Member and Partner Newsletter
March, 2022

Legislative Update

Rx Price Cuts Still in Cross-Hairs
After House passage of the Build Back Better legislation, which would subject many older Part B drugs to price controls and dramatically lower ASP reimbursement in Medicare and the private market, legislative progress stalled in the Senate. Senator Joe Manchin (D-WV) stands as the primary obstacle to the bill, arguing that it is too broad in scope and extensive spending is inflationary. For the bill to pass the Senate, all 50 Democrats must support it.

Democrats are now plotting a scaled back version of the bill that can gain Senator Manchin's support, but plan to retain the Rx provisions because they poll well, provide a "pay-for," and help build a desired narrative that the bill will combat inflation and rising prices. President Biden focused on drug pricing in his State of the Union speech and the Senate Finance Committee is holding drug pricing hearings this month to revive interest in the bill. The bill must be voted on before the end of the fiscal year (September 30), because the budget resolution enabling a simple majority vote rather than 60 votes for most legislation expires at that time.

IPA's Focus: Preserve ASP
IPA's efforts remain focused on maintaining ASP reimbursement for Part B drugs subject to Secretary negotiation. We have lobbied Senate Finance Democrats for an alternate solution that preserves ASP in Medicare and the commercial market but produces the same savings to Medicare. Rather than cutting ASP reimbursement, and the associated 6% add-on payment, Medicare would collect a rebate from pharmaceutical manufacturers for the same amount. This solution would also prevent a downward spiral of reimbursement to infusion providers in the commercial sector, which is tied to ASP.

The question then remains, if drug pricing reforms are not passed by Congress before the summer, would certain discrete provisions from the bill be included in another must-pass, end of year legislative vehicle? Or, will CMS propose Medicare Part B pricing reforms in demonstration programs through its Centers for Medicare and Medicaid Innovations (CMMI)? In addition, the Medicare Payment Advisory Commission continues to present drug pricing reform proposals to Congress. Stay tuned, and be assured that IPA will be monitoring all of these developments closely and proving real-time updates and in-depth analyses throughout the year.

COVID Relief Funds Stripped from Omnibus
Meanwhile, the House had initially included $15 billion in COVID-19 relief funds, to be used for oral antiviral treatments, monoclonal antibodies and pre-exposure prophylaxis, testing initiatives and vaccine efforts. But then at the last minute, that funding was removed due to Member objections on the offsets of rescinding unspent COVID relief dollars provided to state and local governments. The Omnibus did include a provision of importance to staffing flexibility in our freestanding infusion centers through virtual supervision: an extension of telehealth 151 days beyond the end of the Public Health Emergency. In addition, the SCOTUS nomination, Ukraine, China competition legislation and other issues will consume Congress into Q3.

New Corporate Partners

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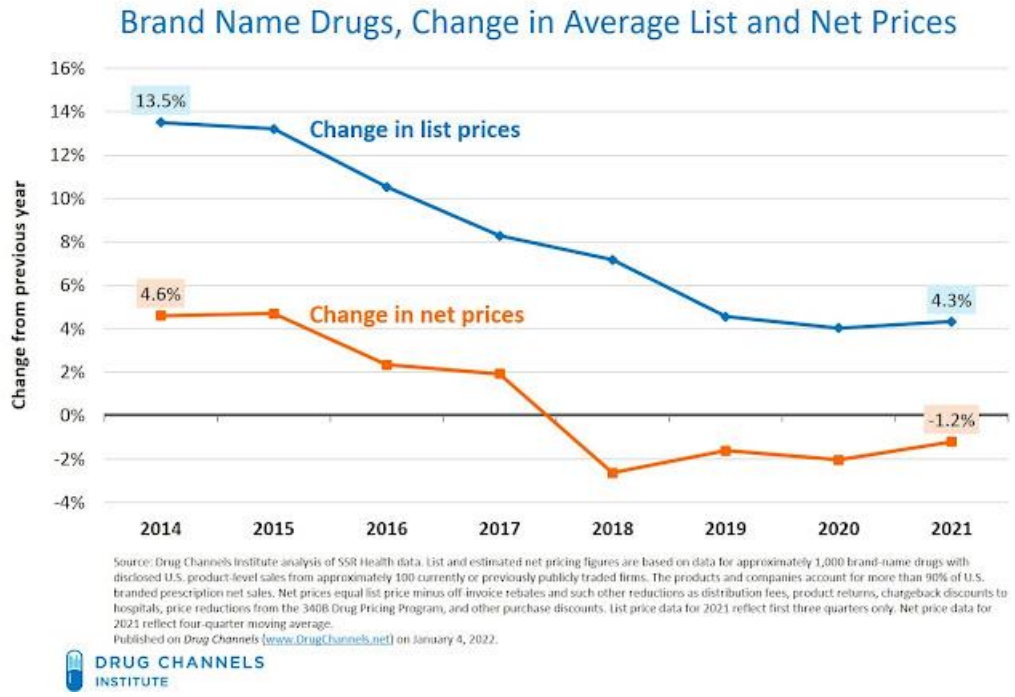
Accomplishments Since Our Last Newsletter

