

December 28, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

RE: International Pricing Index Model (CMS-5528-ANPRM)

Dear Administrator Verma:

On behalf of the National Infusion Center Association (NICA), the hundreds of thousands of patients across the nation requiring provider-administered parenteral medications, and the infusion providers that treat them, I am pleased to submit comments in response to the Administration's advance notice of proposed rulemaking. NICA is a 501(c)(3) nonprofit patient advocacy organization formed to ensure that our nation's sickest and most vulnerable patients can access in-office infusion and injectable medications.

There are many complex, multi-faceted challenges facing the sustainability of our health care system. Specialty medications, particularly biological products, are incredibly expensive and list prices for these drugs continue to increase, translating to increased out-of-pocket (OOP) costs for patients and increased cost burden on payers.

Biological products are used to manage some of the most expensive conditions (e.g., autoimmune diseases, cancer), for which patients are subjected to extraordinary economic burden of disease and high OOP costs. Without access to these medications, the economic burden of disease increases as more health care services are consumed to manage symptoms of disease. If the list prices for biologics continue to increase, patients' OOP costs will continue to rise while shifts in benefit plan design continue to produce insurance plans with reduced coverage at higher premiums. If health care and insurance coverage are unaffordable for those that need it most, eventually no one will be able to afford either.

NICA supports the administration's goals to reduce out-of-pocket costs for Medicare beneficiaries, increase access, and improve adherence. However, there is great concern that increasing complexity in the Part B program by introducing more middlemen into the drug supply chain, increasing infusion providers' administrative burden, and reducing providers' payments may not achieve these goals. Particularly with a mandatory demonstration that would affect half of the Part B program and influence the medical benefit drug market beyond the scope of the demonstration.

NICA submits comments to bring the following concerns to the administration's attention:

- Reform measures that restrict, delay, or disrupt access to care may increase cost burden, produce sub-optimal health outcomes, and adversely impact quality of life.
- Mandatory participation in a demonstration may jeopardize the sustainability of physician practices, adversely reshape the delivery channel, and disrupt patients' access to care;

- Shifting the Part B drug supply chain to be less patient-centric would not be in the best interest of the vulnerable patient populations relying on the Part B program; and,
- There may be strategies to achieve the goals outlined in the advanced notice of proposed rulemaking that are less complex and less disruptive.

Reform measures that restrict, delay, or disrupt access to care may increase cost burden, produce sub-optimal health outcomes, and adversely impact quality of life.

Autoimmune diseases like rheumatoid arthritis, Crohn’s disease, multiple sclerosis, lupus, and psoriasis are complex, chronic diseases that manifest differently in each patient. As such, the management of these conditions are much more individualized than many other conditions. Consequently, it can take months or often years to find a medication that works to manage an individual’s condition. Additionally, these conditions can be incredibly costly to manage. People living with one or more autoimmune disease experience a high annual cost-burden associated their disease. This economic burden of disease includes both drugs and health care services, like specialist visits or hospitalization.

When these diseases are active and displaying symptoms, this cost-burden increases as the individual consumes more health care services to manage disease flares (e.g., emergency room visits, hospitalizations, specialist visits). Economic burden of disease is high. However, when these diseases are in remission, fewer health care services are consumed as the individual adheres to an effective drug regimen. Economic burden of disease is low. For conditions that cannot be managed with conventional therapies, biologics and specialty medications provide the last hope for managing disease progression and minimizing the economic burden of disease.

When individuals living with autoimmune disease in remission find their treatment regimen delayed or disrupted, they may experience a reemergence of symptoms as their disease becomes active and progresses, causing irrevocable harm. The resulting disease progression increases the economic burden of disease, produces poorer health outcomes, and reduces quality of life. Therefore, it is imperative to provide these individuals and their healthcare providers with the flexibility and agility necessary to quickly and effectively manage disease throughout that individual’s life. This is particularly important for Medicare beneficiaries as Medicare is bearing the long-term economic burden of disease across these beneficiaries’ remaining life.

There are many factors that may delay or disrupt an individual’s access to therapy and their ability to remain in disease remission. From NICA’s perspective, the factors creating the most significant barriers to care are: (1) out-of-pocket costs; (2) utilization management strategies; (3) high administrative burden on provider offices to get patients on therapy and get reimbursed; and, (4) volatile reimbursement environment threatening the delivery channel’s sustainability.

