NATIONAL INFUSION CENTER ASSOCIATION

March 15, 2016

Sylvia Burwell
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Part B Prescription Drug Models

Dear Secretary Burwell:

We are writing on behalf of patients and our provider partners to express our deep concern with the proposed Medicare Part B prescription drug payment demonstration project (ASP + 2.5% plus a nominal flat fee of $16.80). We understand the need to address the rising cost of healthcare and medication spending in the growing specialty medication and biologic market. However, we strongly believe that targeting provider Part B drug reimbursement as the point of intervention will significantly restrict patient access to high quality care. The proposed payment model will not achieve the expected impact described in the March 8, 2016 CMS Press Release: ***"encourage better care, smarter spending, and healthier people".***

As stated by Andy Slavitt, Acting Administrator for CMS:

> *First and foremost, our job is to get beneficiaries the medications they need. These [reimbursement reform] proposals would allow us to test different ways to help Medicare beneficiaries get the right medications and right care while supporting physicians in the process... Models like this one can help doctors and other clinicians do what they do best: choose the medication and treatment that keeps their patients healthy. (CMS News Brief, 2016)*

We agree with Administrator Slavitt's above statement; however, we are able to show that **the proposed demonstration model will NOT achieve the goals stated above**. We are very concerned that the Center for Medicare & Medicaid Innovation (CMMI) has not adequately collaborated with industry experts, especially in the non-chemotherapeutic office-based Infusion Center space. We propose that more time be dedicated to research, evaluate, and consider the potential impact of these proposed reimbursement models on the providers who administer these medications and consider the resulting downstream effect for Medicare beneficiaries.

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The current proposed payment model will have an undesired domino effect on office-based infusion providers, Medicare beneficiaries, and Medicare spending. Non-chemotherapeutic office-based Infusion Centers stand in the gap every day for hundreds of thousands of patients across the country who, without these Infusion Centers, would have no choice but to receive their treatments in hospital outpatient departments, hospital emergency departments, or other institutional sites of care. While non-chemotherapeutic Infusion Centers are not yet as widely organized as oncology centers, they are no less significant in the U.S. medication delivery model for Medicare beneficiaries. Accordingly, CMS and CMMI need to further evaluate this critical Infusion Center industry segment before any new reimbursement reductions are considered.

WHY CONSIDER OFFICE-BASED INFUSION CENTERS?

According to the 2014 Medical Pharmacy Trend Report by Magellan Rx Management, "***"Approximately 50 percent of all specialty drug spend is billed under the medical benefit [provider based infusion centers], yet visibility into this spend generally has been limited and benchmarks have not been broadly reported or discussed."***

The need to pay attention to and work with office-based Infusion Centers is illustrated by the data below, which is taken from Medicare's 2014 Drug Spending Dashboard. As illustrated below in Figure 1, 8 of the top 30 Part B medications ***representing $3.45B in spend*** are biologic and specialty medications most commonly administered in the office-based Infusion Center.

FIGURE 1: 2014 MEDICARE PART B – INFUSION CENTER MEDICATIONS

Rank	Brand Name	Scientific Name	Total Spend	Beneficiaries	Treatment
5	Remicade	Infliximab	$ 1,172,607,402	59,748	Rheumatoid Arthritis, Crohn's and Colitis, Psoriasis
7	Prolia	Denosumab	$ 767,348,546	294,936	Osteoporosis
11	Orencia	Abatacept	$ 342,183,172	20,147	Rheumatoid Arthritis
20	Tysabri	Natalizumab	$ 256,002,009	7,302	Multiple Sclerosis
21	Gammagard	Immune Globulin	$ 253,466,883	12,135	Autoimmune disorders
22	Gamunex	Immune Globulin	$ 245,937,276	9,579	Autoimmune disorders
23	Xolair	Omalizumab	$ 220,125,531	11,463	Allergy-induced asthma
26	Privigen	Immune Globulin	$ 189,572,072	9,327	Autoimmune disorders
		TOTAL	$ 3,447,242,891	424,637	

*Source: CMS Medicare Spending Dashboard 2014 (*Accessed 3/15/16)

Figure 1 presents 8 of the top 30 Part B medications that represented $3.4 billion in spend in 2014.

