INFUSION PROVIDERS ALLIANCE

440 1st Street NW, Suite 430
Washington, DC 20001

September 11, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2024 (CMS-1784-P)

The Infusion Providers Alliance (IPA) is pleased to provide comments regarding the direct supervision flexibility that has been granted during the public health emergency (PHE), the downcoding of certain complex biological therapies by Medicare Administrative Contractors, and challenges regarding the Self-Administered Drug (SAD) Exclusion list, as proposed in the CY 2024 Physician Fee Schedule.

Background on the Infusion Provider Alliance

The IPA is a leading voice for in-office and freestanding ambulatory infusion providers, with nearly 1,000 community-based, non-hospital sites across 43 states. Our members are committed to preserving the integrity of the provider-patient relationship in a manner that delivers exceptional care to patients and value to the health care system, typically saving Medicare more than 50 cents on the dollar per infusion compared to hospital administration. Our facilities are major access points of care for patients with complex and chronic health conditions in communities, large and small. The IPA's mission is to serve as a thought leader and to educate on issues critical to safeguarding, supporting, and strengthening provider-directed, patient-focused access to infused medications. More information about IPA can be found on our website: www.infusionprovidersalliance.org.

Overview of IPA Comments

The IPA's comments focus on three issues:

1. CMS should extend the virtual direct supervision flexibility for an additional year to preserve patient safety and maintain a nimble health care ecosystem in the face of future pandemics. We have included updated data that continues to show no clinically meaningful statistical difference in patient outcomes for virtual direct supervision as compared to direct supervision.

2. CMS should adopt a national criteria for determining "complex" drug administration that properly encompasses non-chemotherapy drugs that are similarly resource-intensive as cancer drugs and direct Medicare Administrative Contractors (MACs) to reverse the downcoding of certain complex therapies for chronic and complex diseases, as those decisions are arbitrary and undervalue the significant nurse time and intensity required to provide these products.

3. CMS should revise its application of the SAD Exclusion List to ensure it does not hinder patient access to physician-administered therapies for specific populations that cannot self-administer. The decision-making process of MACs to exclude self-administered drugs should have more oversight, transparency, and consistency, as it has a direct impact on patients and their ability to access certain treatments.

Flexibility for Direct Supervision Requirements Protects Patients and Access to Care

The IPA was supportive of the Centers for Medicare and Medicaid Services' (CMS) decision to change the definition of "direct supervision" to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, during and beyond the PHE. We appreciate CMS's intention to extend this flexibility for 2024, as the most recent year's experience with this approach has yielded additional data that demonstrates virtual direct supervision is a useful and sage way to ensure consistent patient access to care with no adverse clinical impact to patients.

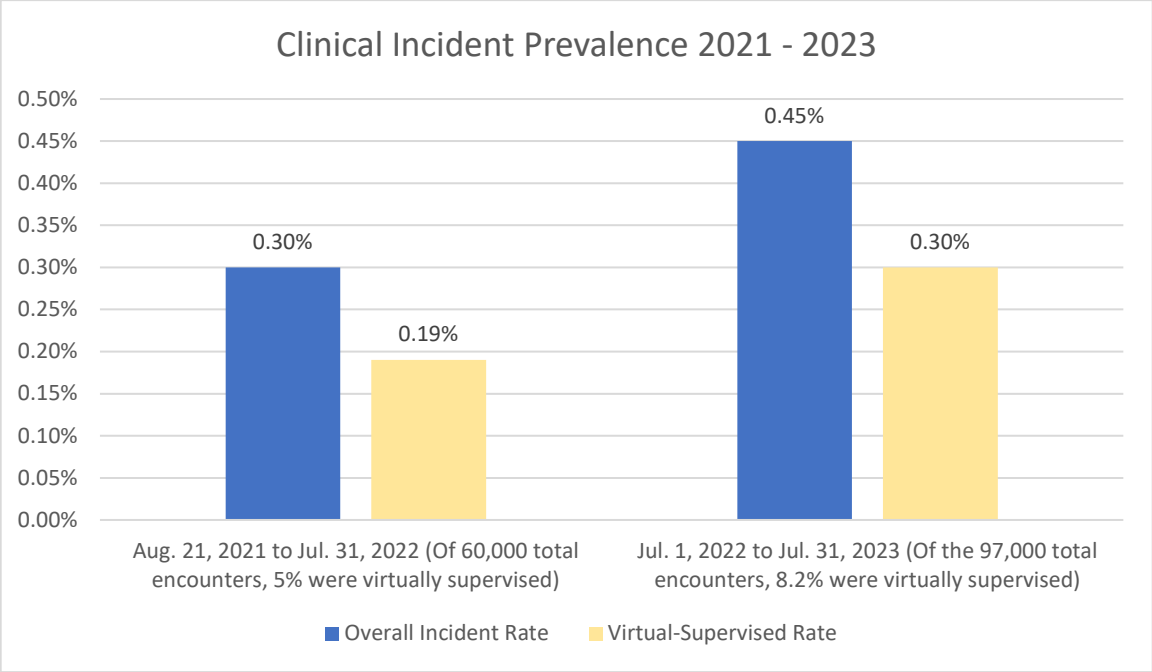
We wish to reiterate from our previous comments that this flexibility ensures that vulnerable patients are able to be treated safely in freestanding infusion centers and physician offices, rather than in hospitals where patients, especially those who are immunocompromised, are more likely to be exposed to other illnesses and infections. The majority of patients who receive infusion therapies suffer from conditions such as Crohn's Disease, Multiple Sclerosis, and Rheumatoid Arthritis, and they typically have weakened immune systems that leave them vulnerable to infections so receiving treatment at freestanding infusion centers and physician offices diminishes these risks. Maintaining flexibilities that promote easy accessibility to care at less risky sites is key to ensuring that our most vulnerable patients are not put at unnecessary risk for treatment.

