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COVID-19's impact on government programs, commercial contracting, and gross-to-net

Navigate the evolving regulations and current environment

Introduction

The health care and life sciences industries have been at the forefront of the COVID-19 pandemic, with governments, manufacturers, payers, providers, and patients working collaboratively to deal with the economic and health crises at hand. In response, US federal and state governments have introduced widespread changes to existing regulations, touching nearly every government health care program, payer, and provider.

The introduction of regulatory changes will affect both prescription coverage and government program spending and reimbursement. These changes may likely impact the pharmaceutical supply chain, clinical trials, pipeline planning, drug pricing, and the production of nonessential drugs and devices. As manufacturers assess the impact of these changes on their business, they should consider nuances such as therapeutic area, manufacturer distribution, and commercial contracting arrangements. In the following sections, we discuss how these changes have already started to transform the life sciences industry and what government programs and commercial finance executives should consider in the COVID-19 climate.

For many manufacturers, GTN forecasts may be transformed by the rising rate of unemployment, implementation of regulatory changes, and a shift toward a digital model for health care advocacy and delivery. We discuss how regulatory and market changes may affect financial accruals and what factors manufacturers should contemplate when remediating forecasts through 2020 and beyond.

Life sciences regulations and industry trends are changing at a rapid pace. By staying abreast of updates in this fluctuating environment, manufacturers can be more agile in planning, responding, and recovering during this time of evolving market and patient needs.

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Understanding the impact: regulations, payers, channels, and utilization

Medicaid and Medicare Program expansion and growth

As of April 24, 2020, the Congressional Budget Office estimates 27 million individuals will lose employment and another 8 million will drop from the labor force, causing a net loss to lives on employer-sponsored plans.[1] These previously commercially insured lives are likely to shift toward other channels, such as the Affordable Care Act (ACA) marketplace, Medicaid, Medicare, uninsured copay programs, or Consolidated Omnibus Budget Reconciliation Act (COBRA). Additionally, many older individuals enrolled in an employer-sponsored plan for primary insurance are facing furlough or layoffs and may elect to retire early. This could result in an individual's primary insurance changing to Medicare as they fall off employer-sponsored plans.

The Medicaid program is an inherently countercyclical program with an influx of enrollees during times of economic hardship. For example, when the unemployment rate peaked at 10 percent in 2009, Medicaid enrollment was up by 7.8 percent for the year.[2] Sources estimate that the total number of Medicaid enrollees may increase from 71 million to 94 million.[3] In response, the Trump administration is expanding Medicare benefits and boosting payments to state Medicaid programs. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Provider Relief Fund provides for a $50 billion general allocation to support Medicare providers.[4] Simultaneously, the Centers for Medicare & Medicaid Services (CMS) recently released guidance encouraging states to utilize the Medicaid waiver process to expand their Medicaid programs. Regulatory changes and waivers may further increase utilization by Medicare and Medicaid populations. As of May 1, CMS has approved 140 requests for state relief in response to the pandemic through a variety of waivers and amendments.[5] Waivers allow states to expand coverage in a variety of ways including broadening eligibility, updating utilization management requirements, and relaxing various provider and administrative requirements.

The postponement of elective health care procedures and patient reluctance to enter health care settings may, in the short term, partially offset the potential increase in utilization. With the influx of new Medicaid applicants, providers may have difficulties submitting Medicaid claims to state agencies on time, which may result in delays in reimbursement submissions to manufacturers for fee-for-service payments. These scenarios should be closely analyzed, as they have the potential to affect or change a manufacturer's GTN revenue forecasts and models, as noted below.

Further exacerbating total Medicaid claim dollars is the prediction that the Consumer Price Index-Urban (CPI-U), as published by the US Bureau of Labor Statistics, will fall during 2020.[31] CPI-U is a component of the Unit Rebate Amount (URA) calculation, which dictates the reimbursement per Medicaid unit that manufacturers owe to states. Drugs are subject to an additional discount if the price of the drug has risen faster than the rate of inflation over time. Decreases in the CPI-U may cause proportional increases in the additional rebate for drugs where prices are already outpacing inflation and could cause an additional discount for new drugs (essentially, a deflation penalty), despite drugs never taking a price increase. Historically, CMS' position has been that if the CPI-U penalty drops, the manufacturer response to deflation in the marketplace should be to lower drug prices to match market trends. A downward trend in CPI-U may disproportionately affect both entrenched and newly launched products by increasing the additional rebate due for each Medicaid unit dispensed. Additionally, an increase in URA may cause a decrease in 340B ceiling price. These effects may be magnified by an increase in Medicaid utilization.

