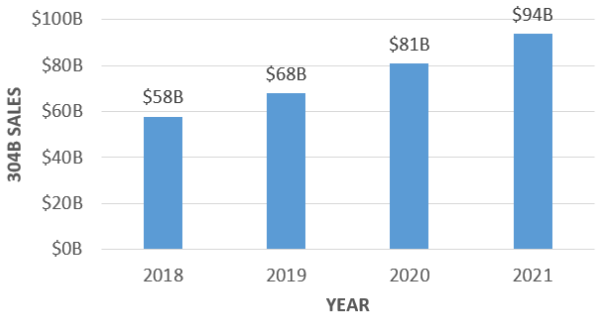
IPA decided to commission a study by Avalere on the issue with the National Infusion Center Association (NICA) and McKesson's US Oncology Network to better understand in a broader sense the fixed and variable costs affecting practice experience with Part B drug administration. A joint agreement was signed and Avalere has initiated a survey that explores the practice economics of buy-and-bill, white bagging, and associated wastage challenges for oncology as well as non-oncology providers. Avalere collaborated with all three organizations to select participants and disseminate the survey. The survey catalogs and quantifies the practice experience with drug administration and white bagging, as well as broader issues affecting community practice economics, such as, but not limited to:

- white bagging wastage estimates across practice (product ordered vs. product administered)
- An assessment of fixed and variable costs for practices related to drug administration
- key metrics of revenue cycle, bad debt, and associated risk

The results of the study will be published in an Avalere-branded 5-page white paper at the end of the year and all three organizations will be recognized as sponsors of the research. The ultimate goal is to defend the buy and bill model against erosion. Our target audiences include federal and state lawmakers and regulators, payers, providers and academicians. This will be particularly useful as state legislators continue to propose legislation next year that limits white bagging practices.

340B Update

A recent report by STAT found that drugs purchased under CMS' 340B Drug Discount Program -- which requires drugmakers to offer discounts that are typically estimated to be 25% to 50% on all outpatient drugs to hospitals that primarily serve lower-income patients --**a**mounted to $44 billion in 2021, a nearly 16% increase from the previous year. In fact, it is now the second-largest Rx drug program in the federal government, according to a June 2022 study by Berkeley Research Group.



Source: IQVIA

IPA has reported in the past how hospitals are financially incentivized by profits generated from the 340B program to consolidate and administer medicines in more expensive hospital outpatient settings. This often results in marked up provider-administered infusions and injections costs, which allow hospitals to receive payments from commercial health plans that are, on average, nearly 2.5 times the amount paid by the hospital to acquire the medicine.

What is more troubling is that there is no clear evidence that consolidation improves the quality of care provided to patients. In fact, evidence has shown that hospital consolidation not only creates higher health care expenditures but causes negative health outcomes.

State Legislative Update

States were active and fairly productive this year in not only getting committees to hold hearings, but actually got several bills passed into law that curb PBM and health insurer activities harmful to the infusion industry. Here is summary of what happened in the states, broken down by issue and outcome:

Issues	State	Outcome
White/Brown Bagging	CA	SB 958 passed senate
	MO	HB 2305 hearing held
	AZ	SB 1161 passed senate
Copay Accumulators	NE	LB 767 signed into law
	ME	LD 1783 signed into law
	WA	SB 5610 signed into law
	NY	S 5299 passed senate
	DE	SB 267 passed senate
PBM Licensure/State Agency Created	NY	S.3762/A.1396 signed into law
		LB 767 signed into law

PBM Spread Pricing & Transparency	MO	SB 737 signed into law
Step Therapy/Non-Medical Switching	CO	HB 1370 signed into law
	FL	HB 459 signed into law
	KY	SB 140 signed into law
	TN	SB 1310 signed into law
	MA	S. 3056 passed senate
Prior Authorization	LA	SB 112 signed into law
	CA	AB 1880 signed into law