As biologics are among the most expensive drugs in our health care system, out-of-pocket costs continue to pose a significant barrier to the fulfillment of prescriptions for biological products and adherence to the prescribed treatment regimen. Additionally, as the insurance landscape continues to incorporate utilization management strategies that inappropriately restrict and delay access to care for a false sense of cost-savings, these strategies will continue to pose a significant barrier to starting a biologic therapy and staying on therapy across plan years, even when renewing a plan with the same insurance carrier.

Finally, market forces and political dynamics continue to threaten the sustainability of the most economical care setting in which to receive these biological medications. As currently framed, the potential IPI model outlined in the administration’s advanced notice of proposed rulemaking would

threaten the sustainability of patients' access to outpatient infusion facilities across the country—both independent, community-based sites of care and hospital-based sites of care.

Mandatory participation in a demonstration that may jeopardize the sustainability of infusion facilities could disrupt therapy for hundreds of thousands of Medicare patients.

Patients rely on healthcare providers, and the sustainability of the infusion delivery channel, for consistent access to the care they need. Without healthcare providers, patients cannot receive care. Healthcare providers are in the business of providing health care. If providers lose money treating Medicare patients, Medicare patients will be displaced with their access to care disrupted, increasing out-of-pocket costs and the cost burden on Federal health care programs.

Additionally, many providers cannot sustain their practice model without their Medicare patients. Therefore, an unsustainable shift in the reimbursement landscape may result in the collapse of office-based infusion facilities, including physician practices, and force Medicare patients to transition into hospital-based care settings at increased cost or go undermanaged posing a significant increase to the annual economic burden of disease.

If infusion facilities go under water as a result of mandatory participation in the model and cannot opt-out, the delivery channel may be adversely reshaped to the detriment of patients, producing poorer health outcomes and reduced quality of life while increasing patients' OOP costs and Medicare's cost-burden. The resulting distortion to this critical medication delivery channel would be disastrous for patient access with steep financial ramifications.

A more middlemen-centric supply chain is not in the best interests of patients and their sustainable access to care.

In his remarks on the *American Patients First* blueprint, President Trump indicated that the administration will work on “increasing competition and reducing regulatory burdens so drugs can be gotten to the market quicker and cheaper.” President Trump continued by emphasizing “[w]e’re very much eliminating the middlemen.”¹

Additionally, in Secretary Azar's remarks on the President's *American Patients First* blueprint, Azar acknowledged that “[t]he American system works incredibly well in so many ways because we have a free market. But right now, we have a drug pricing system that is protected from market forces—that is set up to benefit the manufacturers and the middlemen, not the patients.”²

Implementing a mandatory, wide-reaching model that would make the Part B drug supply chain more middlemen-centric would be counterproductive to removing middlemen's influence. Instead, NICA is concerned that more vendors will further reduce patient-centricity and patient-value within the medical benefit drug landscape, as well as delay access to care as new vendors learn the complexities of the medical benefit supply chain, develop their nationwide distribution tactics, and build their distribution capabilities.

¹ Donald Trump. Remarks by President Trump on Lowering Drug Prices. May 11, 2018. Accessed at: <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-lowering-drug-prices/>

² Alex Azar. Remarks on Drug Pricing Blueprint. May 14, 2018. Access at: <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>

Allowing new players into the distribution market that may not understand the market may create bottlenecks within the distribution channel and delay patients' access to care. Particularly concerning is an apparent appetite to include of pharmacy benefit managers and 340B hospitals—two underregulated business models that have contributed to significant market distortion—as vendors in this IPI model.

As mentioned previously, there are many factors that may delay or disrupt access to care. Within the medical benefit drug landscape, availability of drug and timely distribution are *not* barriers to care. To reiterate, the factors creating the most significant barriers to care are: (1) out-of-pocket costs; (2) utilization management strategies; (3) unnecessarily high administrative burden on provider offices to navigate utilization management strategies and chase reimbursement; and, (4) volatile reimbursement environment threatening the delivery channel's sustainability. Reform measures that could exacerbate one or more of these key factors would adversely impact patients' access to care.

Despite these factors and challenges, patients prescribed biologics and other specialty medications will continue to need these products and prescribers will continue to prescribe these products when appropriate. Autoimmune disease and complex chronic conditions will continue to progress in the absence of consistent access to the appropriate care. Incorporating more middlemen will only further complicate a complicated system without adding value for patients.

