NATIONAL INFUSION CENTER ASSOCIATION

June 27, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave SW
Washington, D.C. 20201

Sylvia M. Burwell
Secretary, Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

BY ELECTRONIC DELIVERY

RE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule [CMS–5517–P] (Proposed Rule)

Dear Secretary Burwell and Acting Administrator Slavitt:

The National Infusion Center Association (NICA) is pleased to submit its comments to the Centers for Medicare and Medicaid Services' (CMS) May 9, 2016 Proposed Rule[1] implementing the Medicare provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).[2]

NICA is a nonprofit advocacy organization, established in 2010, to provide a national voice for patients relying upon office-based Infusion Centers to access high-quality, cost-effective care. Our efforts are focused on improving patient access to non-chemotherapeutic provider-administered medications in non-hospital, office-based Infusion Centers. NICA and its infusion provider partners are committed to maintaining the viability of office-based Infusion Centers as a more accessible, more patient-friendly, and more economical alternative to the hospital care setting.

CMS' efforts to identify, measure, and reward "value" through the Proposed Rule create system-wide shifts in incentives, and requires practice activities that likely will influence health care beyond that delivered to Medicare beneficiaries. NICA is confident that office-based Infusion Centers provide a necessary alternative to hospital settings from a safety, quality, and value perspective. We are concerned, however, that office-based Infusion Centers will be unable to document that value unless CMS' implementation of MIPS (and the APM provisions) is refined toward relevant measures and meaningful comparisons.

[1] 81 Fed. Reg. 28,162 (May 9, 2016).

[2] See 80 Fed. Reg. 41,686 (July 15, 2015); and 80 Fed. Reg. 59,102 (October 1, 2015).

NICA offers its comments to:

- Underscore the importance of office-based Infusion Centers to patients, providers, and third-party payers seeking to optimize site of care for improved, patient-centered outcomes and increased value; and

- Direct CMS' attention to structures and provisions of the Proposed Rule that are either likely to reduce the validity of MIPS in reflecting the value of care provided in office-based Infusion Centers, or that are logistically impractical for these providers.
    - The resource use component of the MIPS composite score places office-based Infusion Centers at an intractable disadvantage by including Part B products while excluding consideration of Part D alternative products;
    - The MIPS methodology may incorrectly identify infusion providers as low performers subject to negative payment adjustments; and
    - The quality component of the MIPS composite score may not have sufficient or sufficiently relevant measures to enable high levels of performance.

Office-based Infusion Centers are a critical part of our healthcare system, particularly for some of our nation's most vulnerable patients needing access to Part B infused or injected therapies.

Commercial health insurers have increasingly recognized the value offered by office-based infusion services, with many specifically designating the alternative hospital outpatient setting as "not medically necessary" for most patients.[3] Research indicates that office-based infusion services create value across stakeholder perspectives in delivering care that is (1) accessible and convenient for patients; (2) more affordable and efficient than other sites of care; and, (3) safe and patient-friendly.[4]

Accessibility -- For patients with the chronic, life-limiting and/or life-threatening conditions that predominate in infusion centers, disease burden significantly impacts quality of life and sense of well-being. Whether these patients require infusion services more frequently than once a week or less frequently than once a month, the hospital outpatient site of care can inject stressors such as long wait-times, a labyrinth of processes and procedures, and an overall environment that is generally less patient-friendly. Additionally, individuals in rural or distant suburban communities often encounter travel distances that can extend infusion services into an all-day activity.

Affordability -- Office-based Infusion Centers are the lowest-cost site of care for patients needing Part B infused or injected therapies. This not only creates savings for Medicare, but reduces the coinsurance amount for its beneficiaries. Table 1 provides an illustrative sample of costs associated with five infused therapies in the hospital, home infusion and Infusion Center settings.

[3] See, e.g., Premera Blue Cross, Utilization Management Guideline, *Site of Service: Infusion Drugs and Biologic Agents*, (effective date 7/1/16) https://www.premera.com/medicalpolicies/11.01.523.pdf (accessed 6/24/16).

[4] Magellan Rx Management (2015). *Medical Pharmacy Trend Report, 2015 6th Edition.*

TABLE 1: Differences in Infusion Therapy Costs Across Sites of Care

BRAND NAME	HOSPITAL	HOME INFUSION	INFUSION CENTER
Remicade	$5,995	$3,255	$3,221
Avastin	$8,832	N/A	$3,024
Neulasta	$5,971	$3,410	$3,081
Rituxan	$9,068	N/A	$4,565
Herceptin	$4,877	N/A	$2,150

SOURCE: Medical Injectables & Oncology Trend Report, 2010 First Edition, by ICORE Healthcare, pg 33.

Table 1 illustrates the differences in costs per claim among five infusion therapies across three sites of care: hospital, home, office-based Infusion Center.

Safety and Patient Experience -- Many infusion patients are immunocompromised due to the nature of their disease, or their prescribed therapies. Office-based Infusion Centers can offer a more controlled environment without exposing patients to the infectious diseases commonly present in hospitals. These smaller offices also provide patients with more consistency in the staff administering each treatment, and are able to minimize patient wait times and maximize comfort. Patients have reported developing deep relationships with the staff at their Infusion Centers, resulting in more compassionate care and a better patient experience.

The resource use component of the MIPS composite score places office-based Infusion Centers at an intractable disadvantage by including Part B products while excluding consideration of Part D alternative products.