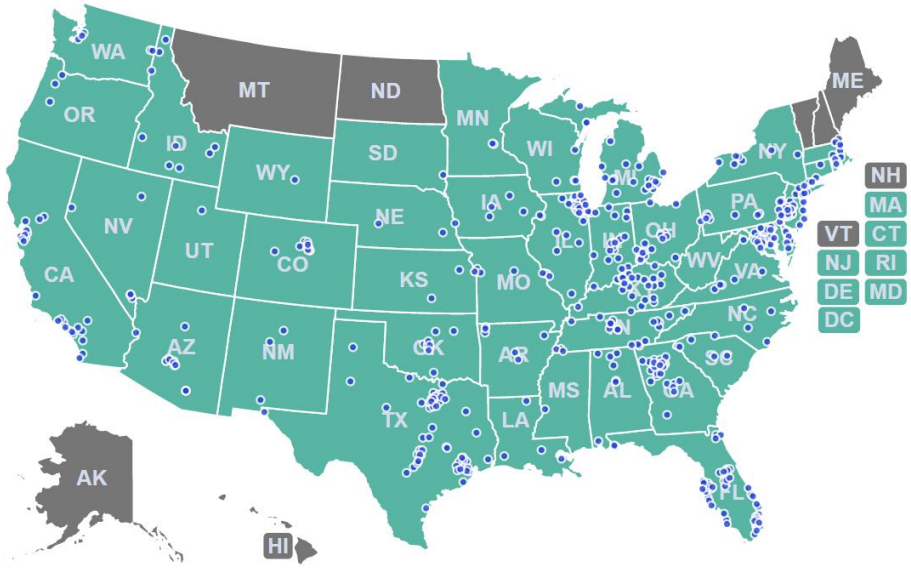
Additions to the IPA family

The newest infusion provider to join the IPA since our last newsletter is American Infusion Centers, with three facilities in Greater New York City. They have been active and engaged from day one and IPA would like to give a shout-out in particular to Dr. Rob Gelfand, MD, whose clinical expertise and business acumen have proved invaluable on several advocacy and research projects.

The most recent IPA Corporate Partner is Amgen, one of the world's leading biotechnology companies. Amgen is focused on six therapeutic areas: inflammation, bone health, neuroscience, nephrology, cardiovascular disease and oncology. Their medicines typically address diseases for which there are limited treatment options, or provide a viable option to what is otherwise available.

Amgen was a vital partner this past quarter as IPA joined others in successfully stopping several Medicare Administrative Contractors (MACs) from adding asthma biologic Tezspire to CMS' self-administered drug exclusion (SAD) list. We look forward to further collaboration in the future.

IPA members provided more than 640,000 infusions to patients at more than 1,000 locations in 43 states nationwide in 2021.



Accomplishments Since Our Last Newsletter

- Facilitated over 40 Congressional Member and staff connections (meetings, letters and emails), including the Senate Finance, House Ways & Means and House Energy & Commerce committees; Senate Majority Leader and House Minority Leader; Senators Kyrsten Sinema (D-AZ) and Joe Manchin (D-WV). WE focused on preserving ASP reimbursement in Medicare and in the commercial market for drugs subject to Secretary negotiation in the Inflation Reduction Act (IRA).
- Meeting with CMS on Medicare Administrative Contractor (MAC) downcoding of complex drug infusions
- Meeting with MAC Workgroup on Correct Coding for Administration of Complex Drugs
- Sent letters to policymakers signed and co-signed by IPA on multiple issues supporting infusion providers, including:
    - IPA statement of opposition to Rx Drug Provisions of the IRA, which was also sent directly to 13 reporters at national and trade publications
    - IPA letter supporting Barrasso amendment, including quotes from an Arizona physician
    - IPA letter-writing campaign supporting Barrasso amendment
    - IPA letter to CMS objecting to MAC downcoding of complex drug infusions
    - IPA letter to CMS objecting to changes in the Medicare ASP Pricing File determining how Aduhelm is reimbursed
    - Stakeholder recommendations to House Republican Healthy Futures Taskforce. Several IPA recommendations were included.
    - Stakeholder letter on narrowing site-of-care payment differentials for drug administration in Medicare
    - Advocating for continued staffing flexibility through telehealth virtual supervision
    - Stakeholder letter opposing CMS' radical limitation to Medicare coverage of Aduhelm
    - 2 stakeholder letters requesting no cuts and predictable payment for physicians under Medicare
    - IPA letter of support for California state legislation restricting white-bagging
- New IPA member (American Infusion Center) and Gold-level Corporate Partner (Amgen)
- Presentation to senior Anthem executives in their pharmacy, medical and market access divisions on value of infusion providers to health plans
- Similar presentation to IngenioRx, Anthem's PBM
- 1:1 meetings held with Aetna, Anthem, Cigna and UnitedHealthGroup
- IPA member surveys responding to Corporate Partner inquiries
- Joined two more formal and informal coalitions
    - Medicare Physician Fee Schedule informal coalition
    - Step Therapy Coalition
- 42 Twitter tweets and LinkedIn discussions from the IPA sites

