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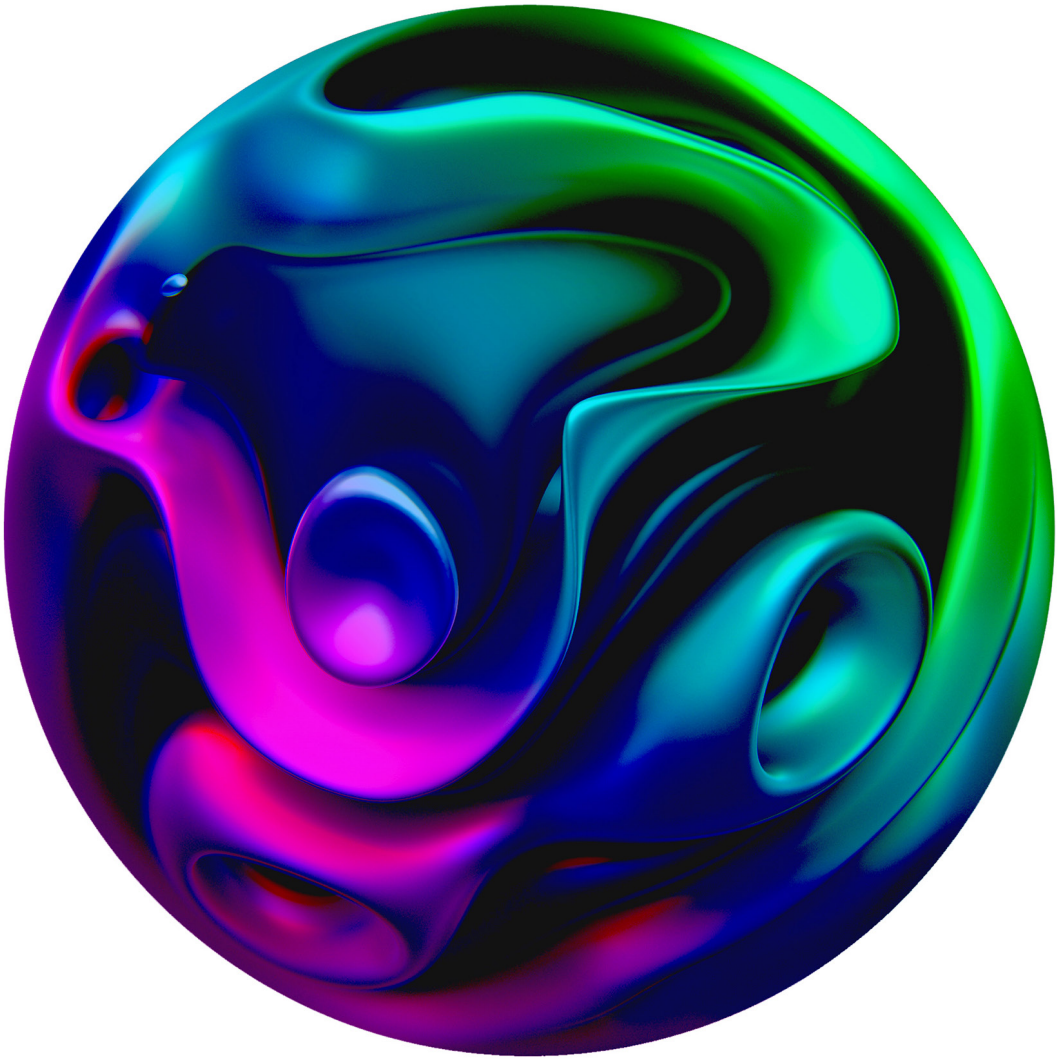

Life sciences regulatory outlook 2021

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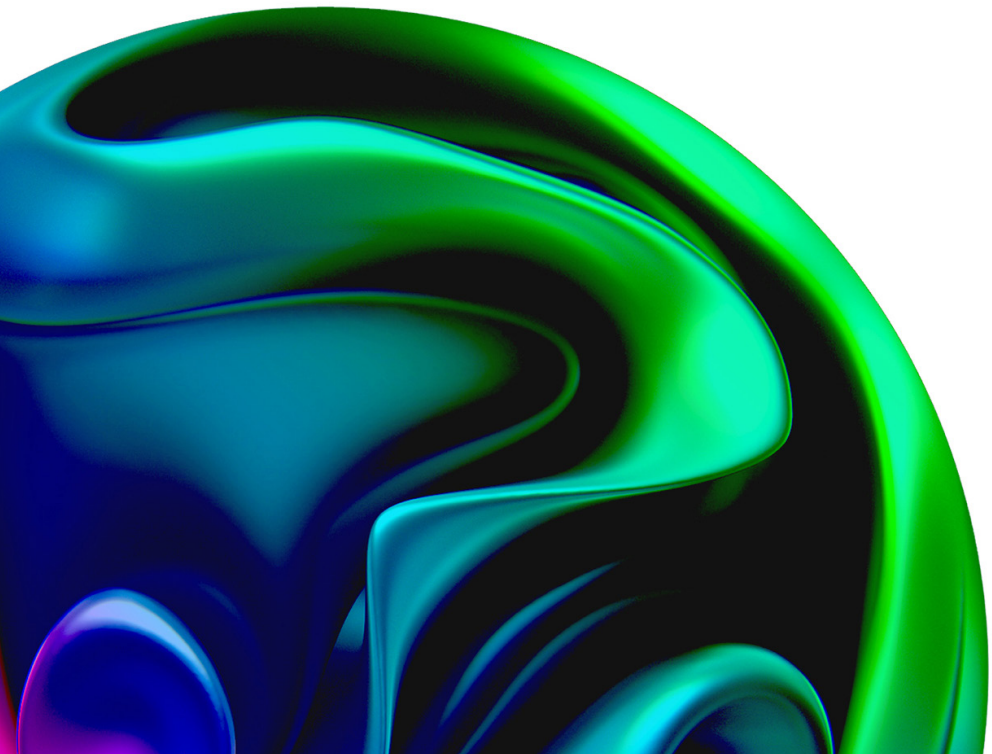


