COVID-19 Part 3: COVID-19 Relief Efforts and Government Pricing Considerations

The COVID-19 pandemic has created a pressing need not only for medicines that help treat known COVID-19 symptoms and vaccines against the virus, but also significant demand for the treatment of prevalent health issues potentially related to COVID-19, including chronic lung disease, hypertension, and chronic kidney disease. It is critically important for manufacturers supporting COVID-19 relief efforts to carefully evaluate the potential spillover effect that various charitable activities may have on their Government Program ("GP") discount liability.

In light of the massive uncertainty surrounding the COVID-19 pandemic and its far-reaching effects, it is increasingly important for manufacturers to accurately understand the impact that different types of transactions may have on their GP discount liabilities, as a key part of their overall gross-to-net considerations.

At Riparian, our mission is to provide clarity on such complex issues by thinking more deeply about the potential challenges and implications that may not otherwise be fully considered and by presenting novel solutions to those challenges. This article is part of a multi-part series in which we examine topics relating to the COVID-19 pandemic. In prior installments, we focused on macroeconomic shifts and then changes in market segmentation. In Part 3, we focus now on key factors companies ought to carefully consider when evaluating potential initiatives to support COVID-19 relief efforts.

Manufacturers are demonstrating significant innovation, ingenuity, and philanthropy during this challenging time. Already, they have ramped up manufacturing capabilities, increased investments in clinical trials, and provided significant cash and in-kind donations. Of course, charitable activities are commendable and encouraged, but it is also important that manufacturers carefully evaluate each charitable opportunity in light of the risk of unintended consequences – specifically, the spillover effect that each type of activity may have on their GP liability.

For example, if a manufacturer would like to donate its drug products directly to hospitals to support the fight against COVID-19, establishing clear guidelines and parameters as to how its products will be donated will mitigate the risk of adversely affecting the pricing metrics that determine its GP liability.

Specifically, pursuant the Medicaid Drug Rebate Program ("MDRP"), branded drug rebates are impacted when a discount on any commercial sale exceeds 23.1% of the drug's Average Manufacturer Price ("AMP"). A discount exceeding this threshold – even for a single unit of a covered outpatient drug, impacts the discount on all Medicaid units. Additionally, the impact also extends to all 340B program units, because 340B discounts are determined on the basis of Medicaid pricing. In theory, this means that, if a manufacturer were to discount a drug to $0 (effectively make it free), every Medicaid and 340B unit would be free as well,[1] and the manufacturer's discount liability under the MDRP and 340B program would skyrocket.

That said, the MDRP rules allow that free goods are excluded from Best Price ("BP"), provided they are not contingent upon any purchase requirement. Consequently, a manufacturer that is providing free product for charitable purposes should ensure that product donations are administered in a manner such that it is clear that there are no "strings" attached, and also that the consideration of the amount of product to be donated to each entity is unrelated to actual or projected purchasing volumes. It is important that the manufacturer is able to ensure that charitable donations are clearly distinguishable from commercial sales incentives. Of note, many manufacturers (especially those that are larger/ more established) set up separate charitable organizations that administer charitable donations of product, which creates a further "separation" between the free product and any perception of potential commercial considerations.

Separately, some manufacturers may be considering selling certain products at cost to support COVID-19 relief efforts. While the MDRP rules provide a pathway for excluding certain nominally-priced sales from BP,[2] this exclusion is specific to the MDRP. Notably, the rules that govern the calculations of other GP metrics and discounts liabilities across the various programs are vastly different.

[1] When Best price discounts are greater than 23.1% of AMP, the Medicaid Unit Rebate Amount ("URA") is equal to AMP less BP (at a minimum). If BP is effectively $0.00, the URA is equal to AMP, and the manufacturer essentially will rebate back to the state Medicaid programs the full amount realized for the product, thereby giving it away for free.

[2] The exclusion is limited to certain safety net providers and to pricing that is less than 10% of AMP.

COVID-19 has, and will continue, to create unique and significant healthcare needs for the foreseeable future. As manufacturers consider the various ways in which they may contribute to COVID-19 relief efforts, it is important to carefully review and evaluate the potential impact that a charitable transaction may have across all relevant programs. As a precautionary measure, manufacturers should undertake a legal review of any contemplated initiatives to mitigate the risk of financial and operational exposure.

About the Author

David S. Chan

Co-Founder & CEO, Riparian LLC

David S. Chan is the Co-Founder and CEO of Riparian LLC, which provides software, outsourcing and consulting solutions to Life Sciences manufacturers. David has overall responsibility for the strategic direction, product development, sales, operations and specific client initiatives. David brings 20 years of experience leading revenue management and contracting teams in the life sciences.

About Our Contributors

Cynthia Hwang

Co-Founder & Senior Vice President, Riparian LLC

Cynthia Hwang is the SVP of Consulting and Managed Services and one of the Co-Founders of Riparian. She has two decades of experience advising a variety of clients in the life sciences industry – including generic drug manufacturers, "traditional" brand drug manufacturers, and manufacturers of specialty therapeutics (including gene therapies). Cynthia is a regular on the speaking circuit covering a variety of operational and compliance matters. Her responsibilities include overseeing the execution of the majority of Riparian's consulting and managed services projects, maintaining high client satisfaction, providing product direction and design, and growing sales.

Susan Dunne

Senior Director

Susan Dunne is the Senior Director and a member of the Riparian leadership team based out of the Virginia / Washington D.C. area. Susan has over 25+ years experience working with life science manufacturers providing support for their interactions with federal pricing programs. Susan has long standing relationships with industry leaders in government, outside law firms, industry executives in large, medium and small pharma, both branded and generic.

Contact Us

Email: info@riparian.com

Website: Riparian.com

Phone: 646-809-4201