INFUSION PROVIDERS ALLIANCE

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September 6, 2022

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

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (CMS-1770-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), changes to the way monoclonal antibodies are covered and reimbursed, the downcoding of certain complex biological therapies by Medicare Administrative Contractors, and the use of JW modifiers, as well as the creation of the JZ modifier, as proposed in the CY 2023 Physician Fee Schedule.

Background on the Infusion Provider Alliance

The IPA is the leading voice for in-office and freestanding ambulatory infusion providers, with over 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 comments focus on four issues:

1. CMS should continue the flexibility regarding direct supervision even after the Public Health Emergency is terminated in order to enhance patient access to care and address worker shortages; our analysis shows no statistical difference in patient outcomes from virtual supervision and in-person supervision.

2. CMS should continue to pay administrative costs for the provision of monoclonal antibodies at the appropriate higher rate even after the PHE and EUA are terminated because these products require significant nurse intensity and monitoring, and their challenges are not tied to a government declaration.

3. CMS should direct Medicare Administrative Contractors 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, which maintain similar risk/staff intensity profiles as cancer drugs that have not been downcoded.

4. We support CMS using the JW modifier to determine manufacturer rebate liability for discarded drug but believe the creation and use of a new JZ modifier is burdensome and unnecessary to implement the vial size provision (Section 90004) of the Infrastructure, Investment and Jobs Act.

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, through the PHE. We also support making this flexibility permanent beyond the PHE, as it has demonstrated to be a useful and safe way to ensure patient access to care.
This flexibility has allowed our members to better serve patients throughout the COVID-19 pandemic and ensures that vulnerable patients are able to be treated safely in freestanding infusion centers and physician offices. Many patients taking infusion therapies for conditions such as Crohn's Disease, Multiple Sclerosis, and Rheumatoid Arthritis have weakened immune systems that make them vulnerable to infections. Even though COVID-19 infection rates are declining, hospitals remain lightning rods for other illness and infections, as the sickest patients tend to seek care at these sites. The immunocompromised patients that receive infusions are much better off getting their treatment in settings away from hospitals, such as freestanding infusion centers and physician offices, where they are less likely to contract other diseases. Maintaining flexibilities that promote easy accessibility to care at less threatening sites is key to ensuring that our most vulnerable patients are not put at unnecessary risk for treatment.

Furthermore, when hospitals were in need of additional space and infrastructure to treat the influx of COVID-19 patients during surges, our centers and physician offices were able to take on their outpatient infusion patients, ensuring that the hospitals had adequate capacity to focus on those COVID-19 and other high-severity patients. As this pandemic illustrated, it is imperative to have a health care system with flexibilities in place that allow