Biologics currently in or recently out of the FDA Approval Pipeline

While this is certainly not an exhaustive list, here are a few recently approved or coming on the horizon which are administered intravenously or subcutaneously:

Approvals

- **STELARA** Approved by FDA to Treat Pediatric Patients with Active Psoriatic Arthritis
- FDA approves **SKYRIZI** for Crohn's disease| AbbVie
- GSK Announces FDA Approval of **Benlysta** for Pediatric Patients With Active Lupus Nephritis

Pipeline

- Amgen announces positive top-line results from phase 3 study of ABP 959, biosimilar candidate to **Soliris**
- New England Journal of Medicine Publishes Positive Phase 2 Data on Litifilimab (BIIB059) in Cutaneous **Lupus** Erythematosus | Biogen
- Everything you need to know before the next big **Alzheimer's** readout | Biogen/Esaia
- Alnylam heralds PhIII APOLLO-B win on way to creating an 'industry leading **TTR** franchise'
- FDA issues CRL regarding bimekizumab for treatment of moderate to severe **plaque psoriasis** | UCB
- FDA sets goal date to Dec. 28 for BLA for ublituximab as treatment of **multiple sclerosis** | TG Therapeutics
- FDA puts PHIII studies of tolebrutinib in **MS and myasthenia gravis** on partial clinical hold | Sanofi
- **Vyepti** Shows Positive Results in the Treatment of Migraine | Lundbeck
- FDA orders Sanofi to stop treating some patients in PHIII 3 trials with experimental **MS** drug tolebrutinib
- Peresolimab as a monoclonal antibody for treatment of rheumatoid arthritis and other **autoimmune diseases** | Lilly
- Remternetug for the treatment of **Alzheimer's** disease - update| Lilly
- Efficacy and Safety of Brazikumab to treat Moderate to Severe **Crohn's** Disease | AstraZeneca
- Fresenius Kabi announces Acceptance of its Marketing Authorization Application by the European Medicines Agency for MSB11456, an **Actemra** Biosimilar Candidate
- Viridian Announces Positive Initial Clinical Data from Ongoing Phase 1/2 Trial Evaluating VRDN-001 in Patients with **Thyroid Eye Disease**
- Applications for first-of-a-kind **Tysabri** biosimilar natalizumab for treatment of MS accepted by US FDA and EMA | Sandoz
- Alvotech announced positive topline results for AVT04, a proposed biosimilar to **Stelara**
- Alvotech Initiates Patient Study for AVT06, a Proposed Biosimilar for **Eylea**
- Innovent Announces Phase 2 Clinical Study of IBI112 in Chinese Patients with Moderate-to-severe **Plaque Psoriasis** Met Primary Endpoint
- Innovent Announces First Patient Dosed in a PhII Clinical study of IBI112 in Patients with Moderate-to-Severe Active **Ulcerative Colitis**
- Top Boehringer Ingelheim drug gets FDA approval in **rare skin disease GPP**

How Can You Get Involved?

If you are interested in learning more about membership or partnership opportunities with the Infusion Providers Alliance, please contact us through the form on our website.

Additionally, feel free to reach out to Brad Traverse, IPA Executive Director, at brad.traverse@infusionprovidersalliance.org or Doug Ghertner, IPA President, at dghertner@ivxhealth.com.