

# NICA ACCOMPLISHMENTS

NICA is frequently involved in both state and national advocacy efforts regarding reimbursement, patient access, and regulatory barriers for office-based Infusion Centers. We focus our resources on objectives where we have specific expertise and can quickly influence change to achieve all-win solutions. However, we do not hesitate to address complex, large-scale issues on both a state and federal level that require tenacious effort. The recent accomplishments outlined below are evidence of the successful execution of our mission and focus.

## 2018 EXPANSION OF ADVISORY COMMITTEE

We expanded our Advisory Committee, and it is now comprised of the biggest players, thought leaders and subject matter experts in the in-office infusion space. Including eight organizations that represent over 300 in-office infusion facilities across the country, this advisory body continues to meet quarterly in the interest of preserving and expanding patients' access to the delivery channel.

### NEW HAMPSHIRE USP 797 ISSUE

After receiving letters regarding mandatory United States Pharmacopeia (USP) Chapter <797> compliance from New Hampshire's Board of Pharmacy, infusion providers across the state contacted NICA to help address this immediate threat to patient access. NICA worked with other concerned stakeholders to draft New Hampshire Senate Bill 581 (NH SB 581), which amends the definition of compounding to preclude the preparation of a single dose of a non-hazardous, commercially available drug or licensed biologic for administration to an individual patient prepared in accordance with the manufacturer's approved labeling. On June 12, 2018, the bill was signed into law by Governor Chris Sununu.

### EXECUTIVE DIRECTOR SPEAKS AT A NATIONAL LEVEL

Brian Nyquist was a panelist at the National Leadership Summit on 340B, a Senate briefing on The 340B Drug Discount Program. Nyquist also met with leadership of the U.S. Department of Health and Human Services (HHS) regarding 340B reform.

### EXECUTIVE DIRECTOR ATTENDS PRESIDENTIAL BRIEFING

Brian Nyquist attended President Trump's drug pricing reform briefing in the White House Rose Garden in May. NICA was the only non-oncology nonprofit organization in attendance.

### EXECUTIVE DIRECTOR SPEAKS AT MCKESSON'S INAUGURAL ONMARK RHEUMATOLOGY SUMMIT

In a joint presentation with Texas Representative Pete Sessions, Brian Nyquist spoke to a room of professionals who administer IV and/or injectable medications in their offices about the importance of advocacy, engaging patients, and fighting for access to care.

### NICA SPEARHEADS TEXAS NON-MEDICAL SWITCHING COALITION

NICA and the Texas Chapter of the National Alliance on Mental Illness (NAMI) are spearheading the Coalition for Stable Patients in Texas in order to improve statutory protections for patients against non-medical switching. To begin this process, NICA and coalition partners launched a survey in July to collect data on the impact of non-medical switching on Texas patients.

### COMMENTS TO CMS ON THE AMERICAN PATIENTS FIRST BLUEPRINT

On July 16, NICA submitted formal comments to Secretary Alex Azar of the U.S. Department of Health and Human Services (HHS) in response to the agency's request for information on the American Patients First blueprint to lower drug prices.

### LAUNCH OF MEMBER RESOURCES CENTER

To better serve our growing number of Provider Members, NICA created and launched its Member Resource Center in July to help infusion providers better connect with and care for their patients. Resources for purchase include sponsored Infusion Center Locator listings, at-stage Biologic & Biosimilars Pipeline Reports, current IV/injectable drug list, and Infusion Center Locator reports.

## THE FIRST IN-OFFICE INFUSION CONFERENCE IS ANNOUNCED

NICA will host its first conference June 21-22, 2019 at the JW Marriott in downtown Austin, Texas. The purpose is to bring together infusion providers and their staff as well as industry professionals and thought leaders to discuss issues that are crucial to the advancement and preservation of the industry, as well as those that affect patient access.

## “SHARE YOUR CHAIR” AWARENESS CAMPAIGN LAUNCHED

“Share Your Chair” is a social campaign to build awareness for the in-office infusion delivery channel. Patients are encouraged to get a picture of themselves receiving their infusion, post it on a social media channel and, using the hashtag #ShareYourChair, share how important access to care is for them.

## COALITION PRESENCE EXPANDS

NICA's Education & Policy Coordinator expanded its coalition presence to participate, along with other national nonprofit organizations, in more than 15 state and national coalitions aimed at improving patient access by promoting legislation that improves statutory protections for patients and increase access to care.