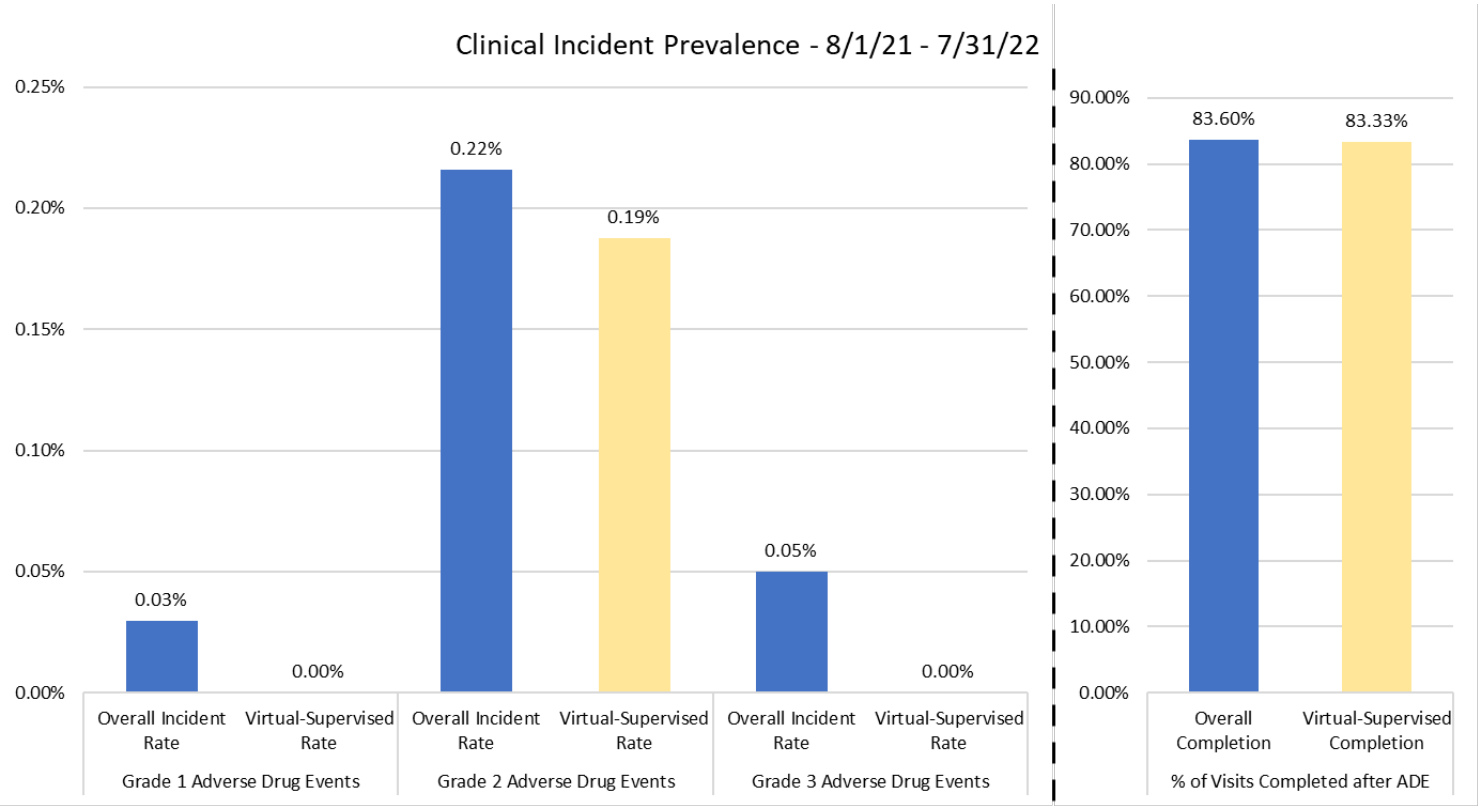
multiple sites of care to be able to operate efficiently and effectively. While we might be nearing the end of the COVID-19 pandemic, other future exigencies and public health threats are inevitable, so maintaining this direct supervision flexibility will allow freestanding infusion centers to effectively treat current patients, but also stand ready to take on more patients in the future if the need arises.

Freestanding infusion centers often utilize Nurse Practitioners (NPs) to provide direct supervision to Medicare beneficiaries in order to bill for infusion services under Medicare Part B, as was required by the Medicare administration and billing CPT codes[1] prior to the March 31, 2020 COVID-19 IFC.[2] NPs, like all members of the general population, are susceptible to COVID-19 and other illnesses that could prevent them from being able to physically report to work in the infusion center to treat these vulnerable patients. However, under the new flexibility highly trained Registered Nurses (RNs) are able to step in and safely provide services to patients while these NPs provide virtual supervision from the safety of their home. It is also worth noting that NP supervision is not required at all for home infusion services, and RNs frequently independently furnish infusion care in the home, which are arguably higher risk settings of care for a reaction. Allowing RNs at infusion centers to administer infusions under the virtual direct supervision of an NP not only keeps patients safe, but also prevents a myriad of logistical issues as patients who were scheduled to receive infusions that day would have to be rescheduled, potentially missing or delaying a vital infusion. It is critical that patients who are treated with these infusions adhere to their treatment plan and missing or delaying doses could be detrimental to their short- and long-term health. The virtual direct supervision flexibility affords freestanding infusion centers the assurance that patients stay on treatment even if the primary NP calls in sick or is unable to come in that day, as is sometimes the case. This scheduling flexibility is important regardless of whether a Public Health Emergency exists.