Under the proposed payment model, providers will be forced to refer these Medicare patients to hospital and institutional sites of care. **Therefore, if the current proposed payment model is implemented nearly all of the $3.45B spend, and much more not identified in this sample data, will be shifted to more expensive and less efficient sites of care.**

DOWNSTREAM EFFECT OF PAYMENT REDUCTIONS ON PATIENT ACCESS

As it stands today, the current Medicare Part B drug reimbursement model (ASP+6%) is barely sufficient for many office-based Infusion Center providers. The pressure to provide affordable access to biologics and other specialty medications has increased alongside the rising cost of care and declining reimbursement environment. Many providers who administer high-cost specialty medications to Medicare beneficiaries in their offices are only able to do so because they have been able to subsidize the lower Medicare patient payments with higher managed care patient payments. In the last 4-5+ years, most Managed Care Organizations have transitioned away from an "AWP minus" model to CMS's "ASP plus" payment model (See Figure 2).

FIGURE 2: PHYSICIAN OFFICE REIMBURSEMENT FOR MEDICAL BENEFIT DRUGS (2011-2014)

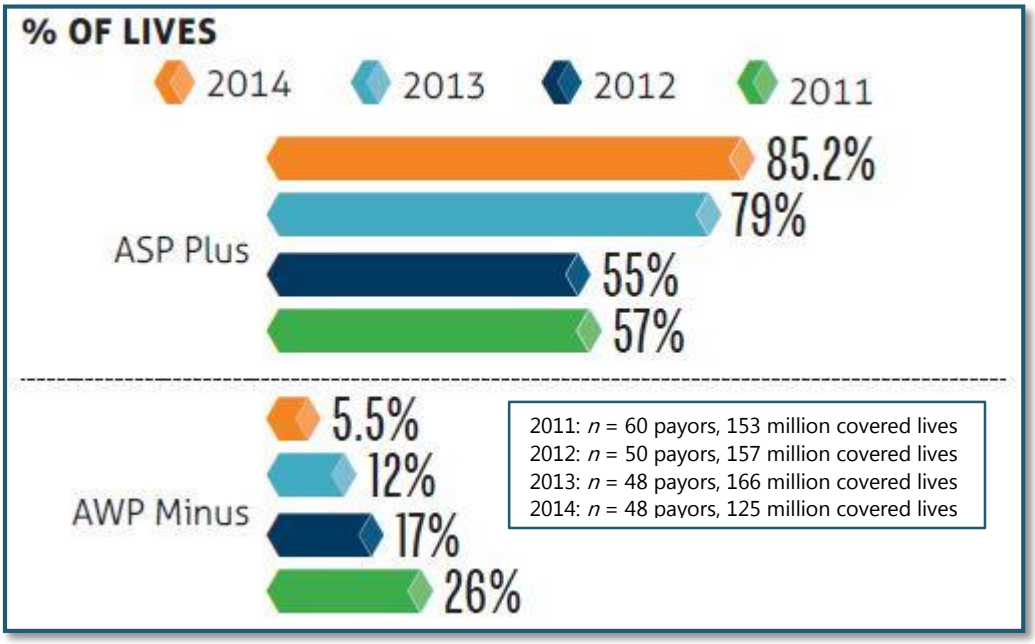

Figure 2 illustrates the physician office reimbursement approach used by payors for drugs paid under the medical benefit as a percentage of lives from 2011-2014 (*Source: Magellan Rx Management Medical Pharmacy Trend Report, 2014 Fifth Edition*)

Many of these private payers also index their payment fee schedules directly to the Medicare ASP+ fee schedule. Reductions in Medicare payment schedules will certainly have global downward effect on

managed care fee schedules, further challenging providers who administer these medications in their offices. **If Part B reimbursement for these medications is further reduced, providers will no longer be able to sustain their Infusion Centers for Medicare patients and will have no choice but to refer them to the nearest available hospital.**

INCREASING 340B ISSUES

340B payments are an obvious concern of Medpac, the Medicare Payment Advisory Committee. In the June 2015 Report to Congress titled *Chapter 3 Part B Drug Payment Policy Issues*, the words *"340B"* appear on 23 pages of the 24 page report. In fact, the 340B Drug Pricing Program is one of two issues outlined in the document – the other being the ASP+6% reimbursement model. However, *45 CFR Part 511*, the 119 paged document that outlines the proposed Part B Drug Payment Model, makes no reference to "340B" or the high profit margins associated with the 340B Drug Discount Program.