## 2017 LOCATOR RELAUNCH

NICA kicked off 2017 with the relaunch of its new and improved Infusion Center Locator. With a new look, improved searchability features, and the option for an office to build a much more robust and detailed profile, the Locator became the largest, most sophisticated list of outpatient infusion facilities that is publicly available. It spans all 50 states, the District of Columbia, and Puerto Rico. The Locator continues to connect patients with the infusion delivery channel by helping them identify the most accessible site of care in their community to receive their medications.

## EXPANDED EDUCATIONAL RESOURCES

In a continuing effort to address deficits in education relating to infusions delivered in the office setting, as well as to assist in expanding the available education related to in-office infusions, NICA created and launched new educational modules including Biologics 101, How to Purchase Insurance in the Marketplace, How to Prepare for Your Infusion, Health Insurance Glossary, and What to Expect from MACRA/MIPS in 2018.

## STRATEGIC PARTNERSHIPS EXPAND

NICA continued to build a robust portfolio of Strategic Partnerships to improve the capacity of the infusion delivery channel. By partnering with organizations that offer goods and services within the infusion market, NICA procured discounted access to these goods and services for NICA Provider Members.

## PROVIDER MEMBERSHIP RESTRUCTURED

In an effort to be more cost effective for every office providing IV/injectable medications to their patients, NICA ended the year with the restructure of its Provider Membership. The membership includes many of the same benefits as outlined in the previous structure, all for a lesser price.

## 2016 LAUNCH OF INFUSION CONFUSION FORUM COMMUNITY

In order to further unite the office-based infusion delivery channel, we created an online forum community for infusion providers. The Infusion Confusion community allows infusion professionals to ask questions, discuss advocacy and clinical concerns, share resources and advice, and ultimately to come together to better understand and support patients.

## COMMENTS TO U.S. PHARMACOPEIAL CONVENTION RE: MEDICARE MODEL GUIDELINES

NICA submitted comments to U.S. Pharmacopeia (USP) regarding the updated Medicare Model Guidelines (USP MMG v7.0) to voice our concerns over aspects of the guidelines that may restrict patient access to care.

## COMMENTS TO PALMETTO GBA RE: DOWN-CODING ADMINISTRATION CODES FOR BIOLOGICS

NICA submitted comments to Palmetto GBA, a Medicare Administrative Contractor (MAC), to express our concerns with their decision to down-code the administrative coding for biologics from complex to simple.

## **LAUNCH OF NATION-WIDE INFUSION CENTER LOCATOR**

We launched our nation-wide, interactive Infusion Center Locator in September 2016. This tool is available through the NICA website and allows offices around the country to better connect with patients seeking infusion services in their area. Office staff are able to list a variety of features which make their centers unique. Patients can dynamically search based on specific needs and can contact office staff or get gps-based directions directly through the locator.

## **PROVIDER MEMBERSHIP CAMPAIGN**

The launch of the third tier of our membership campaign allows providers to more directly connect with our team and support our vision for complete patient access to infusible and injectable medications. Members have access to a number of high value benefits, including member-only resources and enhanced listings in our Infusion Center Locator.

## **OFFICIAL COMMENTS ON MEDICARE PROVISIONS OF THE MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT OF 2015 (MACRA)**

When we learned of the pending provisions to MACRA, our team was concerned that the performance measures being used to define quality, value, and patient-centeredness, might unduly penalize infusion patients and providers. Our official comments to CMS urged them to consider the uniqueness of this particular patient body and to contextualize and adjust expectations, so that care in out-patient settings remains a viable option for chronically ill patients

## **INDUSTRY ADVISORY COMMITTEE MEETING**

NICA formed the Infusion Center Advisory Committee, comprised of leaders and innovators in the infusion industry, with the purpose of creating a mechanism by which the industry can begin to take a more proactive approach to increasing patient access. As professionals in the field, members of the committee provide the NICA with feedback concerning patient and provider needs for education, resources, standards and advocacy. The first official committee meeting was held in Austin, Texas on July 26, 2016.

## **NICA LETTERS AND TESTIMONY BEFORE TEXAS MEDICAID RATE COMMITTEE**

NICA personally testified at the 2016 rate committee hearing on behalf of providers in Texas. In addition, NICA wrote letters to the Texas Medicaid Rate Committee expressing concern with methodologies used to determine Medicaid reimbursement rates and the financial unsustainability of these rates for many office-administered therapies.