We would like to share data from one of our larger member companies who utilized the virtual supervision flexibility. This company examined more than 60,000 encounters between August 2021 and August 2022 and found that approximately 5% of those encounters were virtually supervised. Importantly, the data showed no increase in the incidence of adverse events, which is a very small number to begin with. The below graph illustrates this point, with no statistically significant difference between the two approaches, as the total virtual supervised rate of incidents is 0.19% while the overall rate of incidents is 0.3%. Therefore, patient safety is not threatened when virtual direct supervision is incorporated into clinical practice. Moreover, as the data shows, even when there was an adverse reaction, the percent of encounters completed when virtual supervision was utilized was nearly identical to that of those encounters with in-person supervision. This data supports making the virtual direct supervision flexibility permanent for infusion services, especially at freestanding infusion centers where clinicians are properly trained and supported with the right standard operating procedures and management. If virtual direct supervision was extended or made permanent, freestanding infusions centers would continue to aggressively gather incident reports and implement

[1] 2020 CPT Codebook, p. 732; 42 CFR 410.75
[2] CMS-1744-IFC

policies and procedures that ensure consistent medication mixing and administration. IPA would support CMS requiring the reporting of such data as a condition to continue the policy.



While utilizing the virtual direct supervision flexibility has been safe and effective in the freestanding infusion center of care, as indicated by the above data, this does not necessarily mean that the same could be said about the delivery of care in other settings, most notably, the home. A 2021 study published in JAMA Network Open compared the rate of adverse events in home- and facility-administered biologic infusions and found that there were increased rates of adverse events requiring escalation of care when done in the home.[3] The impressively robust study looked at over 57,000 patients on a variety of healthcare personnel-administered biologics between 2007 and 2017 and found that home infusions showed 25% higher odds for an emergency department visit or hospital admission following the infusion. The study also found 28% increased odds of permanent discontinuation of the biologic after the emergency room or hospital admission. Based on these data, we believe that it is important that CMS further study the safety implications related to administering biologic infusions in the home before extending the option of virtual supervision to the home setting of care. The use of virtual direct supervision in a freestanding infusion center, where the patient is surrounded by trained clinical professionals in a sterile environment, is very different from its use in a home-based

[3] "Comparison of Adverse Events Among Home- vs Facility-Administered Biologic Infusions, 2007-2017." JAMA Network Open, June 2021. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780573

setting. CMS must prioritize the safety of patients and ensure that virtual direct supervision is only used in settings of care where it is appropriate.

Supporting the Health Care Workforce

Making virtual direct supervision a permanent feature for Medicare would also support our constrained health care workforce, which currently faces shortages across the country. The COVID-19 pandemic has exacerbated the U.S. health care system, and a study by Morning Consult found that nearly 1 in 5 health care workers have quit their jobs during the pandemic and 79% of health care professionals said the national worker shortage has affected them and their place of work.[4] Additionally, a healthcare labor market analysis by Mercer, an asset management firm, predicts that there will be a shortage of 29,400 nurse practitioners by 2025.[5] As health care centers struggle to hire and maintain a workforce robust enough to support the patients they serve, allowing for virtual direct supervision is one way to alleviate some of the stress that these organizations face without impacting patient safety and quality. A recent study by Stanford University found that patients receiving infusions in an office-based setting had a 79 percent adherence rate, compared to 74 percent at the hospital and 64 percent at home.[6] Better drug adherence translates into better disease management and health outcome. Therefore, we must ensure that our workforce is able to adapt and be granted certain flexibilities in order to keep patients in their preferred sites of care.

