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Looking ahead: Life sciences regulatory compliance

Updates, trends, and changes affecting compliance leaders in 2022

Life sciences companies continue to focus on the needs of patients and the health care professionals who support these patients while balancing continued industry obligations and regulatory changes.

And while digitalization and modernization are helping regulatory compliance teams work faster and more collaboratively, it also adds another layer of complexity and possible risk.

In this year's Regulatory Outlook, you can explore observations, trends, and actions to consider that may have an impact on new legislative and regulatory changes, as well as your role and focus areas. You'll also gain insight into the digital tools and practices that compliance teams are using to stay relevant, reduce risk, and build resilience to have a positive impact now and into the future.

This year, we focused on these important topics:

- Digitalization of compliance
- Compliance monitoring challenges
- On-target third-party risk due diligence strategies
- A plan for whistleblower reporting programs
- Patient influencers fair market value
- Collaborating during internal investigations
- Pricing and contracting compliance and legal support
- Shining light on Medicaid and Medicare regulatory updates

The Deloitte Life Sciences Regulatory Compliance team is committed and focused to helping our clients with some of the most important needs they have in their mission to make lives better for others.

Accelerating the digitalization of compliance

Two distinct yet synergistic trends shifting the organizational design of the function

In our 2021 regulatory outlook, we outlined some transformative technologies and use cases to show you what digitizing compliance operations looks like. Over the past year, some key trends emerged within life sciences compliance departments. Here's how they are bringing various use cases to life within their organizations.

#1 Centers of excellence—Small teams that work with a centralized technical team to leverage existing enterprise technologies to avoid each building their own unique databases, enabling technologies, or even larger teams of experts.

#2 Existing enterprise technologies—Identifying and developing enhanced technologies to improve operations is not a core area of strength for most compliance departments. Leveraging tools that other business units use helps compliance be more effective and operational.

> *Our compliance analytics program has been established for many years now, however, the impact of the pandemic as well as the OIG Special Fraud Alert have forced us to accelerate our analytics and automation capabilities [...] to keep an eye on what we 'know' and focus on the new emerging areas.*
>
> *– Director, Global Compliance Data Analytics and Transparency, of a multinational pharmaceutical company on the use of technologies to improve compliance operations*

A hard pill to swallow

Six live monitoring challenges and recommendations for drug and device company promotional interactions with HCPs

As a result of the pandemic, drug and device companies continue to be under increased scrutiny when it comes to their promotional interactions with HCPs. To keep patients' best interests in mind, companies should consider recent changes in the market and industry guidance as they monitor the compliance risks associated with speaker programs and sales representatives' detailing of HCPs.

1. Use monitoring results to generate meaningful insight.

   Establish an end-to-end process of collecting, storing, analyzing, and reporting monitoring results to make the data useful for analytics and to deliver proactive compliance risk monitoring and management.

2. Complying with detailing requirements in virtual settings.

   Enhance technology and processes to monitor virtual engagements effectively and efficiently to identify and mitigate compliance risks.

3. Complying with PhRMA Code requirements related to alcohol at speaker programs.[1]

   Establish guidance and provide additional training to company personnel and speakers related to alcohol requirements at speaker programs.

4. Protocols for handling attendees who show up late and miss large portions of the program.

   Create requirements and processes for handling late arrivals to ensure consistency and compliance in speaker program execution.

5. Tracking attendance and topics covered at speaker programs in compliance with the OIG Special Fraud Alert.[2]

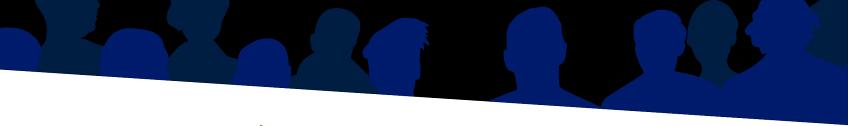
   Implement processes to track attendance and topics covered at speaker programs to help show that attendees are not attending multiple events on the same topics.

6. Providing meals to health care professionals who were not engaged in the business discussion.

   Reinforce requirements (e.g., reminders, training, updated guidance) related to "dine and dash" meals, and use live monitoring to identify potential noncompliance.

Follow the money

Pharma and device companies paid health care professionals more than $2.5 billion in general payments (e.g., non-research-related payments) in 2021.[3]



Does your third-party risk strategy hit the bull's eye or fall short?

Four questions compliance leaders should ask about their third-party due diligence practices

Dramatic global developments, complex regulatory requirements, and companies' own policies have changed global supply chains and third-party relationships. But are companies hitting the mark when it comes to detecting and mitigating third-party risk?

Although the target is constantly moving, it's time to take aim at the due diligence performed on your suppliers, distributors, and other third parties.

How often should we screen a third party for sanctions?

The US Treasury's Office of Foreign Assets Control (OFAC) has announced new sanctions on average **once every 3.7 days.**[4] Today, companies need **continuous monitoring of their third parties,** screening against the ever-changing sanctions and exclusion lists on a weekly—or even daily—basis.

Is our process tailored to a risk profile or is it a one-size-fits-all approach?

While most due diligence should include tiers of investigation commensurate with risk of the third party, **third-party risk has further evolved** with geopolitical conflict and the corresponding sanctions, import and export controls, and possible reputational risk that comes with doing business with the wrong third party. **Now is the time to reassess risk-scoring factors.**

Are we identifying and screening our third parties' beneficial owners?

Today, **companies that fail to account sufficiently for ownership structure face an increased level of risk.** You may need to assess if your due diligence **goes deeply enough** by asking the following questions:

- Does our due diligence include the **identification of beneficial ownership**, to help us abide by OFAC's 50 Percent Rule and more recent European Union rules?
- Does our due diligence include **targeted research** to identify if a third party or its affiliated entities are doing business with sanctioned countries?