There are more effective strategies to achieve the goals outlined in the advanced notice of proposed rulemaking.

In the administration's advanced notice of proposed rulemaking, the following goals were expressed:

- Reduce [Part B] expenditures while preserving or enhancing the quality of care for beneficiaries; and,
- Increase access and treatment adherence by reducing out-of-pocket costs for Medicare beneficiaries.

When developing the space shuttle, NASA doesn't reposition to an entirely new approach when one system isn't working as well as it could be. They manipulate factors within the targeted system, one at a time, until the desired outcome is realized. Testing multiple changes to a system simultaneously does not allow the investigator to identify which change produced the desired outcome.

Instead of pursuing a demonstration that tests multiple complex, wide-reaching reform measures simultaneously, including an overly complicated pricing strategy, an overly complicated computation for reimbursement, and a middlemen-centric private sector vendor distribution model, what if the administration pursued less complicated approaches to testing a single reform measure at a time?

Rather than explore how restructuring several key factors within the Part B program (pricing, drug distribution, reimbursement) could achieve these goals, NICA believes there are less complicated and more efficient strategies CMS could explore to realize these goals.

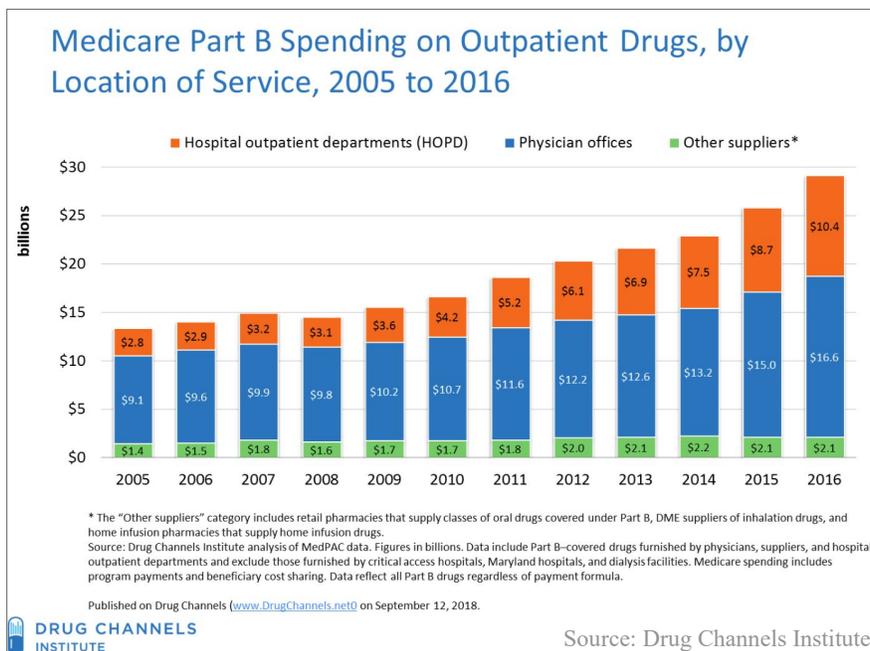
Reduce [Part B] expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. For years, there has been growing concern that medical benefit drug spend is a leading driver of total health care spend, particularly within Medicare Part B. Although Part B drug spend has increased annually over the last decade, drug spend is only a fraction of total Part B spend.

Additionally, since 2008, Part B spending has been shifting from physician practices to hospital outpatient departments (HOPDs). From 2008 to 2016, Part B drug spending at HOPDs grew by about 235

percent (\$7.3B), from \$3.1B to \$10.4B in 2016; whereas Part B drug spending at physician offices grew by only 69 percent over the same time period from \$9.8B to \$16.6B.³ (Figure 1)

Additionally, Part B spending to HOPDs for outpatient drugs has increased annually since 2005, the annual growth rate for Part B payments to hospital outpatient sites of care has been higher every year from 2009 to 2016. In fact, from 2009 to 2016, the compound average growth rate (CAGR) of spending was 7.2 percent per year for physician offices, compared with 16.4 percent for HOPDs. (Figure 1)

