COVID-19 Part 2: How Can the Effects of COVID-19 Create Shifts in Market Segmentation & 340B Covered Entities?

Undoubtedly, COVID-19 will leave an unprecedented impact on our economy for months, if not years, to come. While the life sciences industry is on the front lines of battle against COVID-19 working on vaccinations and treatments to combat the virus, manufacturers must understand and prepare for how the shifts in demand and patient populations will impact their Government Program liabilities and Gross-to-Net.

Given the many moving parts associated with the COVID-19 threat, it is challenging to synthesize the impact they will have on life sciences manufacturers. At Riparian, our mission is to reduce turbidity with outside-the-box thinking; we identify challenges that may be less obvious and present novel solutions. With that in mind, we identified a couple of significant strategic considerations resulting from shifts in market segmentation and patient services that can assist life sciences manufacturers in making better forecasting and planning decisions. In Part 2 of our COVID-19 Planning series, we will address the potential impact on near-term strategies caused by significant shifts in demand.

Shifts in Demand by Market Segment. Precautionary measures mandated by the states and undertaken voluntarily by individuals resulted in massive shifts in demand that will have a significant impact on sales within certain market segments in the near term:

- **Massive increase in the use of telehealth and home delivery services**. The response to COVID-19 paved the way for mainstream adoption of telehealth and home delivery of healthcare services. On its Q1 2020 earnings call, CVS Health announced tremendous increases in the use of telemedicine and home delivery of prescription drugs – by approximately 600% and more than 1,000%, respectively, as compared to Q1 2019.
- **Deferral of elective and/or non-emergency procedures reduces demand for certain drugs**. Elective and/or non-emergency procedures are cancelled and/or delayed due to state-mandated restrictions associated with containing COVID-19. As a result, we have

seen utilization for certain physician-administered drugs used for elective and/or non-emergency procedures drop precipitously.

- **Increased demand for antiviral drugs and drugs thought to help COVID-19 patients**. There is increasing demand for certain drugs in trial treatment scenarios such as hydroxychloroquine and remdesivir, or for the treatment of COVID-19 side effects including issues affecting heart, blood pressure, and kidney function.

There is a notable increase in demand for dialysis treatment, and the urgency to obtain dialysis equipment nearly matches that for ventilators. Patients who are diagnosed with End Stage Renal Disease ("ESRD") become Medicare-eligible regardless of age.

When forecasting, manufacturers should anticipate the shifts to Government Program (GP) discount liability, which are determined by manufacturer-reported pricing metrics that measure the price of sales to different market segments as follows:

- If there is a significant change in the mix of sales that are included in the calculation of weighted average prices (e.g. the Medicaid AMP or Average Manufacturer Price) the relevant pricing metrics will fluctuate, even where pricing strategies have not changed. These types of pricing fluctuations could impact manufacturers' GP discount liability.
- Some GP metrics are influenced by whether certain price concessions are "bundled sales arrangements." Bundled sales arrangements are often determined based on contingencies placed on the strength of one product over another. To the extent there are changes to commercial contracting in response to shifts in demand, such changes may necessitate an evaluation of whether the new arrangement qualifies as a "bundled sale," consequently impacting the calculation of key GP pricing metrics. Alternatively, products that historically may not have had significant market strength may now be targeted for a contracting strategy that bundles it with less attractive products, also creating new bundles that need evaluation and appropriate GP treatment and impact forecasting.

Potential Impact on 340B Program Participants: The 340B Drug Discount Program ("340B") provides significant discounts to certain safety-net providers including Disproportionate Share Hospitals ("DSH"), which make up a significant portion of 340B Covered Entities. DSH are granted their covered entity status based on the percentage of low-income inpatient populations and many DSH teeter on the edge of eligibility. Due to COVID-19, general hospital service volumes have plummeted, especially emergency room (ER) services, where many low-income patients typically seek medical treatment. Although the ER is an outpatient service, many DSH rely on the admittance of those low-income ER patients to meet eligibility, and, because COVID has drastically reduced willingness to seek treatment through ER visits, a number of DSH may lose their 340B eligibility in the near term.[1] As a result, a reduction to the number of 340B Covered Entities could reduce demand for 340B purchases which would ultimately reduce manufacturers' 340B discount liability. From a gross-to-net perspective, these hospitals potentially will then access more utilization through their GPO arrangements, impacting the accruals for GPO administrative fees and discounts as well.

While there are alternate scenarios that could see increases in manufacturers' 340B discount liability, in general, manufacturers with varying pricing strategies by market segment should consider working with their GP teams to evaluate and project the potential financial impact of estimated changes to sales across market segments.

In summary, COVID-19 has already begun to create significant shifts in the paradigm of healthcare, and will likely continue, for the foreseeable future. Many of these shifts have the potential to drastically impact gross-to-net for many manufacturers. It is critically important that manufacturers have confidence in their planning and that their forecasting analyses thoroughly considers the various scenarios that are likely to occur in the foreseeable future. In spite of the tremendous uncertainty right now, GP professionals are uniquely positioned to prepare their company leadership for the potential outcomes of such market shifts, and as a result, enhance the reliability of key indicators of GP discount accruals.

References:

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2. Federation of American Hospitals. COVID-19 Alert: Dramatic GDP Reduction Reflects Unprecedented Financial Stress on U.S. Hospitals. https://www.fah.org/fah-ee2-uploads/website/documents/COVID-19_Alert-_Dramatic_GDP_Reduction.pdf
3. Q1 2020 CVS Health Corp Earnings Call. https://s2.q4cdn.com/447711729/files/doc_financials/2020/q1/CVS-1Q-2020-Transcript-Final.pdf

[1] The Federation of American Hospitals has recently reported that the volume of health care services has "plummeted." They note that a reduction in elective services and expanding coverage of other services will potentially impact their DSH percentages and subsequently their ability to stay in the program.

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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.

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