Medpac conservatively estimated in their June 2015 report that the *minimum* discount for 340B hospitals paid under the OPPS to be at least 22.5%. Medpac also estimated that these 340B hospitals (excluding certain hospitals for various reasons) received approximately $800 million in profits from providing medications covered under Part B to Medicare beneficiaries. To propose reimbursement reform on the grounds that providers may be making excessing profits on a 6% margin, yet ignore the 22.5%+ margins experienced by 340B entities indicates that CMS and CMMI have not sufficiently researched and evaluated this matter.

Indeed a considerable amount of the language in these reports are concerned with addressing the issues associated with 340B pricing in hospitals. Why then, would a new demonstration project be created with a payment model that would directly encourage providers to move hundreds of thousands of patients across the country directly into hospitals, many of which are 340B entities? Unfortunately, these 340B institutions will likely be the only financially capable entities willing to administer biologic and specialty medications under the new proposed payment model.

PATIENTS WILL LOSE ACCESS TO THEIR CURRENT SITE OF CARE

According to the *2016 Medicare Part B Demo Technical Fact Sheet*, ***"This proposed model would not affect drug coverage or any other benefits, and beneficiaries will still have complete freedom of choice of doctors, hospitals, and other providers and suppliers."***

There is a big difference between *"coverage"* and access. If this model is implemented, patients will have the *"...complete freedom of choice..."* to choose which *hospital* is best for their infusion treatment. Currently, many Medicare beneficiaries are able to access Infusion Centers that are geographically convenient, affordable and meet their specific needs. Many of these patients receive their care directly under the supervision of their prescribing doctor.

According to Dr. Patrick Conway, CMS Deputy Administrator for Innovation & Quality and CMS Chief Medical Officer, ***"The choice of medications for beneficiaries should be driven by the best available evidence, the unique needs of the patient, and what best promotes high quality care."*** It is not in the best interest of providing for *"...the unique needs of the patient"*, nor does it *"...promote high quality care"*, to implement payment models that drive Medicare beneficiaries into large, inefficient high-cost institutional and hospital systems far from the observation of their prescribing physician.

ALL PRESCRIBING INCENTIVES ARE NOT CREATED EQUAL

According to the June 2015 Report to Congress regarding Medicare Part B drug payment policy issues, ***"Moving to a flat-fee add-on could have a number of effects. It might increase the likelihood that a provider would choose the least expensive drug in situations where differently priced therapeutic alternatives exist, potentially generating savings for Medicare and its beneficiaries."***

It is important to understand that this broadly proposed payment model will not adequately address all diseases and specialties. In many specialties where these Part B specialty and biologic medications are prescribed, there is not a list of *"least expensive drug(s)"* for the provider to choose from. For many autoimmune disorders like Rheumatoid Arthritis, Crohn's Disease, Multiple Sclerosis, and others, the standard of care for treatment ***IS*** a biologic and/or specialty medication. Beyond biologic or specialty drug choices, other *"therapeutic alternatives"* are, in many instances, decades-old treatments such as high-dose steroids and other older regimens that may *"generate savings"* with the side effect of being significantly less effective and suboptimal health outcomes.

In addition, in many areas of the country, providers refer their patients to Infusion Centers in which they do not own or have any direct financial incentive. Reducing payments for Part B drugs in these situations will have no effect on prescribing incentives and will further undermine the office-based Infusion Center as an option to high-cost hospitalization of these patients.

SOLUTIONS AND A REMINDER TO CMS ABOUT HOW WE GOT HERE

It would not be prudent to bring up objections and not offer possible solutions to the government's concern with provider Part B Drug reimbursement. Before we offer those recommendations, we need to remind CMS and other stakeholders how we got here.