Addressing Payment and Coverage of Monoclonal Antibodies (MABs)

Additionally, CMS is requesting comments on their proposals relating to payment and coverage of MABs used to treat and prevent COVID-19. The IPA supports reimbursement that maintains adequate coverage of administrative costs associate with furnishing MABs for COVID-19 patients, even beyond when the PHE and EUA are terminated.

Whether the PHE or EUA is declared over by the Administration is not relevant to the resources and intensity required to treat COVID-19 patients, and we expect to continue to treat thousands of COVID-19 patients beyond the end of the EUA and PHE. While the number of COVID-19 patients may diminish over time, it is still vital to ensure that payments adequately cover the increased costs of administering MABs to these resource-intensive patients, who require extra personal protective equipment (PPE) and often reverse airflow rooms, which many facilities invested in during the pandemic. Any changes to reimbursement for administrative costs associated with MABs used for treating COVID-

[4] "Nearly 1 in 5 Health Care Workers Have Quit Their Jobs during the Pandemic." Morning Consult, April 1, 2022, https://morningconsult.com/2021/10/04/health-care-workers-series-part-2-workforce/.
[5] "Demand for Healthcare Workers Will Outpace Supply by 2025: An Analysis of the U.S. Healthcare Labor Market." Mercer Health Provider Advisory, 2018, https://www.mercer.us/our-thinking/career/demand-for-healthcare-workers-will-outpace-supply-by-2025.html
[6] "Home Infliximab Infusions Are Associated With Suboptimal Outcomes Without Cost Savings in Inflammatory Bowel Diseases." The American Journal of Gastroenterology, October 2020, https://journals.lww.com/ajg/Citation/2020/10000/Home_Infliximab_Infusions_Are_Associated_With.26.aspx

19 patients following the EUA is not appropriate and would result in decreased access to MABs for the many patients who will still need them.

If CMS pursues the changes outlined in the proposed rule, the IPA also feels it is inappropriate not to extend the MEI adjustments to the payments for MABs. Clinicians who administer MABs face the same level of inflation that impacts practice costs and wage levels, and therefore should be reimbursed in a way that reflects these challenging economic times. Extending the MEI updates for some services and not others is arbitrary and threatens access to care as practices, such as our freestanding infusion centers, struggle to keep financially afloat. CMS should extend the MEI to include updates for administering MABs, as they should be treated like any other clinician-administered service.

Addressing MAC Downcoding of Certain Complex Biologic Infused Drugs

The IPA wishes to, again, raise concerns about Medicare Administrative Contractors (MACs) arbitrarily downcoding certain complex biologic infused drugs. Specifically, the MACs have 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). We sent a letter to CMS on August 30 along with six other groups (American Gastroenterology Association, Digestive Health Physicians Association, Coalition of State Rheumatology Organizations, Florida Society of Rheumatology, National Infusion Center Association, and the National Organization of Rheumatology Management expressing our concern with this policy.

This downcoding is arbitrary and reclassifies drugs for complex chronic diseases, such as multiple sclerosis, rheumatoid arthritis, and Crohn's disease, that have similar risk and administration profiles as drugs used to treat patients with cancer. However, no chemotherapy drug has been similarly reclassified. Both chemotherapy drugs and biologics used to treat other chronic and complex diseases have serious potential side effects including immediate risk of anaphylaxis or other allergic reactions for which monitoring is required, long-term risk of serious conditions such as osteonecrosis, and development of antibodies such as vedolizumab and ustekinumab that requires close clinical monitoring and/or intervention.

Coding classification decisions should be standardized across diseases and guided by nurse time, specialized training, patient acuity, history of infusion reactions, and physician supervision requirements. Specialized training and time working with patients are essential to ensuring patient safety and reduce the risk of adverse reactions for complex drugs, particularly those that are subject to FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) requirements.