- 13 Congressional staff meetings, including all Senate Finance Committee Democrats, Senate Majority Leader Schumer (D-NY) and Senators Kyrsten Sinema (D-AZ) and Joe Manchin (D-WV); focused on preserving ASP reimbursement in Medicare and in the commercial market for drugs subject to Secretary "negotiation."
- 7 letters to policymakers signed and co-signed by IPA on multiple issues supporting infusion providers, including:
  - Objecting to MAC downcoding of complex drug infusions
  - Narrowing site-of-care payment differentials for drug administration in Medicare
  - Advocating for continued staffing flexibility through telehealth virtual supervision
  - Objecting to CMS' radical limitation to Medicare coverage of Aduhelm
  - Requesting a safe harbor from the HHS Office of Inspector General for pharmaceutical co-pay assistance for infused drugs
  - Requesting predictable payment updates for providers paid on the Medicare physician fee schedule.
- 4 notices posted on IPA website and social media announcing:
  - IPA comments to two subcommittees of the House GOP Healthy Futures Task Force
  - Initial objections to CMS on Aduhelm coverage rule
  - Formal comments to CMS on Aduhelm rule
  - Opposition to Part B drug pricing provisions of the Build Back Better (BBB) legislation
- 2 new Corporate Partners: Organon and Novartis.
- Meeting with CMS senior staff to explain our clinical reasons the MAC downcoding of certain complex Part B drugs is inappropriate and harmful to patients.
- Meeting with policy and market access leadership of the Association of Health Insurance Plans (AHIP) and several of their member companies re: savings IPA members can deliver to health plans.
- 1:1 meetings held with 8 health insurance company representatives.
- 4 IPA member surveys responding to Corporate Partner inquiries.
- Joined six formal and informal coalitions with IPA recognition on websites:
  - the Alliance for Site Neutral Payment Reform
  - the Part B Access for Seniors and Physicians Coalition
  - the Alzheimer's Disease Policy Task Force
  - the Medicare Payment Coalition
  - an ad hoc group of 19 provider organizations opposing Rx pricing provisions of BBB
  - an ad hoc group requesting a Medicare safe harbor related to patient cost-sharing assistance
- Creation of toolkit on IPA website to facilitate letters to Members of Congress opposing the drug pricing provisions of the BBB and supporting a legislative fix.

Drug Prices Continued to Decline in 2021 for Fourth Consecutive Year



MAC Downcoding

On February 9, IPA's leadership met with senior CMS staff to discuss recent, unwarranted, and arbitrary downcoding of certain complex Part B drugs by regional Medicare Administrative Contractors (MACs). IPA had met with the MACs last year but received a perfunctory and dismissive response. This meeting was meant to spur oversight over the MACs' unfounded decisions to inappropriately assign drugs that require substantial administrative resources from a "complex" designation to a lower-paid "simple" designation.

IPA argued that it was inappropriate to downcode drugs with REMs, monoclonal antibodies regardless of whether they were prescribed for cancer, drugs that require additional staff time for pre-administration or complexity and drugs with Black Box warnings. CMS staff was very receptive to our arguments and asked engaging questions. They responded positively to IPA's argument that IPA members save Medicare 50 cents on the dollar for drug administration but do not have the financial ability to cost-shift like hospitals for downcoded drugs, which may hinder patient access. CMS is currently conferring with the MACs about the downcoding decisions.

IPA Responds to Medicare's Restricted Coverage of Aduhelm

IPA submitted formal comments last month to CMS regarding its proposed rule to limit coverage of FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (e.g., Aduhelm and other treatments in the pipeline) under Coverage with Evidence Development (CED) in CMS-approved randomized controlled clinical trials. IPA is deeply concerned that limitation of coverage only to clinical trials under CED and only in certain hospitals, and no infusion centers, will dramatically limit coverage of the only FDA-approved therapy for Alzheimer's. Our letter strongly opposed the CED methodology and its downstream impact of current and future AD treatment research and development and should not freeze out infusion centers as a treatment site. Moreover, the lack of adequate coverage in rural areas and the capacity limitations to accommodate urban and minority patients in need of treatment has the potential to meaningfully impact beneficiaries' ability to access appropriate care.

IPA also joined the Alzheimer's Disease Policy Task Force and cosigned a 24-page comment letter addressing these and other issues. We remain actively engaged with the Task Force, providing input, participating in weekly calls, and planning meetings for future advocacy activities, including a March 25 rally in front of HHS headquarters in DC.

Public Health Emergency (PHE) / Telehealth Virtual Supervision

Telehealth waivers have enabled many IPA members to achieve greater staffing flexibility through virtual supervision of infusion sites by nurse practitioners. With workforce shortages persisting even as the country recovers from the pandemic, this staffing flexibility remains important. The telehealth waiver is tied to the duration of the Public Health Emergency (PHE), which currently lasts until the end of April. The PHE has been extended on 90-day increments and HHS has committed to give states at least 60 days of notice before ending the declaration. We were disappointed that the Omnibus only provides a 151-day extension of telehealth coverage after the PHE ends, and we will continue to work with Congress for a more permanent solution.