Figure 1

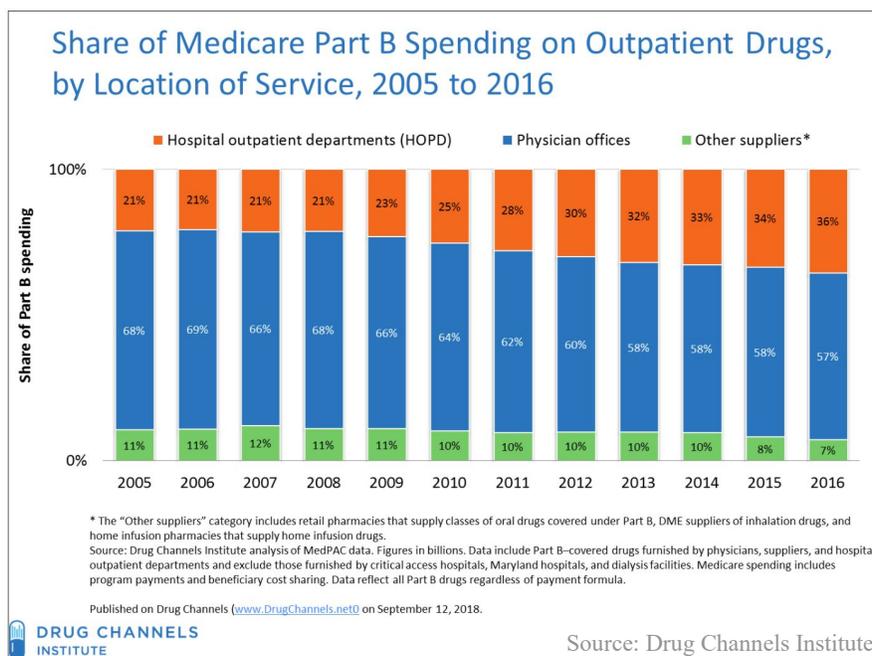


Looking at Figure 1, total Part B drug spending is increasing annually and that spending by place of service is increasing for both physician offices and hospitals. However, when looking at this annual Part B drug spending as share of spending by place of service, we see that hospitals' annual share of Part B drug spending increased by 15 percent from 2005 to 2016 (21 percent to 36 percent). In contrast, physician offices' share of spending *decreased* by 11 percent over the same time period (68 percent to 57 percent). (Figure 2)

Despite this loss of position, spending at physician offices has grown since 2009 due to increased medical benefit drug consumption through Part B. Every year, consumers of medical benefit drugs transition to Medicare coverage. These patients still need access to medical benefit drugs to manage their condition, the cost-burden of these outpatient drugs shifts from commercial insurers to Medicare as a result. As hospital-based sites of care are considerably more expensive than non-hospital care settings, the increasing share of Part B drug spending that hospital-affiliated sites of care are consuming could be a target point for intervention to reduce Part B expenditures.

³ Adam Fein. Updated Part B Data: Hospitals Are Displacing Physician Offices Even Faster Than We Thought. Drug Channels Institute. September 12, 2018. Access at: <https://www.drugchannels.net/2018/09/updated-part-b-data-hospitals-are.html>

Figure 2



Reduce Part B expenditures through site of care optimization. The cost disparity for provider-administered intravenous and injectable drugs between a physician office and HOPD is significant.⁴ By transitioning Medicare beneficiaries to lower-cost care settings for biologics, Medicare could realize significant savings in the Part B program while reducing beneficiaries' out-of-pocket costs.

From a drug spend mitigation perspective, CMS and MedPAC appear to be hyper-focused on the 4.3 percent margin associated with physicians' reimbursement. Not the outrageously larger spread that non-340B hospitals are receiving on their drug payments, or the astronomically absurd spread that 340B hospitals are receiving on their drug payments.

It appears that CMS continues to allocate significant time and effort toward fixing a faucet leaking at a slow drip when the water main is leaking in the basement. The faucet should be addressed, but there is a much larger issue contributing far greater to the water bill that seems to be consistently overlooked.

Although physician offices are accounting for more medical benefit drug spend than hospitals, per capita drug expenditures are significantly lower in physician offices compared to hospitals. Additionally, hospitals' share of drug expenditures is rising sharply. Perhaps the administration should focus on fixing the largest water leaks first before addressing smaller leaks to realize the greatest impact.

