Member and Partner Newsletter

April 2023

Achieving our 2023 Goals

Last year, the Infusion Providers Alliance board approved several goals for 2023 and the underlying objective was simple: ensure that policy-makers recognize our members as the most efficient, most cost-effective and safest site of care for the delivery of drug infusion services; and maintain competitive reimbursement that recognizes the value of our setting. Specific priorities include:

1. **Protect provider drug reimbursement** under the 2022 Inflation Reduction Act (IRA) for infusion providers, beginning with advocating for a bill to be introduced soon by Senate Finance Committee member John Barrasso (R-WY) to keep infusion providers out of the Medicare drug negotiation process, ensuring proper access for our patients by maintaining adequate reimbursement.

2. **Halt and reverse Medicare Administrative Contractor (MAC) downcoding** and obtain longer term clarity on reimbursement for "complex" drugs.

3. **Improve patient adherence** by reducing patient out-of-pocket obligations through copayment caps and safe harbors to allow direct manufacturer copayment assistance to Medicare beneficiaries.

4. **Actively engage** Congress, the Medicare Payment Advisory Commission (MedPAC) and the Center for Medicare and Medicaid Innovation (CMMI) to ensure proposals regarding add-on payment reform in Medicare buy-and-bill do not adversely impact IPA members.

IPA Hits Capitol Hill

We have been laser-focused this first quarter on meeting these objectives, and they were the driving force behind our Washington, DC fly-in event held March 7-8. Over this two-day period IPA facilitated 31 in-person meetings with the people who make health policy in Congress: senators, congressmen and their healthcare staff. We targeted committees of jurisdiction over Medicare, private insurance and public health (House Ways & Means, House Energy & Commerce, Senate Finance and Senate HELP). We also met with several Democratic and independent senators' offices who might be more-inclined to support our efforts. In addition, we held meetings with four IPA Corporate Partners: Boehringer Ingelheim, Horizon Therapeutics, Novartis and PhRMA.

In those Capitol Hill meetings, five IPA company representatives stressed our industry's role as an important access point for patients with chronic, complex diseases and underscored these policy priorities:

1. Protect infusion providers from being collateral damage in the Medicare drug price negotiation provisions of the IRA. Our primary request was support of legislation that will soon be introduced to maintain ASP+6% reimbursement for "negotiated" drugs, and instead collect a rebate from manufacturers.
2. Ensure future telehealth bills considered by Congress include "virtual supervision" as the CMS waiver providing this flexibility is set to expire at the end of this year.
3. Contact CMS to oppose MAC downcoding of complex drugs.

We are already seeing positive results from those visits. Senators and Representatives have offered to introduce legislation protecting provider reimbursement for "negotiated drugs". We are still working on bipartisan cosponsors and encourage further dialogue with Democratic members in both chambers. Several offices also contacted CMS to object to MAC downcoding and inquire about virtual supervision.

Pictured: IPA members meet with Sen. John Barrasso (R-WY)

Pictured: IPA members on steps of U.S. Capitol

Progress Made on MAC Downcoding

Our advocacy efforts on MAC downcoding are also starting to pay off. Last June, CMS directed MACs to temporarily "pause" the Local Coverage Article (LCA) coding corrections through a Technical Directive Letter (TDL) that halted additional documentation requests when five rheumatology drugs identified by MACs as "therapeutic" were billed with "chemotherapy" codes. CMS then issued a second TDL two months later expanding beyond rheumatology, which "directs that the MACs shall not make claim adjustments or edits to claims for CPT codes 96401-96549 based solely on the specific drug or agent being administered. Claims for these codes … shall be paid as complex administration …."

Since that time, **the MACs appear to have stopped downcoding the drugs** identified in Table 1 below. However, the path that led to this debacle – the LCA process which is designed to allow minor technical adjustments rather than significant, wholesale changes to provider reimbursement – remains shrouded in secrecy and void of any semblance of transparency. The MACs have never provided the justifications or data that led to their "code corrections", which then led to significant reimbursement cuts. The TDLs were never publicized, and the MACs never notified infusion providers that the downcoding was in fact paused. IPA will continue to work with CMS to move toward greater transparency and a nationalized definition of complex drug administration.

