



September 6, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

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)

Submitted electronically

Dear Administrator Brooks-LaSure:

Biocom California appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule, *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* (“the Proposed Rule”)¹.

Biocom California is the largest, most experienced leader and advocate for California’s life science sector, which includes biotechnology, pharmaceutical, medical device, genomics, and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors, and service providers. With more than 1,600 members dedicated to improving health and quality of life, Biocom California drives public policy initiatives to positively influence the state’s life science community in the research, development, and delivery of innovative products. California’s life sciences industry generates over \$400 billion in annual economic activity, supports almost 1.4 million jobs, and increases labor income by \$131 billion per year².

¹ Federal Register, 87 FR 45860, pp. 45860-46842, July 29, 2022.

² Biocom California 2021 Economic Impact Report Databook. <https://www.biocom.org/eir/>



Summary of Comments

- Biocom California supports CMS's proposal to make several telehealth services currently temporarily available under the PHE permanent and applauds the inclusion of these services on the CY 2023 Fee schedule. We appreciate the agency's deference to provider's discretion for when to use telehealth visits or in-person visits based on which might be most effective for patients and their conditions. We support CMS's proposed efforts to implement the telehealth provisions in the Consolidated Appropriations Act (CAA) 2022 and we agree with CMS's decision to extend some flexibilities in place for an additional 151 days after the end of the PHE.
- Biocom California believes that CMS should exclude self-administered drugs from the wastage provisions of the proposed rule. We appreciate the agency's consideration that certain drugs may require a higher applicable percentage wastage threshold and we encourage CMS to create an administrative system to engage with manufacturers directly to discuss a drug's characteristics and whether the higher wastage threshold is applicable on a case-by-case basis. Lastly, we support the agency's establishment of a formal appeals mechanism that includes refund report disputes and disputes related to the CMS's denial of a request for a higher applicable percentage wastage threshold.
- Biocom California does not support the proposed payment changes for skin substitute products (SSPs) as these may have the ability to disincentivize innovation for manufacturers in this space and, more importantly, impact a patient's access to wound care management. We encourage CMS to reconsider their proposed payment changes for SSPs and we suggest the agency continue working with stakeholders throughout CY 2023 to develop a more comprehensive approach that does not disincentivize the industry nor reduce patient access to high quality skin substitute products.
- While Biocom California appreciates CMS's efforts to support and expand remote therapeutic monitoring (RTM) services to Medicare beneficiaries, we do not believe a 16-day data reporting requirement for RTM code billing is necessary. We suggest that CMS shorten this data collection requirement and we encourage the agency to reconsider this timeframe for different clinical scenarios.

Telehealth Expansion

Biocom California believes that telehealth can improve patient access to healthcare services and that the telehealth flexibilities created during the public health emergency (PHE), such as easing site of origin restrictions and facilitating cross-state licensure, should be made permanent. Since the PHE was declared in early 2020, telehealth has played a central role in the response to the COVID-19 pandemic. Telehealth services have become a crucial tool in helping patients safely navigate the healthcare system and these services have provided vulnerable patients with safe methods of receiving care that does not jeopardize their risk of contracting COVID-19. Telehealth visits have proven helpful for patients to continue to receive care during the PHE and they provide patients with more accessible healthcare options that can be easily integrated into their lifestyle.

We note that in some cases, telehealth is best used as a complement to in-person care when physical assessment is critical for accurate screening, diagnosis, and treatment of certain patients and conditions. As CMS noted in the proposed rule, patient populations “...may require close observation of their movements within all of their environmental cues, which include, for instance, smell, sound, and colors around the room” and that “two-way, audio and video communications technology would not fully capture these behavioral nuances.” **Both telehealth and face-to-face visits remain an essential part of healthcare during and after the PHE. We appreciate the agency's deference to provider's discretion to determine when to use telehealth visits or in-person visits based on which might be most effective for the patient and their care.**

Lastly, we also support CMS’s proposed efforts to implement the telehealth provisions in the CAA 2022 via instructions or guidance to facilitate a smooth transition after the end of the PHE. A smooth transition will help minimize lapses in patient care, and we agree with CMS’s decision to extend some flexibilities in place for an additional 151 days after the end of the PHE.

Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Biocom California acknowledges CMS’s proposed rule to reduce vial wastage by requiring manufacturers of certain drugs to provide a refund to CMS for discarded amounts from certain single-dose containers or single-use packaging. The proposed rule states that FDA-approved labeling will be used to determine single-dose packaging for drugs where the refund requirement applies and, certain drugs such as radiopharmaceuticals, imaging products, and drugs that require filtration before the administration will be excluded from the policy. However, the proposed rule does not specify whether self-administered drugs (i.e., drugs not administered by the billing supplier), which are paid for under Medicare Part B, will be included or excluded from the proposed wastage provisions. **We believe that self-administered drugs should be excluded from the discarded drug provisions since it would be difficult to hold Medicare suppliers, providers and manufacturers to the drug wastage reporting standards described in the proposed rule; especially in the case where the patient beneficiary self-administers the drug. Under these circumstances, reporting vial wastage would present an increased burden for all stakeholders.**

Additionally, the proposed rule states that “...in the case of a refundable single dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary.”³ While CMS does not intend to increase the applicable percentage for drugs with “unique circumstances” at this time, we appreciate the agency’s acknowledgment that certain drugs with may exceed the 10% wastage threshold based on the properties of the administered drug itself, which would lead to a higher percentage of discarded units. In the proposed rule, the example of the drug reconstituted in a hydrogel illustrates this point as the hydrogel would have an increased viscosity and would result in greater drug wastage upon administration.