Considerations for responding and recovering

- Revisit existing GTN models to determine the potential impact of increased government sales and financial liabilities affected by government sales (for example, Medicare Part D coverage gap liability or IRS branded prescription drug fee liability).
- Monitor payer mix trends in both the commercial and Medicaid space, and determine whether pipeline and demand estimates reflect variable mix expectations.
- Closely monitor third-party or dispense data for real-time trends in Medicaid utilization; lags at both state Medicaid agencies and providers may contribute to a protracted reimbursement period.
- Consider how patient access could change overall drug demand as the number of covered lives increases. Access to Medicaid prescriptions may be limited compared with commercial prescriptions, and patients may be forced to substitute their current medications for those covered under Medicaid.
- For established brands in the marketplace that may already be at "penny pricing" for Medicaid, shifts in Medicaid utilization may have a disproportionate impact on net sales per unit.

Medicare Part D, managed care, and coverage gap changes in 2020

Similar to waivers seen in the Medicaid program, as part of a letter sent on April 21, 2020, CMS stated that Medicare Part D plans can implement several flexibilities that may prevent care disruptions for Medicare Advantage or Medicare Part D enrollees. This includes the option to waive prior authorization requirements to facilitate access to services and lessen the burden on beneficiaries.[6]

Within Medicare Part D specifically, CMS has issued waivers facilitating access to 90-day, mail-order, and out-of-network prescriptions. Additionally, waivers for prior authorization in certain circumstances and relaxation of quantity and days' supply limits on prescriptions is allowing plan participants access to retail products.[7] Each of these measures may increase total Part D utilization in the short term and pull forward drug demand, but utilization may wane as patients adhere to stay-at-home orders with longer prescription fills and quantities. However, manufacturers may see a more variable utilization trend in the Part D channel due to longer refill cycles.[8]

Unrelated to COVID-19, CMS increased the catastrophic coverage gap limit in 2020 to $6,350 per individual (up from $5,100 in 2019).[9] Manufacturers participating in Part D should be aware of this increase in exposure and may want to consider how the impact of increases in 90-day mail-order retail prescriptions and stockpiling may push individuals into the coverage gap earlier in the year than they otherwise may have. This will pull forward coverage gap discount payments from manufacturers to plan sponsors. Overall manufacturer GTN liability may remain steady year-over-year, but accrual timing will be a poignant topic as forecasts are adjusted.

Considerations for responding and recovering

- Adjust Medicare utilization trends as a new steady state emerges and the domestic unemployment rate begins to level off through 2020.
- Leverage third-party, script utilization, and channel inventory data, and perform reconciliations to determine the impact of shifts in demand, customer mix, and pipeline inventory.
- Facilitate alignment between finance, accounting, market access, and government program stakeholders to update forecasts in preparation for quarterly financial close.
- Consider how the increase in the catastrophic coverage gap limit from 2019 to 2020 will affect the duration patients can expect to spend in the gap. Combined with the increase in 90-day prescriptions, expect individuals to enter the coverage gap earlier in the calendar year.

Federal Supply Schedule (FSS) and state and local governments

On March 13, 2020, President Trump declared COVID-19 a national emergency, invoking the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act).[10] As part of the national emergency declaration, state and local governments have full access to the FSS. On Friday, March 20, 2020, the US Department of Veteran Affairs (VA) provided VA FSS vendors a VA guidance document related to state and local government entity ordering procedures. When setting up an FSS contract, manufacturers may have elected not to participate in the disaster recovery purchasing program. Though manufacturers are not required to fulfill these orders under the terms of their contract, the VA permits and is encouraging manufacturers to voluntarily accept orders from state and local government entities.[11]

Considerations for responding and recovering

- To allow for fulfilment and administration of FSS purchases under this authority, there are a few parameters manufacturers should be aware of and consider:
  - Communicate with distributors and third-party logistics providers (3PLs) to reinforce that specific language should be included with orders from state and local government entities.
  - Work with distributors and 3PLs to determine how these transactions will be identified and provided in their chargeback data. Assess the impact on financial forecasts and government pricing and reporting compliance obligations (including industrial funding fee payments).
- Revisit existing GTN models to determine the potential impact of increased FSS contract purchasing.