Table 1 (Source: First Coast Local Coverage Article effective 7-20-22)

Infusion Non-Chemo Brand Name + J-code	**Disease(s) Treated**
Cinqair J2786	severe asthma
Entyvio J3380	Crohn's disease, ulcerative colitis
Nulojix J0485	kidney transplant rejection
Onpattro J022	hereditary amyloidosis
Orencia J0129	rheumatoid arthritis, juvenile idoepathic arthritis and psoriatic arthritis
Radicava J1301	amyotrophic lateral sclerosis (ALS)
Simponi Aria J1602	rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis
Soliris J1300	paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS) and generalized Mysathenia Gravis (gMG)
Stelara J3358	Crohn's disease, ulcerative colitis, psoriatic arthritis, plaque psoriasis
Tezspire J3590	severe asthma
Tysabri J2356	Crohn's disease, multiple sclerosis
Zinplava J0565	c-diff
Subcutaneous Non-Chemo + J-code	**Disease(s) Treated**
Cimzia 0717	Crohn's disease, rheumatoid arthritis, inflammatory arthritis, ankylosing spondylitis, Psoriatic arthritis and Plaque psoriasis
Fasenra 0517	severe asthma
Ilaris 0638	Periodic Fever Syndrome, Still's Disease
Ilumya 3245	plaque psoriasis
Nucala 2182	severe asthma
Prolia 0897	Osteoporosis
Xolair 2357	severe asthma, chronic hives

Medicare Payment Advisory Commission's (MedPAC) New Understanding of Infusion Providers' Economics

IPA's engagement with several key MedPAC Commissioners resulted in a remarkably different dialogue at their February meeting on ASP add-on reform. The Commission has been eyeing add-on payment reform because they believe a percentage add-on payment for Part B drugs encourages prescribing of more expensive drugs. MedPAC has been advocating capping add-on payments at the lesser of $220, 6 percent, or 3 percent plus $24.

IPA met with Chairman Chernew and other commissioners to underscore the inadequacy of the professional fee for drug administration and therefore the reliance on the add-on payment for infusion facilities and physician practices. We noted that our infusion sites are a major access point for care in hundreds of communities across the country and that we provide care much more efficiently for Medicare than hospitals, with better clinical outcomes and more convenience to its beneficiaries. Continued payment cuts could threaten independent infusion centers and physician practices' viability to provide these products and lead to even more hospital consolidation of services and higher costs to the system.

In a recent public MedPAC meeting Chairman Chernew noted "it is important to get the administration fee part right. I wouldn't hang my hat on the proposed percentage and dollar add-on numbers … It's important to make sure that independent specialist practitioners can survive in a reasonable way with whatever new pricing model comes in place … There's a concern that if we change some of these things related to ASP+, we will induce consolidation of certain specialties into big systems. When you do that there's a whole series of problems that arise such as site neutrality (which he supports) … There's general consensus we are balancing a desire to make sure people can hold the drugs, don't drive consolidation, ensure the administrative prices are right, while addressing what we see as a serious incentive problem associated with the current ASP + 6%…."

Commissioner Stacie Dusetzina stated that "stand-alone infusions and physician offices have payment challenges and are using drugs to subsidize more of their services than other sites of care. They're fairly efficient sites of care delivery and we don't want to penalize efficient and convenient sites of care, but we don't need to subsidize them through the drug payments. I think we can pay them better in different ways."

As IPA President Doug Ghertner recently said, "the conversations we've been having with Commissioner Chernew and other members of MedPAC have had the desired impact:

1) They now recognize our setting of care as being distinct and different from the hospital;
2) They appear to appreciate the insufficiency of the administration fee in its current form and the import of drug margin to make up the economic shortfall; and
3) They are at least signaling that there is a concern that if they don't get this right for our setting of care, it could create access issues, increase specialist consolidation into hospitals and harm a more efficient, lower cost setting of care."

Pharmaceutical Benefit Manager (PBM) Reform

Congress has been very active in healthcare on a number of fronts so far this year, but one issue looks to be gaining momentum: PBM reform. The Senate Commerce Committee passed a bipartisan bill empowering the Federal Trade Commission (FTC) to increase drug-pricing transparency and hold PBMs accountable for unfair and deceptive practices. It would prohibit PBMs from engaging in spread pricing, arbitrarily reducing or clawing back drug reimbursement payments to pharmacies, and unfairly charging pharmacies more to offset federal reimbursement changes. It includes exemptions if PBMs agree to pass 100 percent of rebates and offer complete transparency to health plans payers.

The Senate HELP Committee is scheduled to markup prescription drug bills on April 19, including a provision from the Lowering Health Care Costs Act of 2019 requiring PBMs to pass on rebates and provide transparency to their insurance plan clients. In addition, their appeared to be bipartisan consensus at the Senate Finance hearing on March 30 that PBMs' power needed to be reined in and that more transparency is needed as prices of biosimilars are now also being impacted by PBM contracting.