Furthermore, while the COVID pandemic has been declared over, cases are now on the rise and it remains unclear whether the nation will be confronting another wave of COVID cases this winter. Furthermore, it is important to note how the pandemic outbreak strained and overwhelmed our hospital systems, creating dire patient access issues and threatening the health of many who faced increased risk of exposure when getting infusions at these settings. It is imperative to ensure that our national health care system has flexibilities in place that will allow multiple sites of care to be able to operate effectively and efficiently, especially during future pandemics. Maintaining the virtual direct supervision flexibility will allow freestanding infusion centers to effectively treat current patients, while also standing ready to take on more patients in 2024, as needed.

In last year's comments for the 2023 Physician Fee Schedule, we discussed how the flexibility allows highly trained Registered Nurses (RNs) to safely provide services to patients while Nurse Practitioners conduct virtual supervision for these encounters. This was particularly helpful when a nurse practitioner (or family member) became ill or COVID positive and could not be present in a clinical situation with fragile patients. Notwithstanding this important flexibility, it is important to note that freestanding infusion centers utilize this flexibility only as needed; their business models are not built around virtual supervision. The vast majority of cases continue to be monitored in-person by nurse practitioners. Indeed, infusion centers only use the flexibility in situations where NPs call out sick or are otherwise not able to be onsite, which helps reduce the number of patients who would have to be rescheduled and potentially miss or delay a vital infusion dose. Adhering to the treatment plans is vital for the many chronically ill patients who receive infusions.

It is also vital that disruption due to staffing shortages are kept to a minimum and virtual direct supervision flexibilities remain in place to limit potential patient care disruptions. The flexibility is especially critical as our country's physician and nurse practitioner shortages continue to get worse. According to the Association of American Medical Colleges, by 2034 the demand for physicians will exceed supply by a range of 37,000 to 124,000[1], which means the demand for NPs will continue to grow. The U.S. Bureau of Labor Statistics notes that by 2031 the job outlook for NPs will see a 40 percent growth rate, meaning that 118,600 jobs will need to be filled.[2] Effective and safe utilization of virtual direct supervision will allow for efficient use of available NPs while also reducing burnout and allow for better care of patients.

In last year's comments, we shared data from a larger member company, which utilized the virtual direct supervision flexibility and found that clinical incidence prevalence to be statistically identical to direct supervision. The same company examined the following year's data (FY 22-23) and found that adverse events remained extremely low. As illustrated in the graph below, the clinical incident prevalence over the last year has continued to remain low at 0.30% for virtually supervised encounters and 0.45% overall, even with an additional 50 percent increase in the number of patient encounters/treatments. For reference, about 8,000 of those encounters were virtually supervised and 89,000 were directly supervised which means virtual direct supervision accounted for about 8.2% of total encounters. Interestingly, virtual supervision actually had lower incident prevalence than direct in both years.