Medicare Part B reimbursement changes under the CARES Act
The CARES Act includes several provisions that may affect manufacturers. The CARES Act suspends the Medicare sequestration cuts that lowered the payment rate for physician-administered drugs to average sales price (ASP) plus 4.3 percent, restoring the reimbursement rate to ASP plus 6.0 percent for prescription drugs covered under Medicare Part B from May 1 to December 31, 2020.[12]

After December 31, 2020, sequestration will be reinstated and extended one year past the original end date (through fiscal year 2030 rather than fiscal year 2029). Manufacturers should consider updating ASP models and forecasts and revisit contracting strategies and prices that may have been based, in part, on the previous ASP reimbursement threshold of 4.3 percent and corresponding provider cost recovery.[13]

As manufacturers revisit their models, they should also consider the impact of the 340B payment rate cuts that were implemented beginning in 2020. As of May 2020, CMS continues to move forward with updating the payment rate for non-pass-through drugs acquired under the 340B program to ASP minus 22.5 percent.[14]

Considerations for responding and recovering

- Review ASP reimbursement models and forecasts, and make appropriate changes.
- Revisit current commercial contracts with group purchasing organizations (GPOs), integrated delivery networks, and physicians to determine if changes need to be made based on the suspension of sequestration through 2020 and extension through 2030.
- Assess planned drug pricing and contracting strategies to aid providers during the COVID-19 crisis, and determine if additional changes should be made.

Buy-and-bill channel disruption and impact on Medicare Part B
On March 30, 2020, CMS announced through the Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule that it would waive some Medicare reimbursement regulations and allow providers to treat and administer Medicare Part B medications "without physical presence" by using real-time audio and video technologies. CMS will allow providers to receive reimbursements for Medicare Part B drugs that are administered by nonphysician practitioners in the patient's home. Physician-administered drug manufacturers may be able to mitigate erosion in utilization if they are able to effectively claw back a percentage of those lost sales via the telehealth channel.[15]

Home infusion of Part B drugs is not prohibited; however, many Part B prescription drugs are usually only covered when administered in a clinic. A common method for Part B administration of drugs has been the buy-and-bill method, where the provider purchases the product and then administers it to the patient and files the medical claim. Many manufacturers contract with providers for Part B products through GPOs and other provider-based contracts to offer competitive pricing and access to providers. Allowing home infusion could require manufacturers to rethink their commercial contracting strategy for these products since, in many cases, Medicare Part B drugs are not reimbursed individually, but along with the administration of the product (ASP + 6 percent). Though this home infusion provision was created to accommodate social distancing regulations, there is a push for this provision to become permanent. If products are administered more frequently in a patient's home, manufacturers may need to contract for these products through pharmacy benefits managers (PBMs) or retail sources.[16, 17]

COVID-19 has resulted in a decrease in elective procedures and an increase in telehealth treatment. Unsurprisingly, acute drug sales are suffering as patients cancel or forgo appointments at physician offices, leading to declines in new patient starts for many therapeutic indications.[18, 19] As a result, many outpatient centers with high Medicare Part B utilization (such as oncology and ophthalmology centers) are under stress to stay afloat. Before COVID-19, many of these clinics were experiencing significant consolidation through mergers and acquisitions to avoid closures.[20] Many oncology centers, for example, were purchased by private equity groups to avoid being acquired by hospitals or health systems. There is some concern that, because hospitals are being bailed out, they will purchase more of these independent clinics to increase growth of their system. Manufacturers often work to develop purchase-based provider contracts with these independent clinics to allow physicians to have greater buying power of their products. When larger health systems or hospitals purchase clinics, contracting decisions are made at the system level. Manufacturers of Medicare Part B drugs that are administered in these settings should revisit their provider-based contracting strategies and determine the impact of potential consolidation.