Setting the stage

Changing regulations shift the ground beneath your feet. Life sciences companies may need to adjust and find their balance.

For life sciences companies, 2020 was a year like no other. Not only were they called to action to help combat the COVID-19 pandemic on its many fronts, but (like all other companies) they also needed to reassess how they operate their business. With much of their workforce, and the public in general, working remotely, organizations in life sciences have had to reconsider their operating practices and the compliance guidelines and regulatory requirements that govern the industry.

Regulations have taken into consideration this new mode of doing business, and companies need to follow suit. This starts with a thorough reevaluation of existing policies, procedures, and business practices to reconcile them with changed ways of operating so companies can continue moving forward and succeed in the next normal.

The overarching theme for this year's regulatory outlook is for life sciences companies to take a closer look at their compliance activities as an integral part of their overall business strategy. Key focus areas include:

- Digital transformation: Using technology to enhance compliance monitoring
- Virtual interactions with health care professionals: New ways to educate and update
- Third-party risk management: Patient support programs
- Market access and drug pricing: The priorities needed
- State price transparency reporting: Supporting the changing requirements

Life sciences companies have a valuable opportunity to incorporate the lessons learned from the past year and charge forward into the new reality of the future, which will be more interconnected than ever before. The path will likely be challenging; however, many of these inevitable required changes will create new opportunities and advances that benefit the industry, constituents, and patient outcomes—now and in the future.

Digital transformation: Using technology to enhance compliance monitoring and enable business success

Compliance teams are under pressure to do more with less. Digital technologies make that math possible.

Pharmaceutical, biotech, and medical device compliance teams are increasingly being asked to do more with less in the face of rapidly evolving regulatory and marketplace demands. This is far from easy, requiring a fundamental shift that involves the use of technological accelerators. Once these new technologies are up and running, they not only can help drive efficiency and effectiveness, but also may help improve a compliance organization's ability to protect the business and deliver measurable value.

As a key enabling function, compliance monitoring covers multiple areas within the business, including foreign corruption and bribery, patient assistance programs, communications with patients and health care professionals (HCPs), and regulatory reporting. Given the need for specialized expertise in each of these areas (and reliance on other parts of the organization for data), compliance organizations have traditionally been forced to lean heavily on manual processes. As such, a compliance function's ability to add value has generally been limited by the number of people assigned to it.

Digital technologies change the equation, making it possible for compliance organizations to move away from rote tasks, keep pace with the explosion of data, and ultimately transform themselves into value-creating, forward-looking business partners that are better able to anticipate what might go wrong and then proactively work to prevent those problems from happening.

Transformative technologies to modernize compliance programs

Robotic process automation leverages rules-based systems to mimic human behavior and automate parts of repeatable processes, such as sourcing and cleansing data for analysis, performing transactions reviews, and generating real-time dashboards to track risk indicators.

Natural language processing and generation applications process text and allow querying and generation of structured data, enabling capabilities such as monitoring call center recordings and social media to understand and analyze public sentiment, adverse events, complaints, and other risk indicators; reviewing third-party contracts for high-risk services or terms and conditions; and monitoring voice data from virtual speaker programs and call centers.

Artificial intelligence and machine learning applications mimic human behavior such as visual perception, speech recognition, decision-making, and language translation, enabling capabilities such as risk identification for compliance risk assessments and comprehensive monitoring of electronic communications in real time to proactively identify, analyze, and mitigate risk while reducing false positives.

Predictive analytics proactively identify emerging risks and targets for detailed auditing in areas such as third-party due diligence, antibribery, and anticorruption.