In summary, biologic therapies are used not only for treatment of patients with cancer, but for treatment of patients with other serious and complex diseases including progressive

neurologic diseases, erosive rheumatologic diseases, and devastating gastrointestinal diseases because other treatment modalities have proven ineffective. These biologics are comparable in risk and complexity and require the same intense level of clinical care, specialized training, and monitoring regardless of the particular disease state or chronic condition for which the biologic is being used. Disease states should not prejudice reimbursement when the risks, preparation, specialized training requirements, physician supervision requirements, and toxicity management of products are equivalent whether the biologic is being used to treat a patient with cancer or a patient with multiple sclerosis, rheumatoid arthritis, or Crohn's disease. MAC's should not be downcoding these products[7] and CMS should issue guidance preventing this.

Support Use of JW Modifier to Implement New Rebate on Discarded Drug; Oppose Establishment of New JZ Modifier

As CMS notes, the JW modifier was established in 2003 and providers have been using the JW modifier since January 2017 in order to identify and monitor discarded amounts of separately payable drugs. CMS has been publishing discarded amounts since 2017 and that data provided the policy basis for Section 90004 of the Infrastructure Investment and Jobs Act. The relevant language from the statute:

(B) Determination of discarded amounts
For purposes of subparagraph (A)(i), with respect to a refundable single-dose container or single-use package drug furnished during a quarter, the amount of such drug that was discarded shall be determined based on the amount of such drug that was unused and discarded for each drug on the date of service.

This "vial size" provision had been included in almost every bipartisan drug bill for the past several years before it was identified and selected for inclusion in the Infrastructure Act. While aspects of the policy were under debate (e.g. certain exclusion categories), the methodology to determine the rebate amount was not. It would utilize a long-established reporting system that had been in place and required on all claims since 2017. The physician community did not engage on this provision during the legislative process because no new reporting burdens were ever contemplated or discussed by Congress.

In the proposed rule CMS states, "for consistency with our current billing procedures and to minimize provider burden, we propose using the JW modifier or any successor modifier that includes the same data to determine… discarded billing units of a billing payment code." We support this approach as it's entirely consistent with current reporting and provides the necessary information to implement the new rebates for discarded product.

However, CMS also proposes to use a new "JZ modifier" for drugs in which "there was no discarded amount". This is a new and burdensome policy that is unnecessary to implement the policy. If there is any discarded drug, that will be identified by the JW modifier and the appropriate rebate amount can be calculated from that.

[7] See appendix for list of drugs that have been inappropriately reclassified by the MACs

CMS asserts the JZ modifier is necessary because "We are aware that the JW modifier is often omitted on claims, and it's unclear whether the absence of the JW modifier for a single-dose container drug indicates that there were no discarded amounts or that the modifier was incorrectly omitted from the claim." Yet CMS provides absolutely no data to support the assertion that providers are failing to report a JW modifier and how widespread that is. Providers have no incentive to omit reporting the JW modifier and have been adhering to the regulation for the last six years while the requirement has been in place without any previously stated concern from CMS on potential omissions.

The IPA objects to this new requirement as extraneous, burdensome and unnecessary to implement the provision. At the very least, CMS should delay implementation of the JZ modifier for a year and rely on the familiar JW modifier which provides the entire basis for the new rebate policy and does not risk any discarded product from being unreported.

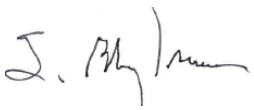
Conclusion

The IPA asks that CMS move forward with making the temporary exception to allow immediate availability for direct supervision through virtual presence permanent, beyond the end of the year that the PHE ends, as it currently stands. This direct supervision flexibility will ensure that patients continue to safely receive the care they need, when they need it, while also continuing to mitigate some of the workforce shortage challenges that continue to plague the health care system. CMS should also re-evaluate their approach to MABs coverage and reimbursement and ensure that the increased costs associate with administering the drugs is accounted for. CMS should work with MACs to ensure that complex biologic products that require intense levels of care are not downcoded but are classified similarly to how other similar products are, such as chemotherapies. Lastly, CMS should use the JW modifier but not establish a new JZ modifier to implement the new vial size provision in the Infrastructure Act.

We thank you for your time and consideration.

Sincerely,

Doug Ghertner
President
Infusion Providers Alliance



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