Senate Majority Leader Schumer has set Memorial Day as a target for prescription drug package floor consideration, which would include PBM reform as well as several drug patent related bills that were reported out of the Judiciary Committee earlier this year.

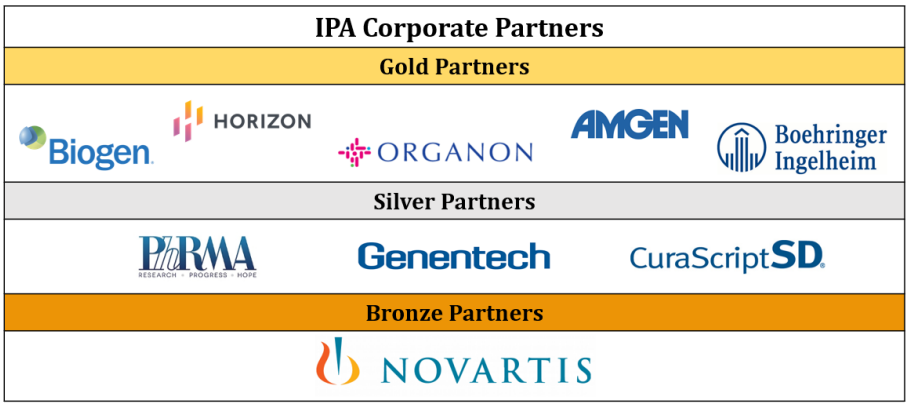
Meetings with Health Plans

Continued engagement with health insurers is another Board-approved strategy currently underway. As background, last March IPA held a teleconference with the trade association representing all commercial payers, AHIP. Representatives from Cigna, Humana, Anthem and others were also in attendance. Our goal was to talk about our value to payers and ways in which we can collaborate, encouraging participation not only from their government affairs staff, but also their site-of-care, clinical, pharmacy or revenue cycle folks to discuss ways infusion providers can work hand-in-hand with them to lower cost and improve patient outcomes. A secondary goal was to create a communications channel for IPA members to engage with plans on process and revenue cycle issues that come up throughout the year. We held subsequent one-on-one calls with Anthem and their specialty pharmacy IngenioRx.

This year we are reaching out to other plans, including two that have already agreed to meet and with whom we are scheduling dates for April: Highmark and Florida Blue. Highmark is the BCBS plan in most of Pennsylvania and all of Delaware and West Virginia. Florida Blue is the BCBS plan in Florida, but is also a subsidiary of Guidewell, which owns two Medicare Administrative Contractors: First Coast and Novitas. We've also reached out to UnitedHealth, Cigna, Humana and HCSC (BCBS plans in IL, TX, OK, NM and MT).

New Members of the IPA Family

We are delighted to welcome Talis Healthcare as our newest IPA member and Boehringer Ingelheim as our newest Corporate Partner. Talis has 34 free-standing AICs in 9 states. Boehringer is a global manufacturer of dozens of life changing treatments including Spevigo, the only FDA approved for treatment of flares in adults with generalized pustular psoriasis (GPP).



State Legislative Activity

IPA continues to closely monitor state legislation that impacts IPA members, primarily health insurer and PBM programs which are not exempt by federal law. As of this writing there have been:

- 3 bills signed into law
- 12 bills approved by one or both state legislative chambers (house/assembly or senate)
- 22 bills approved by a committee or subcommittee
- 14 hearings held (potential committee votes pending)

CALIFORNIA

Co-Pay Accumulators
- AB 874: Referred to Committee on Health

Rebate Pass Through
- SB 873: Hearing scheduled for 4/19

Gold Card
- SB 598: Hearing scheduled for 4/12

COLORADO

Co-Pay Accumulators
- SB 195: introduced 3/16/23

Step Therapy
- HB 1183: Passed both chambers

CONNECTICUT

Step Therapy
- HB 5452: Referred to Joint Committee on Real Estate and Insurance

FLORIDA

Non-medical Switching
- SB 746: Introduced 3/17

White Bagging
- House Bill 203: Referred to Healthcare Regulation subcommittee

GEORGIA

Rebate Pass Through
- HB 343: Approved by House on 3/6
- SB 286: Introduced, read and referred

White Bagging
- HB 417: Passed House committee 3/6/23

ILLINOIS

White Bagging
- SB 1255: Referred to Senate Rules Committee 3/10/23
- HB 2814: Referred to House Rules Committee 3/10/23

INDIANA

Rebate Pass Through
- SB 8: Approved by Senate 42-5 on 2/23; passed House committee 4/11