Real-world examples

Electronic communications monitoring

A global pharmaceutical manufacturer was manually performing communications reviews between its field force, HCPs, and patients. The process was time-consuming and labor-intensive due to the large number of false positives in keyword searches. To address the problem, the company incorporated an AI-driven platform into its review process. In addition to leveraging machine learning and advanced analytics, the new platform integrated additional data sources, including HR role information. The new platform dramatically improved efficiency, reducing the volume of documents that need to be reviewed while allowing a broader set of documents to be analyzed. This helped the company uncover additional risks that would have been missed using its previous manual process.

Transaction monitoring

A global pharmaceutical manufacturer needed to test various transactions across its commercial, medical, and market access activities. The process had traditionally involved manually reviewing invoices to identify high-risk third parties and activities, which was time-consuming and incomplete. To improve efficiency and effectiveness, machine learning models were trained to predictively classify risk at the invoice level—and to prioritize high-risk invoices and vendors. This enabled the company to review every single paid invoice (more than 60,000 per quarter). The highest-risk third parties were then identified for priority review, including many third parties that had previously been seen as low-risk.

Which activities to modernize

Most compliance organizations have tight budgets and need to choose their technology investments wisely. Here are four factors to consider when deciding which compliance activities to digitize:

- Value and risk impact. Value in compliance can often be measured in terms of risk impact. Compliance organizations should consider digitizing processes where improving speed and accuracy can help prevent, detect, or respond to the company's biggest risks.
- Impact on internal compliance operations versus business line processes. Because many first-line-of-defense processes occur at the business level, changing those processes (or implementing new ones) requires coordination and buy-in from the business. This can yield valuable results, but is more complex than digitizing activities internal to the compliance function.
- Technical feasibility. Some of the most compelling use cases for digital technology in compliance may not be feasible if the technology is not yet ready for prime time, or if the company's data and systems environment cannot support it.
- Resource use. When deciding between multiple use cases, it often makes sense to digitize activities that are the most labor-intensive and require the most resources.

Virtual interactions with health care professionals

HCP interactions are under the microscope. Life sciences companies should know what regulators are looking for.

Business interactions with HCPs continue to receive close scrutiny from regulators, legislators, and the media. And as more of these interactions and fee-for-services arrangements go virtual—a trend accelerated by the COVID-19 pandemic—life sciences companies should make additional adjustments to remain compliant.

Specific ongoing risks include potential violations of laws (e.g., the Anti-Kickback Statute) and regulations (e.g., the Physician Payments Sunshine Act) and the prospect of negative media attention. However, with the rapid rise of virtual HCP interactions, there are new challenges to address as well. In particular, life sciences companies should evaluate their processes and controls related to the following activities.

Speaker programs

In November 2020, the Office of Inspector General (OIG) of the Department of Health and Human Services issued a Special Fraud Alert related to speaker programs.[1] The alert highlights the OIG's skepticism about the educational value of speaker programs and includes a number of compliance considerations for designing and executing programs going forward. In particular, the alert identifies the following characteristics that potentially indicate an inappropriate intent and could lead to a violation of the Anti-Kickback Statute:

- The company sponsors speaker programs where little or no substantive information is actually presented
- Alcohol is available, or a meal exceeding modest value is provided to program attendees (the concern is heightened when the alcohol is free)
- The program is held at a location not conducive to the exchange of educational information (e.g., restaurants and entertainment or sports venues)
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information
- There has been a significant period of time with no new medical or scientific information, nor a new FDA-approved or cleared indication for the product
- HCPs attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic)
- Attendees include individuals who don't have a legitimate business reason to attend the program
- The company's sales or marketing business units influence the selection of speakers, or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's products (e.g., a return-on-investment analysis is considered in identifying participants)
- The company pays HCP speakers more than fair market value for the speaking service, or pays compensation that takes into account the volume or value of past business generated (or potential future business generated) by the HCPs

[1] US Department of Health and Human Services Office of Inspector General, Special Fraud Alert: Speaker Programs. November 16, 2020

The OIG acknowledged that the Special Fraud Alert was released during a pandemic, when many companies might not be hosting traditional speaker programs. However, the notes section of the alert states that "[risk] will become more pronounced if companies resume in-person speaker programs or increase speaker program-related remuneration to HCPs. As such, risk assessments and auditing and monitoring of speaker-related activities are imperative—now more than ever—to help confirm that speaker programs are designed and executed in a compliant manner and that risks identified can be mitigated and/or addressed in a timely manner."

Fair market value (FMV)

With the sharp increase in virtual interactions, life sciences companies are getting pushback from HCPs about their reduced total honoraria for fee-for-services arrangements. The reduction is mainly due to the elimination of travel time compensation, as well as the reduced time and effort associated with virtual interactions. In response, life sciences companies should to evaluate the controls and processes they have in place related to the fair market value of virtual interactions.