³ Federal Register, 87 FR 46061, July 29, 2022

We suggest that CMS adopt a higher applicable percentage wastage threshold for drugs under these unique circumstances (e.g., drugs diluted in a hydrogel). In addition to the example provided in the proposed rule, this increased threshold may be applicable to other types of drugs with unique circumstances. We encourage CMS to create an administrative system where drug manufacturers may engage in a conversation with the agency regarding their drug’s unique circumstances and whether the higher applicable percentage may be appropriate. We believe this system will increase transparency and facilitate discussions more effectively between manufacturers and CMS to assess drugs and their vial wastage.

Lastly, in the proposed rule, CMS recognizes the need for establishing a formal dispute resolution process for the successful implementation of the drug wastage provision. **Biocom California supports the agency’s creation of an appeal mechanism that will allow manufacturers the opportunity to dispute a refund report by submitting an error report and we suggest that this same mechanism also include disputes related to CMS’s denial of a request for a higher applicable wastage threshold. Lastly, we recommend that this dispute mechanism be simple to use and can be referenced easily by drug manufacturers.** As mentioned in the previous comment, we believe formal administrative processes as such will increase transparency and facilitate discussions more efficiently between drug manufacturers and CMS.

Payment for Skin Substitutes

Under the proposed rule, CMS will replace the term “skin substitute” with “wound care management products” and will consider these products as “incident to supplies.”⁴ The agency proposes shifting away from the Average Sales Price (ASP) +6% payment methodology and, instead, CMS intends to bundle “the costs of these products as resource inputs in establishing practice expense [resource value units] for associated physician’s services effective January 1, 2024.” This would mean that CMS would stop reimbursing separately for a diverse group of skin substitute products, and instead bundle them together as “supplies” for reimbursement purposes, regardless of their regulatory approvals, efficacy, and clinical outcomes.

Biocom California strongly disagrees with this approach because not all skin substitute products (SSPs) have identical indications for use nor are clinically interchangeable. While some products are simple wound covering supplies requiring minimal Food and Drug Administration (FDA) oversight, some products are complex biologic agents that have undergone rigorous FDA premarket review (i.e., premarket approval applications) and are indicated for the healing of chronic wounds.

We are concerned that the proposed approach could create inappropriate incentives to delay treatment of patients with multiple wounds (i.e., treating one ulcer per visit) or physicians could use an insufficient amount of SSP to treat wounds in their entirety. Bundling payment to cover both the product and the procedure (i.e., the application of the product to the wound) may create a financial incentive for providers to use less expensive and, possibly less effective, SSPs. Ultimately, these policy changes may restrict a patient’s access to the most appropriate products needed for effective care and could result in negative health outcomes for minority Medicare beneficiaries who have multiple co-morbidities which involve chronic wound care treatment and management.

⁴ Federal Register, 87 FR 46029, July 29, 2022

Additionally, the proposed changes to payment methodology may disincentivize manufacturers from investing in research and development and undertaking the regulatory burden to bring innovative products to market in this space. **Biocom California does not believe that the proposed reimbursement approach is commensurate to the cost of research and development in this sector and the lengthy FDA clearance/approval process for some of these products.**

Furthermore, while the proposed rule provides the CPT Code 15271 example demonstrating how the practice expense relative value units (PE RVU) would be determined for a SSP, **Biocom California is concerned by the agency’s lack of proposed PE RVUs for skin substitute application procedures (CPT codes 15271-15278). We believe the agency should provide more granular reimbursement details for these products if they would like stakeholders to have informed comments on the proposed payment changes. This lack of information further reaffirms our position that the agency should postpone finalizing changes to the payment for SSPs in the CY 2023 Physician Fee Schedule. We recommend that CMS transparently engage with external stakeholders throughout CY 2023 to work together on developing comprehensive policies.**

We encourage CMS to reconsider their proposed payment changes for SSPs and we suggest the agency continue working with stakeholders throughout CY 2023 to develop a more comprehensive approach that does not disincentivize the industry nor reduce patient access to high quality skin substitute products.

Remote Therapeutic Monitoring

Biocom California supports increased patient access to remote therapeutic monitoring (RTM) services and we appreciate CMS’s efforts in facilitating home-based care for Medicare beneficiaries. In doing so, the agency is allowing vulnerable populations to receive care at home and reduce their potential risks during the PHE.

In the rule, the agency proposes the creation of four new HCPCS G Codes (GRTM1, GRTM2, GRTM3, GRTM4) for RTM and GRTM1 and GRTM3 require that “at least 16 days of data must be reported.”⁵ **We do not agree with the 16-day data reporting requirement as it would limit the ability of providers to report these services, especially when providers have little control over whether a patient will fulfill 16 days of medical device use for RTM.** Additionally, for some clinical scenarios, 16 days of monitoring data is not needed, and **we encourage the agency to explore the different clinical scenarios and shorten this requirement to account for data that can be collected and monitored in less time.**

⁵ Federal Register, 87 FR 46025, July 29, 2022

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. Please contact Biocom California's Associate Manager of Regulatory Policy, Zoe Bilis, at zbilis@biocom.org for additional information or questions. We look forward to continuing to work with you on this critical matter.

Sincerely,

A handwritten signature in black ink, reading "Joe D. Panetta". The signature is written in a cursive style and is enclosed within a light gray rectangular border.

Joe Panetta
President and CEO
Biocom California