IOWA

Prior Authorization "Gold Card" Status
- SSB 1100: Passed in subcommittee on 2/8

Non-medical Switching
- SF 86: Passed in subcommittee on 1/26
- HF 96: Passed in committee on 3/9

KENTUCKY

Prior Authorization "Gold Card" Status
- HB 134: Passed committee on 2/23/23

White Bagging
- SB 149: Introduced on 2/15/23
- HB 350: Committee referral 2/23/23

MARYLAND

Step Therapy
- HB 785: Passed both chambers and sent to Governor

MINNESOTA

Rebate Pass Through
- HF 1711: Introduced and referred to Health Policy and Finance committee
- SF 1319: Introduced and referred to Health and human Services committee

White Bagging
- HF 544: Passed House committee on 3/8/23
- SF 482: Passed Senate committee on 3/15/23

MISSOURI

Accumulator adjustment programs
- HB 442: Passed House 117-38 on 3/23/22
- SB 269: introduced.

Non-Medical Switching
- HB 324: introduced

Step Therapy
- SB 268: Introduced

Rebate Pass-Through
- SB 283: introduced.

White Bagging
- SB 26: Passed committee 4/4
- HB198 Passed committee 4/2

MONTANA

Prior Authorization "Gold Card" status
- SB 380: Passed senate committee on 3/1; Passed house committee 18-1 on 4/5

White Bagging
- SB 223: Hearing held but tabled in committee 2/10/23

NEBRASKA

Prior Authorization "Gold Card" status
- LB 210: hearing held 3/13/23

White Bagging
- LB 448: hearing held on 3/21/23

NEW HAMPSHIRE

White Bagging
- HB 513: Subcommittee hearing held 3/15/23

NEVADA

Step Therapy
- SB57: Hearing held on 4/12
- SB167: Hearing held on 4/5
- SB194: Hearing held on 4/12

NEW JERSEY

Step Therapy
- A 2010 and S 308: Introduced

NEW MEXICO

Accumulator adjustment programs
- SB 51: **Signed into law** on 4/7

NORTH DAKOTA

Accumulator adjustment programs

- HB 1413: Passed House 51-40 on 2/20; Passed Senate 25-21 on 3/29

Non-medical Switching & Prior Authorization
- SB 2389: **Signed into law** on 4/4

White Bagging
- SB 2378: **Signed into law** on 4/4

OKLAHOMA

Rebate Pass Through
- HB 2853: Passed House on 3/20; passed senate committee 9-0 on 4/4
- SB 879: Passed Senate committee 10-0 on 2/14

Prior Authorization
- HB 1610 introduced

White Bagging
- SB 13: passed in committee

OREGON

Accumulator Adjustment Programs
- SB 565: Hearing held 3/8

White Bagging
- HB 2715: Hearings held 1/24 & 1/25

RHODE ISLAND

Rebate Pass Through
- S 106: Hearing held 4/4

White Bagging
- H 5680: hearing held 3/20

SOUTH CAROLINA
Accumulator Adjustment Programs
- HB 3537 and HB 3618: Referred to committees 1/10

TEXAS

Rebate Pass Through
- HB 2180: Passed committee 6-1 on 3/30

Non-medical Switching
- HB 826: Referred to Insurance committee

Accumulator adjustment programs
- HB 999: Passed subcommittee 7-0 on 3/30

White-bagging
- HB 1647: Passed house committee 9-0 on 4/4
- SB 1138 introduced

UTAH

Accumulators
- SB 184: Approved by the Senate 2/15/23, Approved by House committee 2/28

VERMONT

Rebate Pass Through
- H233: Introduced and referred to Health Care committee

VIRGINIA

Rebate Pass Through
- HB 1782: Left in Committee on Commerce and Energy
- SB 1425: Left in committee on Commerce and Labor

WASHINGTON STATE

White Bagging
- SB 5213: Passed by two committees 2/17 and 2/23
- HB 1253: Referred to Health and Wellness committee

WISCONSIN
COPAY ACCUMULATORS
- SB 100: Introduced 3/1

Stories & Studies

Here is the latest installment of recent updates impacting infusion providers and their patients.

Policy Stories

Sanders, Cassidy game out Senate HELP Committee **drug pricing package** - POLITICO

Physician groups have been pressing Congress to step in and change the **Medicare payment structure**. A new bipartisan House bill aims to do that by tying physician payment rates to inflation**.**

Inflation caused a sizable **drop in net drug prices** in late 2022, analysis finds

FDA issues draft guidance aimed at curbing **manufacturing shortages** - endpts.com

CMS has proposed a **3% boost to hospital payments**

Why Congress should prioritize fixing the **340B program** - PhRMA

Studies and Approvals

The FDA will hold an advisory committee meeting on June 9 to consider the bid by Eisai and Biogen to convert accelerated **approval of their Alzheimer's disease therapy Leqembi** into a full approval – Pharmaphorum

Early data for Lilly's next-gen **Alzheimer's drug** shows 'rapid and robust' amyloid reduction, but a familiar adverse event.