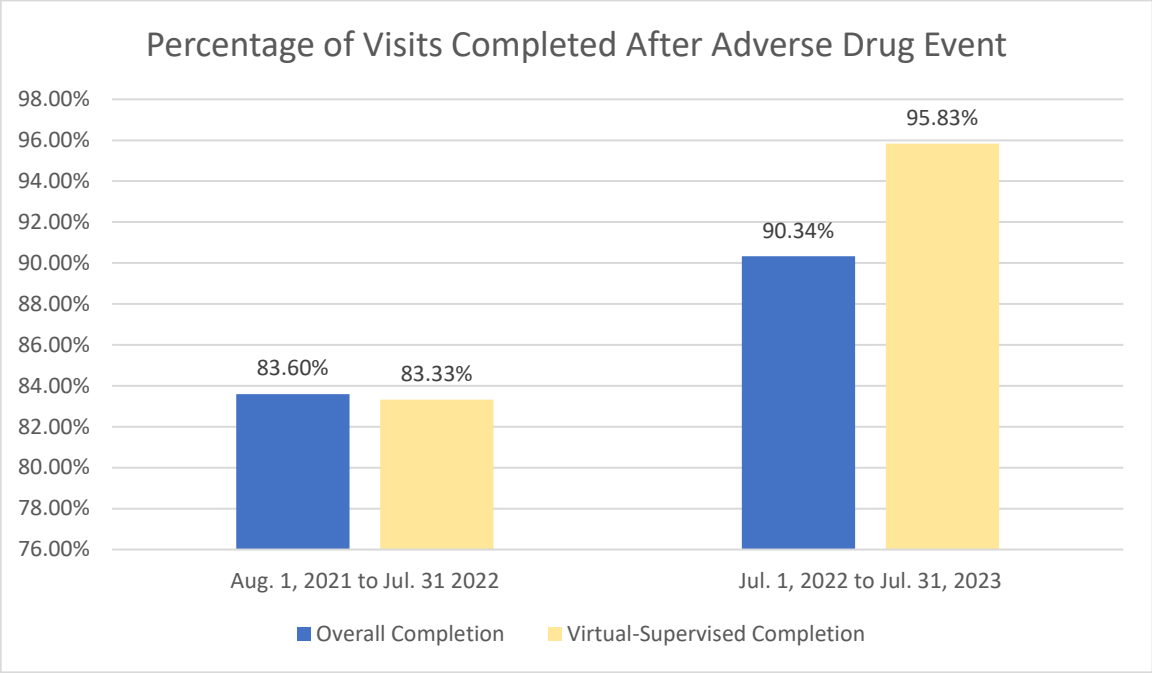


Additionally, as noted in the graph below, the percentage of visits completed after an adverse drug event during a virtually supervised encounter was on par with the overall encounter rate, and over the last year has even surpassed the overall percentage rate, meaning that more patients are able to complete infusions after an adverse drug event (ADE) under virtually supervised encounters than directly

[1] Association of American Medical Colleges. "The Complexities of Physician Supply and Demand: Projections From 2019 to 2034," June 2021

[2] U.S. Bureau of Labor Statistics. "Occupational Outlook Handbook: Nurse Anesthetists, Nurse Midwives, and Nurse Practitioners," 2021.

supervised encounters. This clearly illustrates that the highly trained nurses and NPs that conduct virtual direct supervision can handle these ADEs and therefore there is no degradation of clinical outcomes when it is utilized. The over 90% completion rate after an ADE for both directly and virtually supervised patients goes directly to adherence and patient satisfaction, and strongly supports virtual supervision being a safe adjunct to ambulatory infusion care.



It has been made evident over the last several years that patient safety is not threatened when virtual direct supervision is incorporated into clinical practice. The freestanding infusion centers that utilize this flexibility do so in a setting where clinicians are properly and extensively trained and supported, and incidents are effectively managed to minimize patient safety issues. Members of the IPA continue to judiciously gather incident reports and adjust their policies and practices to curtail these occurrences as much as possible. The IPA would be supportive of CMS requiring the reporting of such data in order for the flexibility to be used on a permanent basis moving forward.