Considerations for responding and recovering

- Review distribution models and existing Part B contracts as the shift in site of administration is established. Consider if PBM arrangements are appropriate for traditionally physician-administered products that are now being dispensed to the patient's home.
- Consider how stay-at-home orders and curtailing of elective procedures are likely to affect sales forecasts by delaying patient utilization. Consideration should be given to therapeutic specialty area and perception of urgency in physician prescribing behavior. With lower utilization in the marketplace and potentially a shorter shelf life than retail products, consider how much product is already in distribution, and reprioritize or redeploy resources to effectively manage shifting sales forecasts.

The rise of telehealth and its impact on retail and mail-order pharmacies

With many states under stay-at-home orders, the manner through which patients are treated and receive medications is evolving. For example, telehealth is becoming a more prominent method to diagnose patients. The Federal Communications Commission (FCC) has established the COVID-19 Telehealth Program to help providers care for their patients from their patients' homes or other nonclinic locations.[21, 22] Additionally, large chain pharmacy providers have facilitated access to medications through free home delivery and drive-through services.[31]

Increases in telehealth adoption and prevalence of 90-day prescriptions have manifested primarily as an increase in mail-order prescriptions, which are up almost 4 percent year-to-date compared with 2019.[24] The shift away from retail pharmacies may necessitate a renewed look at manufacturer distribution strategies. Patients are encouraged, and enabled through regulations such as the CARES Act, to request 90-day supplies instead of the typical 30-day supply.[12] These trends may also be seen in other government programs, such as TRICARE. With local and state stay-at-home orders effectively closing military treatment facilities (MTFs), manufacturers may see an increase in TRICARE mail-order pharmacy (TMOP) prescriptions in the short term. Whether this shift in utilization from MTFs to TMOPs will persist past the peak of the pandemic is unclear.

Telehealth engagement has also increased for specialty indications such as oncology, and telehealth visits now contribute to more than 10 percent of total oncology patient interactions.[23] This could meaningfully contribute to patient adherence for Part B or traditionally physician-administered drugs. Further, with CMS' announcement that they will allow providers to treat and administer Medicare Part B medications without physical presence by using real-time audio and video technologies, adoption of telehealth services for specialty products is imminent as physicians seek alternatives to in-office treatment.[15]

Increases in both telehealth and mail-order prescriptions have the potential to cause fluctuation in manufacturers' average manufacturer price (AMP) calculations by causing unexpected variability in the amount of mail-order sales and retail sales of certain oral solids and other products. For products that oscillate between the standard (retail) and alternative (5i) AMP methodology, changes in customer mix could be significant and should be monitored. As prescription utilization shifts toward mail order, manufacturers may want to consider how a change in methodology could affect AMP and flow into subsequent URA and 340B ceiling price calculations.

Considerations for responding and recovering

- Revisit existing government pricing models, and assess the potential impacts to AMP, Medicaid URA, and public health services (PHS) pricing and utilization.
- Monitor changes (such as relaxed guidelines on supply limits) that may affect existing Medicaid validations, and determine if updates are needed.
- Consider how mail-order and telehealth adoption will affect service fees paid in the distribution channel.
- Consider the impact that mail order and shifting to 90-day supply will have in pulling forward demand in current periods and what the long-term impact is on demand trends on a brand-by-brand basis. Determine if provider prescribing patterns and patient fill behavior are likely to have lasting impacts on demand fluctuation.
- For specialty products, determine if telehealth is a reasonable method for administration. Identify distribution changes needed to facilitate in-home administration and the impacts on fees and the supply chain.

State drug price transparency climate

Rising drug costs and overall spending on pharmaceuticals has become a hot-button issue over the past few years. In response, numerous states have ratified state price transparency legislation that includes price increase reporting, drug pricing reports, new drug entry, advance notice of price increases, and price disclosures to health care professionals and states. This legislation is not consistent across states and involves careful analysis by manufacturers to confirm the potential impacts on their business and compliance with reporting requirements. States such as Oregon are beginning to track price changes for drugs that could potentially treat COVID-19, as well as drugs that may have shortages due to increased use in COVID-19 treatment.[25]

While COVID-19 has sparked debates on drug pricing and incentives, it has also brought renewed recognition that drug prices fuel innovation and help pay for research and development. Many manufacturers have started sharing intellectual property that may expedite the development of COVID-19 treatments or vaccines. Some manufacturers are providing large numbers of free prescriptions that may be useful in treating COVID-19. Over time, the life science industry's rapid response to this pandemic may change public perception of drug prices and the appetite for state and federal governments to require oversight for drug price transparency. For now, states continue to enact drug price transparency legislation that aligns with existing legislation and expands beyond existing requirements (i.e., the Minnesota SF 1098 newly acquired prescription drug report).