Many life sciences companies already have established business rules and level-of-effort assumptions, including preparation time, and service time, for in-person HCP fee-for-services arrangements. However, as in-person interactions continue to rapidly give way to virtual interactions, companies should adjust their level-of-effort assumptions accordingly. Virtual interactions generally involve shorter sessions, more time spent confirming that technology platforms are working correctly (before and during the session), and increased Q&A time with program participants.

Honoraria for virtual interactions should align with the HCP's level of effort for the activity and should not be paid based on the volume of instances through which a recording of the interaction could be shown. The latter might be interpreted as deriving value from "potential future business generated," which the OIG's Special Fraud Alert specifically cites as an arrangement that could violate the Anti-Kickback Statute.

Meals

In 2020, following industry guidance related to the pandemic, life sciences companies began providing occasional modest meals to HCPs as part of virtual clinical and scientific presentations. Although many of the rules for in-person meals also apply to meals in a virtual setting, life sciences companies should ensure their processes and controls are updated to account for this new dynamic.

One key nuance in a virtual setting is tracking attendance and which individuals receive a meal. Companies need technology that enables them to capture attendee names. They also need processes, including a designee in the HCP office, to capture signatures from all individuals who receive a meal, then provide those signatures to a company representative.

In addition, the guidance makes it clear that meals should be limited to in-office settings and that home delivery of meals is still prohibited. Even as company representatives grow accustomed to providing meals in a virtual setting, companies should continue training their representatives on the special requirements and considerations for executing such activities. Also, compliance departments should continue auditing and monitoring those activities to help ensure compliance.

Given the release of the OIG's Special Fraud Alert (and the sharp rise in virtual interactions with HCPs), this is an opportune time for life sciences companies to assess their end-to-end HCP engagement processes to ensure the associated policies, processes, and controls are aligned to govern this new way of working.

Third-party risk management: Patient support programs

COVID-19 is putting patient support programs to the test. The right moves can help companies pass with flying colors.

Patient support programs (PSPs) provide an opportunity to support patients throughout their treatment journey and improve access to life-saving therapies. As PSPs are often implemented for patients with complex disease states and the corresponding complex treatments, there is not a one-size-fits-all approach to their successful delivery. In particular, delivering PSPs through a federation of suppliers creates a complex ecosystem and data landscape. This makes it difficult to ensure that treatments are effective and that patients receive the intended experience. It also introduces a variety of potential risks.

As with many aspects of the health care system, COVID-19 has pushed the limits of existing PSPs, creating increased demand and need. During the pandemic, millions of people lost their jobs (and their associated health insurance), causing them to seek support and coverage. Further, patient care and treatment has largely shifted to a virtual environment, triggering a shift in how patients become aware of and engage with PSPs, as well as a shift in reimbursement, access, and adherence services.

As COVID-19 begins to recede and the health care ecosystem settles into the next normal, PSPs will likely continue to play a critical role. While it is hoped that many patients will regain their health insurance, there will likely be changes to the overall health care ecosystem that affect how reimbursement, adherence, clinical, and other critical patient support services are provided. This will continue to increase the complexity and uniqueness of PSPs and expand the federation of suppliers.

Third-party risk in PSPs

Most life sciences manufacturers have robust third-party risk management programs across their businesses. These programs have evaluated third parties both in the due diligence phase and throughout execution of their service arrangements. However, in many cases, these risk management programs have not been applied to PSP providers.

Many life sciences companies outsource their PSPs to third-party vendors that provide a wide range of services, including:

- Hubs
- Specialty pharmacies
- Clinical nurse educators
- Field reimbursement services
- Product delivery services

However, whenever a third-party vendor is engaged, new risks are introduced, such as:

- Regulatory compliance risks (e.g., compliance from the FDA or OIG)
- Financial risks (e.g., data security risks, such as management of confidential patient data, and knowing what type of data the vendor is going to have access to)
- Reputational risks (e.g., data breaches)

Because PSPs rely heavily on third parties and their data, and because life sciences companies have less oversight over a third party's operations and reporting than their own, it is crucial to periodically test PSP contractual requirements and business processes. A third-party audit enables a company to assess if its commitment to patient support is being delivered as intended.

Reducing risk exposure through advanced analytics

Beyond extending an organization's third-party risk management program to encompass PSPs, the application of advanced compliance analytics to the information collected allows life sciences companies to identify trends within the data and more accurately forecast likely gaps in compliance. In contrast with a traditional risk assessment, which is more retrospective, compliance analytics allows companies to view risks through a forward-looking lens. Given the vast amounts of data that life sciences companies typically now have access to, homing in on specific pieces of data (and the related insights such data might yield) is a leading practice to garner information that is meaningful and actionable.

In PSPs, advanced compliance analytics can help detect:

- Government pay patients who are receiving prohibited support;
- Adverse events that might not be identified through other more traditional channels; and
- Privacy risk exposure, such as lapses in patient consent.

Applying advanced analytics in these areas and others can generate significant compliance insights and business value.

Market access and drug pricing

Drug pricing is a hot topic. Here are some considerations to stay out of the hot seat.