## **OP-ED PUBLISHED NATIONALLY**

NICA Executive Director Brian Nyquist wrote an opinion editorial regarding the Part B Payment Demo which has now been syndicated by over 30 media outlets nationally. The article addresses our many concerns and explains the potentially harmful effects this demo could have on patients with chronic illness, specifically those managing rheumatoid arthritis with office-administered biologics. The article sheds light on the great difficulties that patients and providers will face if the experiment proceeds as written, concluding that eventually most Medicare patients will be shifted to hospitals as primary site of care for infusions and injections.

## **NICA MEETING WITH CMS LEADERSHIP**

As a result of advocacy efforts on behalf of stakeholders across the nation, NICA was able to secure a meeting with key members of CMS leadership to discuss the Part B Payment Demonstration and its potentially catastrophic affects on infusion providers and patients. The NICA team presented concerns and a list of questions coupled with compelling data from an infusion provider based in Texas in order to convince CMS decision-makers to reconsider the ill-conceived proposal.

## **MEDICARE PART B ADVOCACY PORTAL**

In response to the proposed Medicare Part B payment demonstration, we launched our first ever online grassroots advocacy campaign. We built an advocacy portal through which patients, providers and concerned citizens could easily voice concerns to their elected representatives by sending emails, tweets and even calling at the district office. Through our portal, members of advocacy organizations, providers and health care organizations could also sign on to the coalition letter NICA sent to CMS administration, submit official comments to CMS administration or download educational handouts. In just a short time we saw an overwhelming response. Since launching the campaign, more than 40,000 letters have been sent through our advocacy portal. We have also seen an enormous increase in activity on our social media networks, with many stakeholders responding to the portal and sharing updates, opinions and concerns regarding the proposed demonstration.

## **NICA PROVIDER COALITION LETTER TO CMS**

We formed a coalition comprised of almost 200 infusion providers across the country and drafted a letter in opposition of the proposed payment demonstration to CMS Administration. We secured a meeting with CMS Administration on behalf of our coalition on May 12, 2016

## **LETTERS TO CMS, CMMI + MEMBERS OF SENATE COMMITTEE ON FINANCE, HOUSE COMMITTEE ON WAYS & MEANS, AND HOUSE COMMITTEE ON ENERGY AND COMMERCE**

Following the March 8, 2016 CMS News Brief outlining the proposed Medicare Part B payment demonstration, we drafted a letter to CMS and CMMI Administration expressing our (overwhelming) concern and requesting withdrawal of the proposal. Our letter focused on the non-hospital, non-Oncology office-based Infusion Center delivery channel and the significant population of non-cancer patients that would be impacted. This letter was also distributed to the Committee Chairmen and Ranking Members of the Senate Committee on Finance., House Committee on Ways & Means, and House Committee on Energy & Commerce. Through our efforts, we were involved in closed-door meetings with committee staff and the industry's leading advocacy/lobby groups.

## **AETNA RITUXIN DOSAGE DENIALS**

We sent a letter to Aetna regarding Rituxan dosage denials many providers were encountering across the nation. We quickly began communications with the individuals who oversaw the claim edit system to identify the issue and develop a solution to ensure Rituxan was appropriately covered per FDA dosage guidelines. Although the situation has been resolved, and many providers are now receiving the appropriate coverage, we continue to work with Aetna and providers to ensure appropriate processing of all affected claims. Through these engagements, we discovered additional coverage issues affecting Orencia and Simponi Aria. We are working with Aetna to identify and correct the underlying causes.

# 2015

## **CAMPAIGN IN OPPOSITION OF STEP THERAPY FOR BIOLOGICS**

We sent several letters to prominent private health plans across the nation regarding their Step Therapy policies. We were involved in numerous conversations with BlueCross BlueShield of Michigan regarding their Step Therapy policies for biologics and the exemption processes they had in place for providers to circumvent these requirements through the Prior Authorization phase.

## **NICA LETTERS AND TESTIMONY BEFORE TEXAS MEDICAID RATE COMMITTEE**

NICA personally testified at the rate committee hearing on behalf of in Texas. In addition, NICA wrote letters to the Texas Medicaid Rate Committee expressing concern with methodologies used to determine Medicaid reimbursement rates and the financial unsustainability of these rates for many office-administered therapies. As a result of continued advocacy efforts by NICA, several of our provider partners and other coalition groups, the Medicaid rates were adjusted and released on October 22, 2015. Final reimbursement rates for 9 of 10 medications we brought to their attention were increased up to 33% over the proposed reimbursement rates, effective November 1, 2015.