Reduce Part B expenditures by reducing non-drug expenditures. Although medical benefit drug spend in Medicare is high, and has increased in recent years, it is a small proportion of total Part B spending. In

⁴ Magellan Rx Management. Medical Pharmacy Trend Report. 2017; 8th edition.
https://www1.magellanrx.com/media/722153/tr2017_final_for-website-use.pdf

2015, Part B drug expenditures were less than 10 percent of total Part B expenditures (\$25B compared to \$280B).⁵

Most of these expenditures are for outpatient services rendered in physician offices or hospital outpatient departments (e.g., PCP visits, specialist visits, lab work, diagnostics, and outpatient surgeries). In the case of active autoimmune disease, patients are consuming more non-drug health care services than they otherwise do when their disease is in remission.⁶ If more Medicare beneficiaries prescribed drugs covered under Part B were able to get their disease state in remission, their consumption of other health care services covered under Part B may decline. This, in turn, could significantly reduce non-drug expenditures through Part B.

In terms of total Part B spend, it appears that CMS is allocating significant time and effort to exploring reform measures that may disrupt access to care for the most expensive beneficiaries to manage that are consuming the most non-drug health care services, *particularly when they are already in the lowest-cost care setting*. Restrictions, delays, or disruptions in care for these beneficiaries could be driving unnecessary consumption of high-cost health care services. Instead, CMS could be focusing on reform measures that promote the sustainability of lowest-cost care settings, educating beneficiaries on annual economic burden of disease, site of care options, and improve transparency with out-of-pocket cost disparities across care settings. In 2015, Part B drug spending was less than 10 percent of total Part B spending. Again, the focus appears to be on the leaking faucet upstairs when the basement is flooding.

If CMS accepts this theoretical postulation, it would suggest that getting patients in remission as quick as possible and for as long as possible could significantly reduce the cost burden of the Part B program—perhaps more so than reducing reimbursement for Part B drugs. Additionally, driving consumption of high-cost Part B drugs into the lowest-cost settings would further magnify projected cost-savings.

Through CMMI's authority, CMS could explore a demonstration project through which Medicare beneficiaries obtain Part B medicines (e.g., biologics) in lower-cost physician office settings instead of hospital settings. To evaluate effectiveness, CMS could compare the Part B cost burden through the demonstration to the projected cost-burden the program would have realized if the demonstration project was not initiated. This model could be tested using small study groups in numerous geographies across the nation, then scaled up if results appear promising.

Additionally, CMS could engage with advocacy groups like NICA to develop educational materials—similar to those we have published—for Part B beneficiaries to empower them to make better decisions relating to consumption of health care services and mitigate their out-of-pocket costs by choosing lower-cost care settings.

Increase access and treatment adherence by reducing out-of-pocket costs for Medicare beneficiaries. A low-hanging fruit, so to speak, in this area would be allowing the extension of manufacturer cost-share assistance programs to Medicare beneficiaries *when there is no less expensive and equally effective generic available*. For instance, in the case of complex biologics for which there are no generics available. Although this strategy does not solve the drug pricing issue, it would reduce

⁵ Health Affairs. Prescription Drug Pricing #5: Medicare Part B. Health Policy Brief. August 10, 2017. Accessed at: <https://www.healthaffairs.org/doi/10.1377/hpb20171008.000171/full/>

⁶ Rubin DT, Mody R, Davis KL, Wang CC. Real-world assessment of therapy changes, suboptimal treatment and associated costs in patients with ulcerative colitis or Crohn's disease. *Ailment Pharmacol Ther*. 2014; 29:1143-1155.

patients' out-of-pocket cost burden and would improve treatment adherence among beneficiaries that would otherwise discontinue therapy for economic reasons.

Fixing the issue of high and rising drug prices, particularly among biologics, is an incredibly complex and arduous challenge. In the meantime, patients' diseases are still progressing, and they need consistent, uninterrupted access to biologics to manage progression of disease, minimize the annual economic burden of disease, and maximize quality of life.

Manufacturer cost-share assistance programs help patients access their medication when they otherwise could not afford the cost-share. These assistance programs are particularly important for people living with autoimmune disease or cancer that are prescribed expensive biologics or other provider-administered IV/injectable medications. Many of our nation's sickest and most vulnerable citizens rely on these assistance programs to access this class of therapy when conventional treatments have failed. For autoimmune patients—for which conventional treatments have failed to manage disease progression and could not otherwise access biologics without manufacturer cost-share assistance programs—these assistance programs help them manage disease, improve health outcomes, reduce long-term out-of-pocket cost, and improve quality of life.