Drug pricing, and the associated scrutiny on pharmaceutical and biologic products, remains a hot topic for manufacturers in 2021, fueled by discussions in the public, media, and federal and state governments about the high cost of drugs in the United States (and by the growing number of personalized and advanced medicines, which are leading to even higher-cost therapies in the market).

The regulatory environment surrounding drug pricing has always been complex and continues to grow and change as life sciences companies and commercial and government payers increasingly implement innovative strategies that shift the focus from volume to value.

Meanwhile, drug manufacturers in 2021 are increasingly elevating the public spotlight for the 340B Drug Pricing Program (340B Program). This program provides significant discounts on outpatient drugs to eligible health care providers that serve uninsured or underinsured patients.

Some of the industry's largest manufacturers have implemented market access strategies that impose data provision requirements and/or limit distribution on 340B-covered sales through contract pharmacies. These strategies attempt to mitigate the significant challenges manufacturers have faced for more than 10 years related to noncompliance by 340B-covered entities, duplicate discounts, and revenue leakage.

Many companies are now realizing the dire need for collaboration and coordination across their commercial, compliance, and regulatory organizations to develop sophisticated technology and operational solutions capable of supporting new pricing strategies while meeting ever-changing regulatory compliance requirements.

Innovative contracting

Across the industry, manufacturers are shifting from "pay-per-pill" to "pay-for-performance" contracting strategies, focusing on quality of care and value rather than the volume of drug dispensed. This trend is being supported by emerging therapies that are personalized to an individual patient and by advanced products such as cell and gene therapy. Yet, when innovative manufacturers started to announce these therapies could be priced at a million dollars or more, questions arose about covering the costs.

How can an insurance company that subsidizes its costs via premiums endure up-front payments of millions of dollars? Can and should these costs be passed down to all the lives that are covered? The "golden solution" to this problem is still being actively developed; however, the industry is looking into innovative contracting methods as a viable solution.

Three types of contracting models have emerged to maximize patient access for innovative therapies in a way that can benefit both payers and manufacturers, with value-based contracts (VBCs) appearing to be the preferred choice (figure A).

Figure A. Contracting models for innovative therapies

Payment model type	Method	Description
Volume-based	"All you can treat" Buy in bulk	Volume-based payment models reduce the impact of high-cost cures by determining either a set amount of product or a maximum price. An example of this is when (i) the parties agree on a maximum price for all product used during a predetermined time period or (ii) the parties agree on a discounted price for a predetermined amount of product.
Elongated payment (AKA annuity-based payment models)	Structured payments	Elongated payment models spread the payment over a predetermined time period, typically on an annual basis.
Outcome- or value-based	Pay only when it works	The payment is provided (or a rebate is granted) only if certain verifiable outcomes are met after administering the therapy.

These models provide a path to make one-time treatments profitable for manufacturers while at the same time improving patient access to crucial, potentially life-saving therapies. However, adoption has been slowed by numerous operational challenges. Here are some key operational areas for manufacturers to think about when considering an innovative contracting model.

Government program methodology and compliance. A manufacturer should understand the impacts on its government programs in the following areas:

- Compliance with the latest regulations. Centers for Medicare & Medicaid Services (CMS) Final Rule, published in December 2020,[2] provides a commitment to support evidence- and outcomes-based contracting by enabling multiple Best Price reporting or Bundled Sale allocation approaches specific to value-based purchasing (VBP) strategies within the Medicaid Drug Rebate Program. Implementing VBP arrangements for compliant Medicaid drug pricing reporting can have a significant financial impact on Medicaid rebate liability, as well as process, technology, resourcing, and other operational impacts. Prior to the January 1, 2022, effective date of the new regulations, a manufacturer should ensure its contract model design meets the VBP definition and that its implementation adheres to the new requirements.
- Program and methodology design. A manufacturer should ensure that government pricing calculations can support the innovative contracting solution, taking into account how discounts can or should be brought into the calculation system and applied across reporting periods, how the discounted price-per-reporting period is determined, and how the calculation is affected by payments occurring after the product has been terminated (or after the Medicaid Drug Rebate Program three-year restatement window).

Operational costs and net impact. Every innovative payment model will require increased time, cost, and effort for initial setup and ongoing maintenance. A manufacturer should review the time commitment and financial burden associated with each model across both private and government payers, as this will provide crucial insight about the model's profitability, as well as help identify gaps in resourcing and technology.

Infrastructure and technology challenges. Enabling any of the innovative contracting solutions will require a manufacturer to have a system that can collect, aggregate, store, analyze, and report on data from different sources. A manufacturer should perform a gap assessment on both (1) its data needs and (2) the supporting technology necessary to integrate or update its existing revenue management systems.

[2] Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements, 85 Fed. Reg. 87000 (December 31, 2020).

