

# Is CMS Ignoring the Realities of Biopharmaceutical Costs?

*Healthcare Business Today*

April 17, 2023 | Publications

**Richard H. Hughes, IV** and **Mark E. Lutes**, Strategic Advisors with EBG Advisors and Members of the Firm at Epstein Becker Green, along with **William (Will) Walters**, Associate at Epstein Becker Green, co-authored an article in *Healthcare Business Today*, titled “Is CMS Ignoring the Realities of Biopharmaceutical Costs?”

Following is an excerpt:

On March 15, the Centers for Medicare and Medicaid Services (CMS) released guidance on the drug price negotiations provisions of the Inflation Reduction Act (IRA). The guidance contains CMS’s interpretations for a range of elements in the drug price negotiation process, including the manufacturer specific data elements that it will review in potential adjusting its view of the appropriate price.

While other data elements also deserve manufacturers’ attention, CMS’s approach to accounting for manufacturer costs associated with research, development and manufacturing will have profound implications for biopharmaceutical manufacturers. The agency’s proposed factors omit substantial investments while improperly treating others as sunk costs. As innovators prepare to comment on CMS’s guidance, they will want to convey the need for more fulsome consideration of these investments in the upcoming negotiations.

This article originally published on Epstein Becker Green’s *Health Law Advisor blog*, April 4, 2023.

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