Considerations for responding and recovering

- When evaluating pricing actions, consider the public relations and reputational implications, particularly if the drug could be related to a COVID-19 treatment.
- Evaluate the financial impact of drug price changes given evolving government programs enrollment and reimbursement.

340B drug pricing program utilization

To date, no significant regulatory changes related to the 340B Drug Pricing Program have been implemented in response to COVID-19. Stakeholders, however, have advocated for additional support to help safety-net providers who participate in the 340B program. In March 2020, the Health Resources and Services Administration (HRSA) released a set of FAQs that address many of these requests. [26]

- **340B "patient" definition:** HRSA has stated that they are unable to waive the existing definition of a patient, but that "in determining whether an individual qualifies to receive 340B drugs, HRSA believes that it is appropriate to consider the realities of the COVID-19 pandemic."
- **GPO prohibition:** HRSA clarified that hospitals subject to GPO prohibition may use a GPO to purchase medications due to shortages if they are unable to purchase the medication at either the 340B price or at wholesale acquisition cost (WAC).
- **Conducting 340B entity audits remotely:** HRSA indicates that they are moving toward conducting 340B program covered-entity audits virtually for the next several months.

It is estimated that three quarters of 340B claims are derived from physician-administered drug prescriptions. With decreases in doctors' visits and reduced physician-patient interactions, the total number of 340B claims may fall until stay-at-home orders are relaxed.[16] These changes may also impact 340B covered entity eligibility (e.g., for disproportionate share hospitals), which could decrease the number of 340B claims or shift utilization toward GPOs. Alternatively, the changing business models and policies on items such as telehealth may indirectly increase 340B utilization. The industry dynamics regarding 340B should be evaluated carefully on a product-by-product basis. The 340B statue prohibits duplicate discounts on covered drugs—a situation where a manufacturer pays both the Medicaid rebate and 340B discount on a single dispensed prescription. An influx of Medicaid lives may add to the operational complexity of identifying and remediating these duplicative transactions.

Considerations for responding and recovering

- Monitor changes in HRSA's guidance and new legislation to assess how these changes may affect overall 340B program utilization, planned oversight and audits of 340B covered entities, and disputes with 340B covered entities.
- Consider how the current environment and rise in telehealth use could temporarily or permanently affect hospital policies regarding the "patient" definition and create potential changes in expected 340B utilization.
- A shift from commercial insurance to Medicaid coverage may decrease the number of 340B claims. For GTN purposes, the unrealized 340B discount dollars may wash out to a proportional (but delayed) uptick in Medicaid utilization in the same period.
- Consider immediate 340B chargeback trends, and factor these changes into your short-term pipeline accruals. Adjust chargeback reserves if lags in processing are observed for either the 340B Drug Discount Program or other contracted agreements.

Additional channel disruption and managing the gross-to-net environment

Gross sales, drug demand, and pipeline inventory
As state and local governments issued the first stay-at-home orders in March 2020, supply chains felt the initial strains of stockpiling drugs, particularly those treating chronic conditions. Inelastic demand for these drugs appears to have manifested in a decrease in days-on-hand inventory at wholesalers as order rates increased sharply from downstream customers (such as pharmacies and hospitals), indicating a depletion of drugs in the channel.[24] This trend has effectively pulled unit sales demand forward for some retail drug manufacturers.

It appears, however, that script utilization has begun to normalize in April after this initial stockpiling. With relaxing of social restrictions in the second half of 2020, pent-up demand for both acute and Part B prescriptions may bounce back as elective procedures are restarted.[18]

Considerations for responding and recovering

- Determine if stockpiling behaviors have the potential to pull sales forward and result in a volatile 2020 demand forecast. Consider if wholesaler purchasing trends are increasing pipeline inventory meaningfully and how anticipated spikes in demand may affect the overall supply chain.
- Leverage third-party, script utilization, and channel inventory data, if available, and perform reconciliations to determine the impact of shifts in demand, customer mix, and pipeline inventory.