Contract administration expertise. A common barrier to successfully deploying an innovative contracting solution is lack of consensus on industry standards. This can create misaligned incentives or hinder tracking of patient outcomes. One way to combat this ambiguity is by deploying professionals with a strong data background and the ability to understand outcomes and potential impacts on various pricing scenarios. Manufacturers need to evaluate the proficiency and skills of the professionals who would be responsible for deploying and managing these innovative contracting solutions to ensure they can effectively administer and adjudicate the agreements.

Analytics. Operationalizing an innovative contracting solution is an arduous task. However, being able to analyze results and gain insights that support smart, data-driven decisions is equally challenging and important. Advanced analytics can help ensure the value proposition agreed on between the payer and manufacturer is realized in practice, providing essential insight into the drivers that are affecting performance.

340B Program trends

The 340B Program has experienced tremendous growth over the years, reaching ~$30 billion in annual discounted drug sales in 2019 (more than 8% of US drug sales and ~16% of total government and commercial rebates and discounts provided by manufacturers).[3] A significant driver for this growth is the increase of more than 2,000% in 340B contract pharmacies from 2010 to 2020.[4]

Duplicate discounts, which occur when a manufacturer sells a drug at the 340B discounted price while paying a Medicaid rebate for the same drug, has been a growing and costly issue for manufacturers participating in the 340B Program. Although expressly prohibited by statute, it has been notoriously difficult for manufacturers to detect or prevent duplicate discounts from occurring. A lack of detailed data, combined with operational challenges and resource constraints, limits manufacturers' ability to remedy duplicate discount issues, especially those originating from contract pharmacy transactions or in the Medicaid Managed Care arena.

In an effort to address this problem, some of the industry's largest manufacturers have implemented market access strategies that impose data provision requirements and/or limit distribution on 340B-discounted sales through contract pharmacies.

These strategies have met resistance from 340B-covered entity groups, including legal actions to block the strategies. This, in turn, has triggered counterreactions from manufacturers, including legal actions to stop regulatory implementation of a new 340B Program binding administrative dispute resolution process. As of spring 2021, the 340B Program landscape continues to evolve rapidly, on a weekly or even daily basis.

Manufacturers that participate in the 340B Program, especially those that have not already implemented market access and/or dispute discount and diversion mitigation strategies to reduce revenue leakage, should proactively seek to understand the impacts of 340B discounting on their gross-to-net financials at a product-specific and channel-mix level.

To effectively prepare for any changes, manufacturers need to understand (1) what factors affect the calculation of the 340B ceiling price, the composition of current 340B customers, and the use of contract pharmacies; (2) if current 340B Program integrity operations are effective (e.g., what is the revenue leakage exposure, and how can the operations detect and prevent duplicate discounts and diversion); and (3) how the regulatory landscape might evolve in the future.

A manufacturer can drive business value by defining and implementing a proactive and thoughtful 340B strategy that is tailored to its product portfolio and market access conditions, and that can be operationalized in an efficient and compliant manner.

[3] Drug Channels Institute. "New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales." June 9, 2020.