In its Proposed Rule, CMS indicated that it would neither include, nor account for, Part D costs in the resource use performance category. However, Part B costs would be included, or accounted for. We urge CMS to ensure that the resource use scoring methodology is designed to ensure that infusion providers are not penalized for treating patients with medications that are incorporated into their composite performance score. Infusion providers are treating patients that have failed all conventional treatment protocols covered under Part D. To penalize infusion providers for delivering the only effective medication goes against MACRA's intent and CMS' objectives.

For many patients, disease pathophysiology and other factors may lead a clinician to prescribe a Part B product over a Part D alternative. To the extent that this decision is based upon clinical expertise and experience, and consistent with or directed by the patient's priorities and preferences, the decision is one with which Medicare should not interfere. Under the Proposed Rule's resource use methodology, however, the clinician may be penalized. Providers treating a patient population for which this is common could face substantial disincentives.

Office-based Infusion Centers are disproportionately impacted by CMS' Proposed Rule. Regardless of whether the Infusion Center is within the prescribing physician's office or is a dedicated Infusion Center, patient populations are likely more resource-intensive, with Part B therapies carrying a high resource use burden regardless of the actual quality of the care or value of the infusion setting.

As such, NICA urges CMS to delay implementation of the resource use component until stakeholder input has been reviewed, potential solutions can be identified, and an equitable incentive-based methodology can be developed. NICA asks that CMS revise its resource use performance category calculation to remove inappropriate disincentives or pressures on clinician prescribing decisions. The office-based Infusion Centers that patients rely upon to receive essential medical care should not be penalized for administering a prescribed treatment or prescribing a medically necessary therapy that is the best option for a particular patient. We suggest that CMS ensures that (1) MIPS implementation does not discourage infusion providers from treating some of our sickest Medicare patients; and, (2) the resource use calculation does not penalize infusion providers for delivering high quality, cost-effective care to these patients.

In the event that stakeholder comments to the Proposed Rule identify reasonable alternative solutions for equitable resource use calculation, we urge CMS to present these options through notice and comment rulemaking so that stakeholders have a meaningful opportunity to comment on this significant component of the MIPS.

The MIPS methodology may incorrectly identify infusion providers as low performers subject to negative payment adjustments.

As proposed, the resource use performance category appears to ask the question "Are patients in this office more expensive to treat than other patients?" The answer to that question will, with respect to office-based Infusion Centers, almost always be affirmative, yet irrelevant to quality or value. The salient question is "Are these patients more expensive to treat in this office than in other settings?"

Office-based Infusion Centers generally treat a subset of patients that are sicker and more expensive to treat than the overall patient population. Clinicians treating these patients may have a disproportionate number of patients with poor outcome measures that are associated with high care costs. It is difficult to imagine a scenario under which these practices would not fall below the performance threshold and subjected to year-over-year negative payment adjustments, regardless of the actual quality of care delivered to their specific patient population.

NICA asserts that if the result of the MIPS is to render office-based Infusion Center participation in Medicare infeasible from a financial perspective, the Proposed Rule will have failed to meet its goals of quality, value, and patient-centeredness with respect to administration of Part B drugs. We understand that there may be a variety of mechanisms available to ensure equitability, including patient relationship categories and resource-use exclusions that are currently available to non-patient-facing clinicians.

NICA and its infusion provider partners are eager to work with CMS to devise equitable mechanisms to incorporate the realities of office-based Infusion Center practices into MIPS so that Medicare beneficiaries retain access to this critical service.

The quality component of the MIPS composite score may not have sufficient or sufficiently relevant measures to enable high levels of performance.

NICA is concerned that many office-based Infusion Centers, particularly dedicated infusion centers, will have difficulty identifying quality measures that are relevant to the services they provide. We note that CMS proposes that any provider with fewer than three scored quality measures for a performance period, would be considered to have insufficient measures for the 2019 MIPS payment year quality performance category weight. For these office-based Infusion Centers, CMS proposes to reduce the weight of the quality category from 50% to 40% and redistribute the weight proportionately to the other performance categories.

NICA urges CMS to recognize that office-based Infusion Centers provide a necessary, valuable service to Medicare beneficiaries with chronic, life-limiting, and/or life-threatening diseases that required infused drug and biologic products. We understand that the MIPS measures and categories may not have been designed to accommodate the office-based Infusion Center care delivery model. It would be fundamentally unfair, however, to penalize providers for falling outside the parameters CMS considered in its MIPS proposal.

NICA is further concerned that those office-based Infusion Centers for which general quality measures may exist treat a preponderance of patients with rare diseases or complex conditions that have few, if any, reliable quality measures. We urge CMS to give careful consideration to these Infusion Centers so that the MIPS requirements do not unduly penalize them based on their patient population, or create disincentives for treating Medicare beneficiaries with rare diseases, multiple chronic conditions, or comorbidities.

NICA and its infusion provider partners are committed to delivering high quality care that is cost-effective and patient-centered. We welcome the opportunity to work with CMS toward a set of quality measures, clinical improvement activities, and meaningful use measures that reflect excellence in office-based Infusion Center care. In the interim, if CMS intends to finalize its MACRA rule for January 1, 2017 implementation, we would appreciate the opportunity to work with the Agency toward identifying means through which office-based Infusion Centers can appropriately utilize the MIPS structure to demonstrate the quality of care they provide.

Conclusion

NICA appreciates the opportunity to submit its comments on behalf of the office-based Infusion Centers serving the Medicare population. We are eager to work with CMS toward resolving the issues and concerns expressed in this letter.

Respectfully,

BRIAN NYQUIST, MPH | EXECUTIVE DIRECTOR
NATIONAL INFUSION CENTER ASSOCIATION