Addressing MAC Downcoding of Certain Complex Biologic Infused Drugs

The IPA thanks CMS for acknowledging the payment issues related to the downcoding of certain non-chemotherapy complex biologic drugs and inviting comment on how to address these inadequate payments. The MACs have arbitrarily downcoded approximately 20 complex biologics relevant to our practices to the less complex "Therapeutic Prophylactic, and Diagnostic Injections and Infusions codes" (CPT 96360-96379) from the correct and long-standing "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration Current Procedural Terminology (CPT) Codes" (CPT 96401-96549). Despite our efforts to work with the MACs on resolving these downcoding issues, and an August 12, 2022 Technical Direction Letter (TDL) from CMS instructing them to no longer downcode these drugs, they were largely unwilling to change their practices or acknowledge the significant amount of time and intensity that providers expend to administer these drugs to some of the most vulnerable patients. These arbitrary drug reclassifications apply to complex chronic diseases such as multiple sclerosis, rheumatoid arthritis, and Crohn's disease, and the drugs used to treat these conditions have

similar risk and administration profiles as drugs used to treat cancer patients. Therefore, it is illogical to downcode these administrations when chemotherapy drugs are not similarly downcoded. The mere fact that a drug is an infused non-oncology biologic is not an indicator of less administration complexity or clinical risk relative to chemotherapy products.

While the IPA agrees that eligible intravenous drugs drug administration services billed under the Chemotherapy Administration CPT code and Other Highly Complex Drug or Highly Complex Biological Agent Administration must exhibit certain resource-intensive characteristics, it is important that this criterion be applied consistently across all drugs and guided by nurse time, specialized training, patient acuity, history of reactions, frequency of adjustments to dosage or infusion rate, and post-administration monitoring. In that vein, CMS should adopt a nationwide approach and direction to the MACs for the coding of highly complex drug, regardless of the disease it is meant to treat. CMS criteria for Highly Complex Biologic Agent or Drug could use the following criteria:

- Drugs that are subject to FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) requirements, which typically require advanced training, specific certifications, and special considerations for preparation, dosage, or disposal. Examples of biologic drugs that fall under this category include eculizumab (Soliris) and natalizumab (Tysabri).
- Monoclonal antibodies used in a noncancer context, as ones used for cancer are not subject to downcoding. Regardless of what the monoclonal antibodies are used to treat, the same pre-medication protocols and monitoring requirements are used.
- Drugs that require extra nurse time for pre-administration or complexity. An examples of this includes edaravone (Radicava) which treats amyotrophic lateral sclerosis (ALS). The pre-administration preparation for this population, which commonly suffers from significant logistical and health equity challenges, often requires not only careful scheduling of dosing days but also close physician and caretaker collaboration, including multiple caretakers to assist in moving the patient in and out of the treatment facility, and documenting and managing substantial changes in patient health status.
- Drugs that have black box warnings, which are the FDA's most stringent warnings for drugs to alert patients and providers of the potential serious side effects, including injury or death. Examples of drugs that fall under this category includes reslizumab (Cinqair), which requires observation after infusion and belatacept (Nulojix), which may put a patient at risk for post-transplant lymphoproliferative disorder (PTLD).

We request that CMS develop and publish in its Program Manual a standardized definition of complex drug administration, with which all MACs must comply. The IPA has developed a draft definition, which is outlined below, for CMS' consideration:

Recommendation	**Notes**
Used in settings, labeled or unlabeled indications requiring clinical work and/or clinical staff monitoring that is well beyond that of therapeutic drug agents. The determination of complexity should consider the totality of patient care associated with the infusion, including incidence of severe adverse patient reactions, and the requirements to maintain ongoing treatment that are typically greater than	The Current Procedural Terminology (CPT) codebook contains the following information and direction for the Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration CPT® codes: *The highly complex infusion of chemotherapy or other drug or biologic agents requires clinical work and/or clinical staff monitoring well beyond that of therapeutic drug agents because the incidence of*

therapeutic drug agents. Such enhanced monitoring also typically requires advanced practice training and competency.	*severe adverse patient reactions are typically greater. Such enhanced monitoring also typically requires advanced practice training and competency.* Complexity needs to take into consideration the disease being treated, the overall picture of care rendered, the mechanism of action of the administered drug agent, and other characteristics of the services beyond the drug alone. Services for many oncology drugs are relatively the same and non-complex if considered in a vacuum but are reasonably considered complex if the disease and the resource requirements of managing the complete infusion administration are taken into consideration.
Has special considerations for dose preparation, dosage, or disposal; and commonly, the infusions entail significant patient risk and frequent monitoring.	The original Local Coverage Article (LCA) text reads: *Has special considerations for preparation, dosage, or disposal; and commonly, the infusions entail significant patient risk and frequent monitoring.* This edit distinguishes preparation of the medication from preparation related to logistics and patient management.
Changes in the infusion rate, prolonged presence of the nurse administering the solution for patient monitoring and infusion adjustments, and frequent conferring with the physician or other qualified health care professional about these issues.	The original LCA text reads*: Changes in the infusion rate, prolonged presence of the nurse administering the solution for patient monitoring and infusion adjustments, and frequent conferring with the physician or other qualified health care professional about these issues.*
Significant pre-treatment and post-treatment encounter considerations requiring ongoing patient and caretaker education, care planning, and pre-administration preparation.	Some biologics require significant resources.
Use in elevated risk patients or patient populations exhibiting characteristics including age, treatment progression, significant comorbidities, and barriers to independent self-care that are at significant risk.	Patients receiving complex biologics have a disproportionate number of comorbidities compared to the general population.