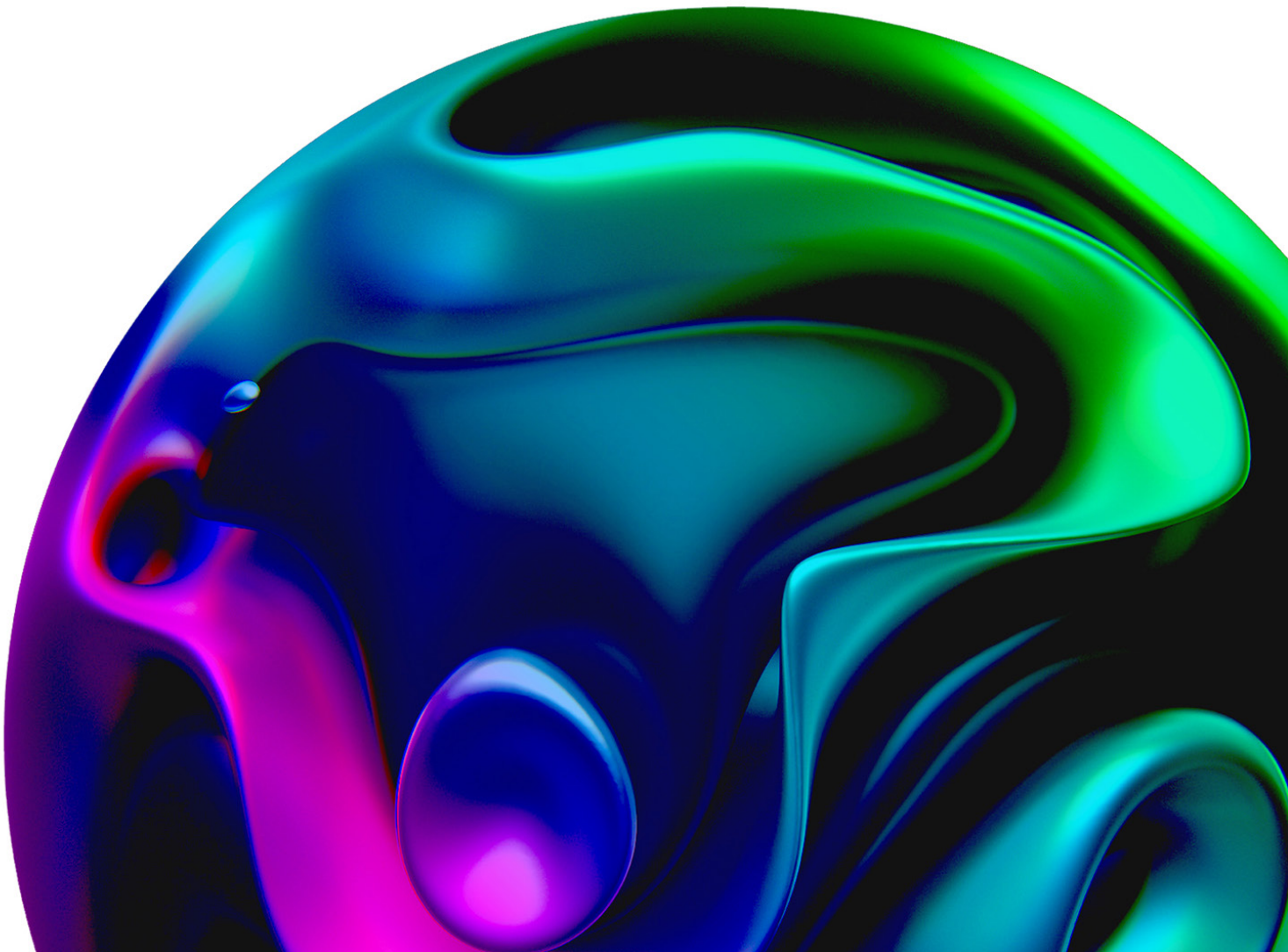
[4] Drug Channels Institute. "Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?" July 14, 2020.

Continuing regulatory activity related to drug pricing

The regulatory environment for drug pricing shows no signs of calming down. Between July and August 2020, the Trump administration released a number of executive orders, including the Most Favored Nation (MFN) Interim Final Rule,[5] which ties drug reimbursements to the lower prices offered by US manufacturers in other countries. However, the interim rule has been met with a series of lawsuits since its inception. Also, the regulatory freeze that occurred in January 2021 as the Biden administration transitioned into power has eased the pressure on manufacturers to take immediate action. However, with similar legislation pending, such as the Elijah E. Cummings Lower Drug Costs Now Act (H.R.3), the requirement to align US drug pricing with international benchmarks may eventually become a reality.

As the Biden administration moves forward, it may pick up MFN or similar legislation and enact it as an interim rule. Manufacturers that sell both domestically and internationally (especially those with product portfolios in the top tier of Medicare spend) should evaluate their current US pricing strategies and pursuits in international markets. Manufacturers should also make it a priority to pressure-test their system capabilities to ensure they can identify international sales on demand and categorize price points by geography. In addition, they should perform scenario planning to see how new legislation might affect their government pricing, gross-to-net, and commercial contracting operations in the United States and internationally.

[5] Federal Register. Most Favored Nation (MFN) Model , 85 Fed. Reg. 76180. November 27, 2020.



State price transparency reporting

States are raising the bar on drug price transparency. Life sciences companies should boost their compliance fitness.

More and more states are taking it upon themselves to curb drug price increases and improve drug price transparency. This trend has gained significant momentum recently and is likely to continue in the years ahead. As additional states introduce and pass legislation related to price transparency, it will be important for pharmaceutical manufacturers to understand the requirements and implications for their current and future business.

State price transparency requirements

Across the United States, a growing number of states have enacted laws designed to improve transparency and visibility related to both significant drug price increases and the introduction of high-cost drugs to the marketplace. These state price transparency efforts generally focus on a manufacturer's responsibility to report new drugs, commercial price points, and/or price increase information in a defined manner and with defined timing (figure B).

Figure B. Enacted state price transparency laws (as of May 2021)

State price reporting requirement (1)	Periodic WAC reporting	New drug		Price increase		Other
		Notice	Report	Advance notice	PI report	
California—SB 17		X	X	X	X	
Colorado—HB 1131						X
Connecticut—HB 5384		X	X		X	
Louisiana—SB 59; HB 436; SB 283	X				X	
Maine—LD 1162			X		X	X
Minnesota—SF 1098			X		X	
Nevada—SB 539; SB 262					X	
New Hampshire—HB 703		X	X			
New Hampshire—HB 1280			X		X	
New Jersey—S2389	X					
North Dakota—HB 1032	X	X			X	
Oregon—HB 4005; HB 2658		X		X	X	
Texas—HB 2536/HB 1033	X				X	
Utah—HB 272					X	
Vermont—SB 92; SB 216; 18 V.S.A. § 4633		X	X		X	X
Virginia—HB 2007			X		X	
Washington—HB 1224		X	X	X		
West Virginia—SB 689	XXX (2)				X	

Status Legend

Blue (Shading): There are defined financial penalties for non-compliance

(1) There are states with active, enacted laws, yet there are no current state price reporting requirements, such as Maine (LD 1499, LD 1406), Maryland (HB 768), and New Hampshire (HB 1418). These states create oversight boards for various drug price transparency efforts, and some have the authority to request information from pharmaceutical manufacturers.