Risankizumab (Skyrizi) Meets Primary Endpoint of Clinical Remission for Moderate to Severe Ulcerative Colitis (pharmacytimes.com)

Horizon touts PhIV win for **Tepezza**

Single Infusion of **Rituximab** Associated with Glucocorticoid-Free Remission in Polymyalgia Rheumatica - Rheumatology Advisor

Cyclophosphamide Plus **Rituximab** May Lower ANCA-Associated Vasculitis Relapse Risk

AbbVie's Upadacitinib Meets Primary Endpoint for Systemic **Lupus** Erythematosus

Breakthroughs in Paroxysmal Nocturnal Hemoglobinuria (**PNH**) Treatment | myCME Webinar

Real-World Evidence **Comparing Entyvio and Stelara** in Antitumor Necrosis Factor-Experienced Patients with Crohn's Disease

Data Support the Use of Ravulizumab (**Ultomiris**) in Myasthenia Gravis Treatment

Psoriasis Progression to Inflammatory Arthritis **Reduced with Biologics**

Orphan drugs are the fastest-growing segment of the pharmaceutical market, but the Inflation Reduction Act (IRA) clouds the future of new treatments for rare diseases, says a report released last month by Evaluate.

Trends in Biologics Use Assessed Among Patients with **Psoriatic Arthritis**

FDA & Lupus Community Launch Novel Public-Private Partnership - Lupus Research

Payer stories

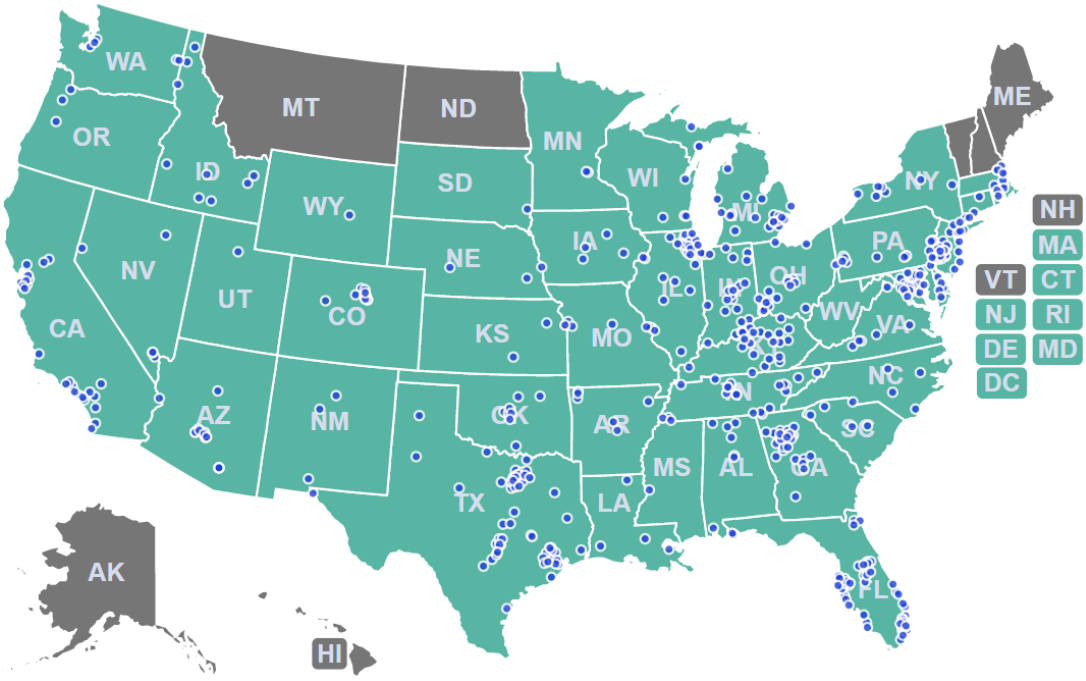
UnitedHealthcare cuts back **prior authorization** requirements | Healthcare Dive

UnitedHealth's physician practice buying spree continues

1 in 3 doctors has seen **prior auth** lead to serious adverse event - AMA

PBMs face mounting pressure from federal government and states-Market Watch

IPA Member Locations



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.