Patient adherence during the economic downturn
With the unemployment rate reaching a historic level, patients may not prioritize prescription drug refills due to economic hardship, loss of employment, or their perception of the urgency to treat. For chronic diseases (e.g., diabetes, autoimmune, immunosuppressants), patient adherence is compulsory for effective treatment and, as such, these prescriptions observed a surge in demand in March 2020. Sales by specialty area vary widely and are subject to both patient and physician perception of urgency to treat. Rates of decline observed for specialties such as dermatology, ophthalmology, and fertility have far outpaced the rates of decline in oncology-related prescriptions thus far.[27]

For Part B products, patients are reducing the number of physician office visits and prefer self-administration when the option is available. For many self-administered specialty and retail drugs, prescriptions can be fulfilled by mail-order pharmacies, but utilization will be contingent on both the financial status of the patient, as well as the patient's willingness and ability to self-administer. Specialty products, oncology and otherwise, that do not offer alternate methods to physician administration may see decreased utilization as individuals avoid in-office visits. Pharmacy activity for targeted oral oncology products has shown modest growth through mid-April compared with two months prior, a shift indicating supply chain interruption and conversion to oral administration where possible.[28]

Considerations for responding and recovering

- For traditional retail products, consider therapeutic indication when determining if patient adherence will meaningfully affect the sales forecast. Work closely with stakeholders (such as patient services and external reimbursement HUBs) to mitigate drops in patient adherence.
- For specialty products, consider administration route and adherence when adjusting sales forecasts. Specialty products offering alternative methods to physician administration are better positioned as utilization shifts to self-administered routes.

Increases in patient assistance programs, copay programs, and returned goods

As discussed above, unemployment inevitably leads to a decrease in employer-sponsored health plan participants and may qualify many more individuals for Medicaid, while others will flow into the ACA Marketplace or become uninsured.

This increase in uninsured lives may increase qualification rates for patient assistance programs (PAP), patient rebate programs, drug discount cards, and copayment (copay) assistance programs. To date, copay program usage for manufacturers in 2020 has outpaced 2019 and is expected to stay at this pace or increase through the year.

Further, manufacturers have seen an increase in the maximum benefit paid in these programs—a direct result of more uninsured patients.[23] Additionally, increased participation in copay programs may be one mechanism by which patient adherence can be maintained through the downturn.

Returned units may also increase in 2020 due to an escalation in purchasing within the supply chain. To address potential surges in demand, wholesalers are vying to keep more days-on-hand inventory. This may increase the rate of return as drugs in the supply chain reach the end of their shelf life.

Considerations for responding and recovering

- Evaluate potential changes to copay program utilization, balancing the decrease in individuals receiving employer-sponsored insurance with the increase in uninsured or ACA Marketplace patients taking advantage of available copay programs.
- Consider increasing PAP units (pulling utilization from commercial sales units) to reflect the estimated increase in the uninsured population.
- Consider adjusting return rates if days-on-hand inventory in the supply chain increases above normal levels.

Breaking into the marketplace with new-to-brand drugs

While the CARES Act facilitates the development and manufacturing of vaccines and treatments for COVID-19 and other pandemic-related products, the downstream impact to manufacturers' existing drug pipelines is somewhat uncertain. While there is speculation that fewer new drugs will be approved and launched, many sources have observed no evidence of this shift.

New-to-brand (NTB) drugs may face major hurdles in 2020 due to a decrease in market uptake for novel products relative to historical trends. This may be a result of patient or prescriber reluctance to change brands without in-person visits, risk-averse behavior in a time of uncertainty, or reduction in face-to-face marketing by pharmaceutical representatives. Both at the national level and in COVID-19 "hotspots," NTB share of total prescriptions dropped in March and April of 2020 compared with the previous two months.[23] In the coming months, marketing campaigns and launch initiatives may be limited in some parts of the nation as disparate social distancing guidelines are implemented.

Product differentiability will be important during the COVID-19 pandemic due to hesitation in exchanging established brands for new products. Overall, this will likely be an uphill battle for NTB drugs. Strategic marketing campaigns aligned with nimble manufacturing and sales deployment will be crucial to getting drugs to the right providers and patients at the right times.