(2) West Virginia has three (3) periodic reports that may be required for manufacturers: the Annual WAC Report, the Research & Development Cost Report, and the Loss of Patent Exclusivity Report. Each of these, if triggered, would be due annually by January 15.

Some of the required reportable information is subject to public disclosure, which could lead to exposure of trade secrets and enable sophisticated and potentially damaging analysis by competitors, the media, and special interest groups. For these reasons, as well as possible penalties for noncompliance, it is essential for pharmaceutical manufacturers to stay informed about regulatory changes and to carefully manage changes to business processes that could affect state price transparency reporting.

Today, many pharmaceutical manufacturers have already evaluated the various state price transparency laws and created processes, along with some form of documentation, to comply with the reporting requirements. However, because of the evolving complexity and cross-functional nature of their capabilities necessary to interpret and assess requirements (and provide the required reports), the people involved are under tremendous strain. Also, different functional areas are not always fully aligned on what is needed (and when) in order to meet the individual state deadlines. In addition, most state price transparency processes remain highly manual, and many pharmaceutical manufacturers are not aware that automated systems and advanced tools are available that could help them rethink their overall governance and operations related to state price transparency reporting.

For compliance programs, this is an area of growing importance and focus, and penalties for noncompliance with state transparency provisions are already mounting. In 2019 and 2020, regulators have issued or threatened to issue fines in the tens of millions specific to noncompliance with state transparency laws.

How to prepare

In response to the rising state price transparency compliance and operational challenges, pharmaceutical manufacturers should periodically undergo comprehensive compliance assessments and reviews of state transparency regulations, then seek out leading industry practices for maintaining compliance and operational effectiveness.

After gaining a clear understanding of the regulatory landscape and establishing robust mechanisms for assessing and addressing changes, the next step is to develop standard operating procedures for state price transparency to ensure the necessary data is assessed, captured, and reported in a way that meets the growing permutations of reporting requirements from state to state. These procedures should identify the cross-functional groups within each organization that are responsible for completing the steps required for compliant and timely reporting.

Some legislation does not explicitly define the required information, timing, or manner of reporting. In these cases, manufacturers have begun to develop standard "reasonable" assumptions to guide their compliance efforts. Similar to the reasonable assumptions manufacturers have developed in response to other government agency reporting requirements, legal counsel will likely be needed to drive development of the assumptions by determining the legislation's intent, then collaborating with the business to establish the approach that makes the most sense.

Finally, as new states enact price transparency legislation (and states with existing legislation change their operational requirements), manufacturers should begin looking at available technology solutions. As with other compliance areas such government price reporting and aggregate spend, technology can help reduce the burden of manual processing which in turn can help mitigate risk.

Strategic opportunities in state price transparency

Pharmaceutical manufacturers have historically viewed pricing compliance as a complication in their pricing strategies. State price transparency reporting requirements are complex and often require close coordination with brand teams, market access, legal, compliance, and government price reporting to help ensure the required reporting occurs on time and in accordance with the legislation.

Successfully navigating the compliance and operational challenges associated with state price transparency involves a highly integrated and cross-functional effort. If integrated within a company's broader pricing decisions, this can help create a unified strategy and approach toward reporting that not only satisfies the state price transparency requirements, but also creates new synergies and companywide benefits that span related functions.

Moving into the future

Now is the time to continue to modernize compliance, shifting the focus from hindsight to foresight.

Over the past several years, life sciences companies have faced mounting pressure from many directions, including increasing regulatory requirements, nonstop technological advances, and intense pricing pressure. And the unprecedented events of the past year only provided more reason to modernize compliance and elevate the value and partnerships within your organizations and with external stakeholders.

To continue thriving and leading, life sciences companies need to meet the industry's new challenges head-on. Compliance organizations have historically focused on point solutions and analyzing tactical, transactional data in search of what went wrong. Now is the ideal time for the compliance function to evolve its focus from hindsight to foresight, teaming with the business to produce information that enables business growth. This generally requires modernization of the compliance function and new approaches to compliance.

Today's compliance and regulatory organizations have an opportunity to elevate their alignment with business needs and requirements and to respond more efficiently and effectively to external opportunities, challenges, and pressures. Modern compliance functions need to continue to be risk-intelligent and efficient, serving their organizations through important business partnerships.

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Digital transformation: Using technology to enhance compliance monitoring and enable business success

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