## **NICA CAMPAIGN IN OPPOSITION OF STEP THERAPY FOR BIOLOGICS**

NICA launched a campaign against Step Therapy policy where health plans interfere with the patient-physician relationship to determine the correct course of therapy. As a result, these policies significantly impact access to intravenous and injectable medications. NICA sent letters and emails to BlueCross BlueShield of Michigan, Regence BlueShield, and Health Alliance Plan of Michigan regarding their Step Therapy requirements, taking a stance in support of preserving the physician-patient collaborative approach to determining the most appropriate treatment. We are awaiting responses and opportunities to discuss the impact of these policies.

## **LETTERS TO PAYERS RE: SPECIALTY PHARMACY MANDATES**

NICA joined with industry partners on a campaign against Specialty Pharmacy mandates implemented by BCBS of MA to move specialty drugs, like Remicade, from the medical to pharmacy benefit. We are still working with affected partners to address and resolve this issue.

# 2014

## AETNA CLAIM EDITS ADDRESSED FOR WEIGHT-BASED UNIT LIMITS

A public and private campaign by NICA was created to target Aetna claim edits that limited the number of weight-based units allowed without regard for the FDA approved weight-based dosing. Aetna reviewed their claim edits and responded by increasing the upper limits, effectively eliminating this issue affecting providers and patients.

## NICA FORMS ADVOCACY COALITION TO ADDRESS PAYER CLAIM EDITS LIMITING WEIGHT-BASED UNITS

The Coalition includes the National Psoriasis Foundation (NPF), Alliance for Patient Access (AfPA), and the National Organization of Rheumatology Managers (NORM). Coalition letters and campaign efforts proved successful in addressing claim edits that are hurting patient access.

## HUMANA CLAIM EDITS ADDRESSED FOR WEIGHT-BASED UNIT LIMITS

A public and private campaign by NICA was created to target Humana claim edits that limited the number of Remicade units allowed without regard for the FDA approved weight-based dosing. Humana responded by increasing the upper limits, effectively removing this issue affecting providers and patients.

# 2013

## INFUSION CENTER DIRECTORY LAUNCHED

The NICA infusion center directory is one of the only independent infusion center directories (i.e. our directory is not maintained by a pharmaceutical company). The directory is a vital part of NICA's mission to improve patient access to infusible and injectable medications.

## PUBLICATIONS AND CALLS TO ACTION FOR PROPOSED MEDICARE ASP+6% CUTS

Email newsletter and social media campaign educating our partners about possible cuts to ASP+6% reimbursement and the negative effects on patient access.

# 2012

## MEDICARE PATIENT ASSISTANCE CAMPAIGN BEGINS

NICA introduces the co-pay assistance problem to our partners.

## OVER 100 ADVOCACY LETTERS SENT TO KEY POLICY MAKERS AND COMMERCIAL PAYER EXECUTIVES PROMOTING INFUSION CENTERS

Many policy makers who had never heard the term "Infusion Center" outside of oncology were introduced to and educated on the delivery model, resulting in many new relationships which we maintain today.

# 2011

## NICA LETTERS AND TESTIMONY BEFORE TEXAS MEDICAID RATE COMMITTEE

NICA personally testified at the rate committee hearing on behalf of in Texas regarding rate changes that negatively affect dual-eligible patients receiving biologic therapies in infusion center. As a result of continued advocacy efforts by NICA and other coalition groups, the Medicaid rates were adjusted and released on April 1, 2012.

## REGIONAL ADMINISTRATIVE CONTRACTOR OR RAC AUDITS FOR HIGH LEVEL ADMIN CODES FOR IVIG

The audits were dismissed by CMS and Connolly Consulting (RAC) after NICA letters and phone conferences with Connolly, Trailblazer (MAC), and CMS demonstrated such audits were unwarranted. The dismissal of these audits likely established a national precedent as no other national RACs decided to target additional providers/practices for this issue.

## LETTERS TO CMS, GAO AND PUBLICATION REGARDING THE USE OF HIGH LEVEL ADMIN CODES FOR IVIG

Our compilation of information has helped several of our partners to appeal and overturn high level denials.

## REGIONAL ADMINISTRATIVE CONTRACTOR OR RAC AUDITS FOR BIOLOGIS (KX MODIFIER ISSUE)

The audits were dismissed by CMS and Connolly Consulting (RAC) after NICA letters and phone conferences with Connolly, Trailblazer (MAC), and CMS demonstrated such audits were unwarranted.