In summary, non-chemotherapy biological drugs should not be downcoded to be paid at a lower rate simply because they are not used to treat cancer. Resource-intensive characteristics should dictate whether or not a drug is considered "complex," not the diagnosis that the therapy is being used to treat. The MACs' decision to reclassify these products does not somehow erase the significant staff time, training and clinical diligence needed to safely administer these biologics to Medicare beneficiaries. All of those things are still required. The only changes worked through reclassifications are devastating cuts in

payments for these drugs when they are administered in the most cost-effective setting: community-based infusion centers and physician offices. The consequence of this decision will be reduced patient access to cost-effective care because physician offices and infusion centers will no longer receive the reimbursement, they require to continue delivering the services. Additionally, CMS should work with the MACs to ensure that the August 2022 TDL is being followed by all to ensure consistency across the country. CMS should also revise the definition of complex drug administration to ensure it properly encompasses the various elements that go into the administration of these biological drugs. In addition, CMS should direct the MACs to permanently rescind and remove all Local Coverage Articles titled "Billing and Coding: Complex Drug Administration," or that have the same intended effect.

Increasing Transparency and Consistency Regarding the SAD Exclusion List

The IPA thanks CMS for the opportunity to comment on the issues surrounding the way MACs reimburse drugs that are subject to the self-administered exclusion. CMS and its MACs have concluded that "not usually self-administered by the patient" means that if more than 50% of the beneficiaries are using the self-administered version of a medication, rather than the physician administered version, then those drugs are added to the SAD Exclusion List and can only be covered through Part D.

First and foremost, the IPA is concerned that the MACs application of the SAD Exclusion list hinders patient access to vital physician-administered biologics. Certain patient populations are not able to self-administer, such as those with physical disabilities, and others face social and economic challenges that prevent them from having a Part D plan. CMS and the MACs should not prevent patient access to crucial physician-administered drugs, simply because half of the beneficiaries that use the drug receive it in a different form. The administration method that best meets the patient's needs is the method that should be used and dictate how the drug is covered.

We would also like to highlight the fact that the 50% regulatory threshold for determining whether a drug is self-administered is a relatively arbitrary one, especially when considering there is a lack of explanation and transparency around how this number was decided and on how CMS and the MACs make decisions for what should and shouldn't be added to the SAD Exclusion list. CMS should establish a transparent analytical framework for MAC decision-making on determining if a product is "not usually" self-administered. This framework can implement certain requirements that MACs must complete before they can add a drug to the SAD Exclusion list, such as reviewing FDA-approved labels for drugs to determine whether or not they must be self-administered, conducting a quantitative review of data claims as part of its determination process, and publicly posting detailed explanations for how and why a product is determined to be "usually" self-administered. These are just several examples of different criteria CMS can impose on MACs to ensure there is more transparency and consistency for patients seeking treatment.

Conclusion

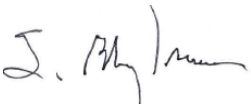
The IPA asks CMS to extend the virtual direct supervision flexibility that has been used by practices since the PHE began in 2020 and has proved to be a safe and effective way to treat patients while supporting our health care workforce to 2025. CMS should also address the MAC downcoding issues for non-chemotherapy complex biologicals, which require intense levels of care that take up a lot of time and energy for practices, so should be reimbursed accordingly. Lastly, CMS should implement changes to the way MACs are applying the SAD Exclusion list to ensure patient access to physician-administered drugs

are not being hindered unnecessarily, and to increase transparency and consistency in the MACs' process for making list determinations.

We thank you for your time and consideration.

Sincerely,

Doug Ghertner
President
Infusion Providers Alliance



Brad Traverse
Executive Director
Infusion Provider Alliance
Brad.Traverse@infusionprovidersalliance.org