While there has been a surge in virtual marketing models, these channels have yet to bear out for the NTB market. A look at the long-term disruption to brand launches found a net ($10B) impact through 2028 that may affect recently launched (2018 and 2019) and ready-to-launch (2020) drugs significantly compared with drug launches in 2021 and beyond.[19] With an eye on the horizon, NTB drug manufacturers should consider the long game. The short-term forecast through 2020 and into 2021 is daunting. Although sales may be uplifted once stay-at-home orders are rescinded and the pent-up demand is accessible, adjust forecasts to reflect an overall decrease in patient uptake. Further, trends indicate that overall NTB drug sales could be affected through 2025.[29]

Considerations for responding and recovering

- Consider gross sales forecasts, and adjust expectations as a result of fewer in-person engagement activities.
- Determine if there is impact to product launch dates, and revisit commercial strategies if needed.
- Appropriately manage any changes to timelines for securing government programs contracts.
- Be ready for asymmetric geographic launch activities as state and local governments initiate or roll back stay-at-home mandates. Adjust forecasts in real time with changing state and local guidelines.

Managing GTN in times of uncertainty: Monitoring trends to inform decision-making

GTN calculations have been a growing challenge for life sciences companies as they navigate complex supply chains; a changing regulatory environment; population shifts; market expectation pressures; and the enhanced negotiating power of consolidated payers, providers, and distributors. From an increase in Medicaid enrollment to a shift in patient adherence and demand, COVID-19 is redefining the dynamics of the market that drive manufacturers' GTN estimates. As a result, companies may necessitate one-off adjustments within their GTN models to account for the shift in market dynamics.

Considerations for responding and recovering

- Monitor trends from both internally and externally sourced data to support informed decisions and adapt to the implications of COVID-19.
- While these adjustments might be short-term in nature, it is important to appropriately document and support changes made to models, including significant judgements made and the impact of these changes. Recognizing and documenting the variability in inputs that function as drivers of financial estimates is important to a strong control environment.

GTN controls and processes reevaluation

Companies are rapidly responding to the business impacts of COVID-19 and, as a result, are redefining the existing processes and controls.

Stay-at-home orders have made it more difficult for stakeholders to collaborate on the critical information needed to effectively estimate these GTN rebates and accruals. When the evidence of a control is affected by remote work arrangements, consideration may be given to alternative means of obtaining control evidence. This may include a revision to internal policies and control design. Further, companies should consider the limitations on control activities and effectively adapt to a more segmented and remote organizational environment.

A change in the design or operation of controls due to COVID-19 should be appropriately evaluated, approved, and documented by organizations. Additional focus should be given to controls that have a degree of management judgment or are a review of estimates. For new and/or modified processes and controls, organizations may consider documenting the following as part of their monitoring of the control environment:

- The new or additional risks identified as a result of COVID-19
- Reasons for the proposed change
- Detailed description of the change in the control or how the new control operates
- How the new control or proposed change addresses the newly identified risks
- Effective dates of changes or implementation
- How changes are communicated to relevant stakeholders and control owners

Considerations for responding and recovering

- For public and private companies alike, consider the impact of COVID-19 on the current internal control environment, with special consideration of GTN estimates and other significant management judgments made as a result of the disruptions from COVID-19.
- Changes in internal controls that have materially affected, or are reasonably likely to materially affect, entities' internal control over financial reporting should be disclosed in Item 4 of Form 10-Q or Item 9A of Form 10-K of entities' quarterly or annual filings, respectively.

How we can help

Deloitte's life sciences professionals are closely monitoring and assessing COVID-19's impact in the areas discussed above. Our Pricing and Contracting Solutions practice is helping clients focus their efforts and recover by helping to assess and build compliant and adaptable business strategies and operations.

Contact us to learn more about how we can assist your company during this challenging COVID-19 environment.

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Additional resources

For more information, visit some of Deloitte's COVID-19 resources for life sciences manufacturers.

- COVID-19 resources for life sciences and health care leaders
- Deloitte Health Forward Blog
- Life science compliance considerations and challenges amidst COVID-19
- COVID-19 response capabilities: Life sciences virtual close preparedness
- COVID-19 response capabilities for life sciences: combating COVID-19 with resilience
  - Clinical development
  - Supply chain and manufacturing

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