SUBMITTED VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1744-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Re: RIN 0938-AU31 Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

May 30, 2020

To Whom It May Concern,

On behalf of the 30 million Americans who live with a rare disease or condition, we write to comment on the Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, Interim Final Rule with Comment Period (IFC). Specifically, we wish to focus our comments on the actions being taken to ensure patients continue to have the option for access to in-home services, including home infusion and injection services as well as telehealth, during the COVID-19 public health emergency. Many members of our community are at higher risk of contracting or experiencing complications from COVID-19 but must continue to receive infusion care during these unprecedented times. For these individuals, reliable access to home infusion and injection services is life-sustaining. Further, telehealth has enabled members of our community to access needed care while mitigating the risk of infection during the COVID-19 crisis. We commend CMS’s quick actions to loosen restrictions on the provision of telehealth in the Medicare program and ask you to consider fully the most appropriate services that can and should be delivered remotely.

We applaud CMS for taking actions under the IFC to facilitate greater access to home infusion services by broadening the definition of “homebound” for Medicare patients, expanding access to telehealth, and permitting providers to contract with third-party home health agencies to support home-based infusion care. While these actions have been critical, we are hearing continued concerns from members of the rare disease community regarding the ability of patients to truly access this in-home infusion care. Specifically, we are concerned about providers’ ability to implement the policy changes, particularly those who have minimal experience using telehealth tools and those who do not have existing relationships with home
health agencies. Furthermore, we share the concerns of others that the work-around does not fully capture the level of care provided by specialty trained home infusion care providers, potentially resulting in modest use of these new authorities.

As you work to update this IFC and take subsequent actions to ensure access to care during the public health emergency, we urge you to consider addressing the following points:

- Clarify the scope of drugs covered during the public health emergency and ensure the policy includes all clinically appropriate infusion and injection drugs that should be administered in the home during the emergency.

- Ensure the policy fully covers home infusion equipment, supplies, and professional services. For the duration of the current public health emergency, Medicare should cover all essential elements of home infusion for drugs, including those billed to the Medicare Part D program, upon receipt of a physician order. CMS should provide clearer guidance on this process given the patchwork nature of current Medicare home infusion policies that cut across home health and the durable medical equipment (DME) benefits.

- Clarify that flexibilities for the delivery of care in the home apply to injection services as well as infusions. Some patients who routinely receive injections in the outpatient setting may be unable to access this care due to risk of infection outside the home. For example, patients suffering from neuroendocrine disorders require monthly injections that are typically delivered by a doctor or a nurse in the office setting. However, these injections can be administered by a provider or even self-administered in the home. We request that CMS further clarify the IFC to address injectable drugs in these situations.

- Consider expanded access to appropriate telehealth, home infusion, and home injection services as the country enters a stage of reopening. For patients with underlying conditions who are more at risk of developing complications from COVID-19, access to remote care for certain services may be necessary even after the rest of the country returns to “normal.” CMS should consider the experience of patients during the COVID-19 pandemic to inform continued or expanded policies around the provision of remote care.

- Overall, ensure that the emergency policy allows for the most complete and efficient delivery of home infusion care to all Medicare beneficiaries who meet the amended requirements and who have such needs documented in their medical records.
In closing, as we noted, for many Medicare beneficiaries living with a rare disease or condition, access to health care has been greatly disrupted during this public health emergency. It is essential that we work to ensure patients receive the care they need, including care delivered in non-facility settings like the home. We ask that you consider this vital access not only for the duration of the current public health emergency but also as the country begins to reopen, particularly given the “new normal” we will navigate and the continued challenges to vulnerable populations including those impacted by rare diseases and disorders. In the coming weeks and months, as non-emergent care returns and facilities reopen, we ask that CMS recognize continued access to care from the safety of the home setting may be necessary to mitigate their risk of infection for some at-risk patients.

Thank you for your consideration of these requests as you collect and consider comments for an update to this important IFC.

Sincerely,

Julia Jenkins
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EveryLife Foundation for Rare Diseases

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Chief of Policy & Advocacy
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CC: Mark Dant, Board Chairman
Frank J. Sasinowski, Board Vice-Chairman