IPA delivered multiple letters to Senate and House champions of legislation to extend telehealth reimbursement beyond the PHE, asking that the virtual supervision aspect of telehealth approved by CMS be recognized for its importance to vulnerable Medicare beneficiaries.

House Republican Healthy Futures Taskforce

The House Republican leadership established a Healthy Futures Taskforce comprised of 17 Members of various committees to develop a positive healthcare agenda in the increasingly likely event they re-claim control of the House. This will be an ongoing project, with issuance of white papers this summer and bullet points for Members to use in townhall meetings, issue papers, speeches, and other public outreach formats.

The Taskforce subcommittees addressing affordability and treatments sought input from stakeholders; consequently, IPA provided comments. We joined several allied provider groups in comments to the Affordability Subcommittee making recommendations on narrowing site-of-care costs differentials, deterring vertical integration of physician practices, improving competition between outpatient providers and large hospital systems, and reducing patient out-of-pocket exposure in the physician office or ambulatory infusion setting for Part B drugs.

IPA also delivered its own recommendations to the Treatments Subcommittee to make changes to the Medicare program that would 1) create a safe harbor from the anti-kickback statute to permit manufacturers of Part B drugs to provide cost-sharing assistance to Medicare patients; and 2) provide a statutory cap for Medicare Part B drugs equal to the hospital inpatient deductible ($1,484).

We anticipate heightened activity by the Taskforce that could include stakeholder meetings either in a group or 1:1, and IPA will remain heavily engaged as these ideas are translated into legislation.

IPA Meets with the Health Insurance Industry

On Feb. 25th, IPA met with key staff from AHIP (the trade association representing health insurers) as well as several companies including Aetna, Anthem, Cigna and Humana. We had four goals in mind:

1. Introduce clinical and public policy health insurance representatives to the infusion industry generally, and IPA member executives specifically;
2. Tout the financial and clinical benefits of infusion providers to insurers and their policyholders;
3. Explore ways IPA and AHIP can collaborate on common goals; and
4. Secure subsequent meetings with the market access and clinical decision-makers at insurance company HQs. Anthem and Humana have already expressed in interest in a follow-up meeting.

The call began with an in-depth review of multiple studies from independent, renowned academic institutions confirming the cost and clinical benefits of IPA infusion treatments as a site of service compared to hospitals and, in some cases, in-home treatments. An IPA member clarified that infusion centers are much less expensive v. hospitals; compared to home our costs are often lower when "total costs" are calculated (e.g., adverse events like hospital and emergency-department admissions, non-adherence, fewer follow-up appointments with their physicians), while maintaining better clinical outcomes. We asked that insurers consider IPA facilities as a "near-home" alternative, particularly in the treatment of serious, complex conditions.

In terms of common goals, AHIP recognized the 50%+ savings compared to hospitals and saw room for policy and advocacy collaboration on site-of care differentials and hospital acquisitions of physician practices.

We also discussed several health plan policies that are particularly challenging to the AIC setting of care, with a rather lengthy discussion surrounding "white bagging." An IPA member said that the administration fee alone is simply not sufficient to cover our costs, and also that many infused biologics are weight-based so any change in dosage means we need to get a new supply. Patient stockpiling is another outcome, leading to non-adherence, expired dosages and wastage. We stressed that IPA facilities are better clinically than a specialty pharmacy, with higher quality, adherence and compliance.

An AHIP representative asked if this has led to a circumstance when an IPA member is simply not able to take patients because of the financial risk. We confirmed that many IPA members have said they are increasingly not able to take these patients, leading to a vicious cycle of having to refer patients to a hospital, so the cost to the plan goes up. The AHIP staffer emphasized that white-bagging and similar practices are "client-driven" to control costs but seemed amenable to making accommodations.

We concluded by offering to schedule similar calls with corporate market access and clinical staff of individual AHIP member companies, and also mentioned that Anthem has already requested one in mid-March.

PBM Oversight

The Federal Trade Commission is requesting public input on how insurer acquisitions of PBMs are affecting drug affordability and access. The Request for Information covers a wide range of issues in the PBM market, including contract terms, rebates, fees, pricing policies, steering methods, conflicts of interest, and consolidation. The agency seeks information on these practices and their impact on patients, physicians, employers, independent and chain pharmacies, and other businesses across the distribution system. IPA member companies are encouraged to provide comments prior to the April 25 deadline and will be submitting comments for the industry.

House Ways & Means Committee Changes

- **Rep. Vern Buchanan (R-FL)**, new Ranking Member of Health Subcommittee (6 IPA facilities)
- **Rep. Greg Murphy, M.D. (R-NC)**, a practicing urologist in an independent practice, (1 IPA facility), replaced Devin Nunes (R-CA) who left Congress last year

IPA Corporate Partners

Gold Partners

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Silver Partners

PhRMA · Genentech · CuraScript SD

Bronze Partners

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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.

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