In the current regulatory landscape, beneficiaries of Federal health programs cannot access manufacturer cost-share assistance programs. Commercially insured patients that have relied on manufacturer cost-share assistance to access a drug—and have become stable on the drug—are facing disrupted and delayed therapy when they transition to coverage through Medicare. Additionally, current Medicare beneficiaries that need a biologic to manage their condition but cannot afford the cost-share are undermanaging their condition. Those that cannot afford supplemental insurance will not be able to access, or adhere to, the biologic medication they need if they cannot afford their 20 percent coinsurance. These Americans face significant challenge in managing disease progression and mitigating long-term increases in the economic burden of their disease if their condition is undermanaged.

In a September 2014 Special Advisory Bulletin, the Office of Inspector General (OIG) indicated that the Federal anti-kickback statute is implicated when manufacturer cost-share assistance covers some or all of a drug for a beneficiary of a Federal health care program when a less expensive and equally effective or generic alternative is available. These concerns are certainly valid in the case of conventional oral medications for which less expensive and equally effective generics are available. For these products, the anti-kickback statute has prevented the Medicare program from experiencing a significant increase in financial burden.

In the case of biologics, however, there are no generics and the only other effective alternative may be a different biological product. For the most part, biological products are comparable in price. With biosimilar biological products posing nominal cost-savings over the innovator product, biological products should receive safe harbor from federal anti-kickback statute.

Although Medicare's cost-burden may increase as more beneficiaries are consuming Part B drugs, the increase in cost could be heavily outweighed by cost-savings associated with the appropriate management of patients' conditions that were otherwise undermanaged because they could not afford a prescribed biologic.

Through CMMI's authority, CMS could explore a demonstration program through which Medicare beneficiaries are eligible to receive manufacturer cost-share assistance for a limited number of drugs (e.g., the top 10 biologics by drug spend). To evaluate effectiveness, CMMI could compare treatment fulfillment and treatment adherence rates within the demonstration to those outside the demonstration.

Conclusion

There are many complex, multi-faceted challenges facing the sustainability of our health care system. Medicare Part B reform should first and foremost be focused on sustainability and uninterrupted access to care. Patients rely on uninterrupted access to care to keep their autoimmune disease in remission, minimize the economic burden of disease, and maximize quality of life. Without healthcare providers, patients cannot receive care. If providers are forced to participate in a mandatory model that would disrupt the sustainability of their practice, their ability to treat Medicare patients may be jeopardized.

Sustainable reform should consider market dynamics, as well as potential changes in site of care behavior in response to landscape reform and focus on preserving and expanding access to care in the most economical care settings, like in-office infusion care settings (e.g., physician practice-based infusion suites and freestanding infusion centers). Reform that threatens the sustainability of this critical medication delivery channel would conflict with the administration's goals of reducing program expenditures, reducing patients' out-of-pocket costs, improving access to care, and improving treatment fulfillment and treatment adherence.

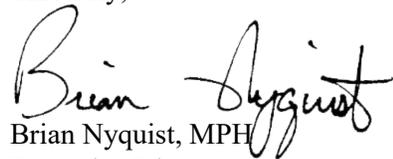
NICA applauds actions the administration has taken to address the rising cost of drugs and patient out-of-pocket costs. We support several goals outlined in the advanced notice of proposed rulemaking in concept, so long as reform measures do not interrupt, restrict, or delay access to care. Due to our concern that an IPI demonstration would adversely impact access to care, we implore the administration to not move forward with an IPI demonstration.

If the administration decides to move forward with an IPI demonstration, we urge the administration to ensure that access to care will not be inadvertently disrupted by reform measures explored in a demonstration project by: (1) developing a strategy in collaboration with advocacy organizations to ensure that patients will be able to get the care they need, including a contingency plan if a demonstration inadvertently restricts, delays, or disrupts access to care; (2) making provider participation voluntary; and, (3) if participation is mandatory, providing a mechanism through which infusion providers whose ability to treat patients may be jeopardized as a result of mandatory participation in the demonstration project are able to opt-out.

Thank you for the opportunity to submit comments on this potential International Pricing Index Model outlined in the administration's advanced notice of proposed rulemaking. NICA and its Advisory Committee comprised of in-office infusion thought leaders and subject matter experts would welcome the opportunity to serve as a resource in the exploration, development and implementation of reform involving the provider-administered parenteral medication delivery channel.

Should you have any questions or need more information, please feel free to contact me at brian.nyquist@infusioncenter.org or 512-402-6955.

Sincerely,



Brian Nyquist, MPH
Executive Director
National Infusion Center Association