In 2006, when parts of the Medicare Modernization Act (MMA) were implemented and the ASP+6% fee structure was put into effect, it was widely sold by CMS with the promise of higher administration payments. These new payments were supposed to more appropriately compensate the provider for the skilled services that were being performed. Indeed, procedure/administration code reimbursement was improved under the new 2006 fee schedule. Unfortunately, procedure and administration code payments have been systematically reduced year after year (see Figure 3) while the costs of providing infusion care have increased substantially over the same time period.

FIGURE 3: EVOLUTION OF INFUSION PROCEDURE CODES

CPT Code(s)	Description	2006	2014	% Change
96413	High Level Infusion, 1st Hour	$ 174.94	$ 135.42	**-23%**
96415	High Level Infusion, Add 'l Hour	$ 39.37	$ 28.40	**-28%**
90765, 96365	Therapeutic Infusion, 1st Hour	$ 78.17	$ 69.88	**-11%**
90766, 96366	Therapeutic Infusion, Add 'l Hour	$ 26.01	$ 18.92	**-27%**

Figure 3 illustrates the decrease in reimbursement and % change for various CPT codes from 2006 and 2014 (*NOTE: the 90765, 90766 codes were transitioned to 96365, 96366 in 2009)

Looking at just one of the primary costs of administering infusions, Registered Nurses (RN) wages, we found that they increased from an average of $27.54 per hour in 2006 to $33.55 per hour in 2014 – a nearly 22% increase in direct labor cost. This hourly cost does not include the increased cost of providing healthcare benefits to nurses *(now also a government requirement),* according to a 2007 Bureau of Labor Statistics news brief.

FIGURE 4: AVERAGE PAYMENTS FOR PART B INFUSION ADMINISTRATION

Example payments for a 3 hour infusion administration	2006	2014	% Change
High Level Medication	$ 253.68	$ 192.22	**-24%**
Therapeutic Level Medication	$ 130.19	$ 107.72	**-17%**
Infusion Nursing Labor Cost	$ 82.62	$ 100.65	**22%**
High Level Administration Fee LESS: Nursing Cost	$ 171.06	$ 91.57	**-46%**
Therapeutic Level Administration Fee LESS: Nursing Cost	$ 47.57	$ 7.07	**-85%**

Figure 4 illustrates the decrease in average payments and % change for Part B infusion administration from 2006 to 2014 (*Source: CMS Fee Schedule Lookup Tool*)

Anyone with a calculator plainly observes that the Infusion Center provider is having to do more with less. The simple and publicly available math provided here does not include many of the other costs associated with infusion drug delivery. There are currently no available codes to reimburse office-based Part B Infusion Center providers for the cost of medical supplies, infusion pumps, patient observation/assessments before, during, and after treatment, and countless hours of case management and coordination of care.

Providers have had the procedure reimbursement rug pulled out beneath them so it is no surprise that they have come to rely on the narrow margin created by Part B Drug reimbursement to help subsidize their Infusion Center operations.

We may only begin to address Part B drug payment solutions after we adequately address infusion administration payment reform. The NICA along with our provider members and partners are ready to begin discussions and propose payment reforms that would move the conversation away from medication payments and move forward with measureable patient-centered outcomes that more accurately reflect the skills and efforts of the Infusion provider and staff.

For any proposed reimbursement model to produce positive effects, treatment options must be financially viable for the provider to administer and affordable and accessible for the patient to receive. **We implore CMS and CMMI to delay implementation of the proposed payment model so that a more thorough investigation of the proposal's impact can be performed with input from office-based Infusion Center providers.**

We respectfully request that DHHS, CMS, and CMMI reevaluate the impact of the proposed reimbursement reform and seriously consider collaborating with thought-leaders in the office-based Infusion Center space. As a 501(c)(3) nonprofit organization, our interests lie in collaboratively developing all-win solutions to improve patient access to affordable, high quality care. Based on our knowledge of the office-based infusion industry, the current proposed reimbursement model does not represent an all-win solution to *"help Medicare beneficiaries get the right medications and right care while supporting physicians in the process."*

Thank you for your time and consideration,

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