Does our due diligence include media monitoring?

Monitoring news coverage and internet chatter on your critical third parties provides greater insight into the kinds of risks a relationship poses to your business—in real time. And it can help **alert you to emerging risks sooner** before their problems become your problems.

A four-point plan to hold the line on your whistleblower reporting program

Amid increased attention on employee whistleblower cases, new guidance from US and global regulators urges companies to reevaluate whether their whistleblower reporting programs are tackling the problem or just punting on responsibility.

#1 Be a team player—A comprehensive program is more than a hotline and involves individuals from different parts of the organization (compliance, legal, HR, etc.) with resources devoted from intake to initial triage and from investigation to remediation.

Extra points: Roles and responsibilities are constantly assessed throughout the lifecycle.

#2 Update your game plan—Guidance emphasizes the need to regularly refresh programs based on changing company dynamics such as emerging risks, operations, and culture. Employee culture surveys provide insights on how to evolve programs, and historical learnings can identify areas for improvement.

Foul play: Historically low anonymous reporting rates could indicate a lack of trust in the process.

#3 Don't ice the kicker—Research[5] shows a lack of trust in the process leads to lack of reporting. Create an environment where a) the whistleblower reporting process is widely communicated, known, and transparent; and b) employees have sufficient trust to participate in the process without fear of retaliation.

#4 Practice makes perfect—After critically challenging your company's whistleblower protection program, it's time to identify metrics to see if progress is on track and proactively design data-driven insights to uncover potential issues.

Patient influencers are going viral

But what does it mean for HCP fair market value (FMV)?

Social media influencers and a subset group known as "patient influencers,"[6] can be patients, physicians, patient advocates, nurses, and others who are involved in delivering or receiving care. They have become a part of the health care system and are now significant voices providing educational and promotional support to the life sciences industry.

Social media has changed the marketing landscape of the life sciences industry in many ways, but in particular, the way in which information is provided, disseminated, and gathered.

Interactions and engagements specific to social media differ from those of the traditional FMV model with HCPs. Nonetheless, the concept of FMV continues to apply. These interactions go beyond the hourly level of effort of a social influencer whereby the FMV will depend on the social media platform, number of followers of the influencer, and relevance of the content, among other factors.

Likes

Research[7] has shown that among patient influencers:

94%

utilize social media to advocate on a specific health condition or topic

80%

turn to social media to connect with peers and access support

94%

say that online communities play at least a "somewhat important" role in their health conditions

Challenges

The use of social influencers by life sciences companies is relatively new and carries regulatory risk related to the Federal Trade Commission (FTC), US Food and Drug Administration (FDA), fair and balanced disclosures, Anti-Kickback Statute, and the Stark Law. Therefore, companies must remain vigilant and ethical in their pursuit to expand their reach.

Now is an opportune time for companies to assess their end-to-end HCP engagement processes to help ensure the policies, processes, and controls—including those related to FMV—are aligned to govern this new way of working.

Magnifying internal investigations through teamwork

Three areas where compliance and legal can (and should) collaborate

Compliance and legal can combine their unique perspectives and expertise to enhance internal investigations and reduce time-consuming redundancies and costly errors. Here are three areas where collaboration can improve outcomes:

1 Early case assessment and investigation plan development

- **Stakeholders with different areas of expertise may identify additional issues** and **offer unique perspectives** to more efficiently triage and scope investigations
- Collaboration can provide access to other avenues for **securing additional resources**
- **Centralizing and synchronizing** strategies, resources, evidence collection, analysis of results, and tracking of recommendations may help **reduce redundancies**

2 Evidence collection and review for data analysis and interviews

- Stakeholders from different areas may have **unique insights on types of data, documents, and other information** available for analysis
- **Additional resources may increase the speed** of the investigation allowing for **more timely communications** if there's a need to pivot
- Different focuses of each department allow for review of information from **multiple angles** and allows for the **review of information in parallel**
- Additional resources to **identify information gaps and/or offer technological solutions** to collect overlooked or inaccurately analyzed data
- Different departments can **more quickly identify relevant interviewees** based on areas of responsibility and skill sets
- Resources to jointly develop, review, and synthesize information may **increase efficiency**
- Diverse backgrounds and expertise infuse **fresh perspectives** to supplement the data analysis and interview processes

3 Reporting and remediation of cases

- Multiple perspectives may lead to **more comprehensive conclusions**
- Additional viewpoints may help provide **more practical, actionable recommendations** for go-forward remediation
- A coordinated response to mitigate risks going forward helps **ensure operational and cultural alignment** throughout the organization

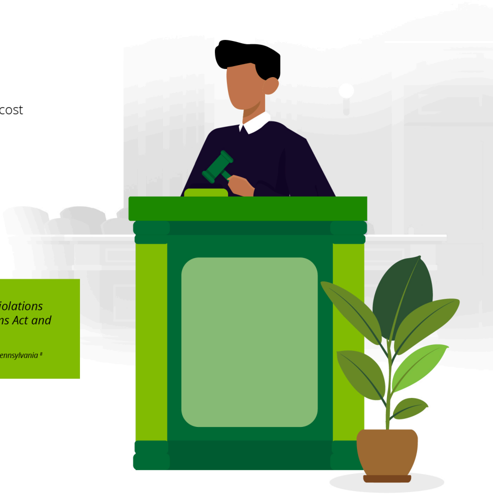
Compliance's and legal's support of pricing and contracting

Resolution of alleged False Claims Act liability can cost manufacturers large sums of money

Here's how some drug manufacturers are responding to increased scrutiny on pricing and contracting functions:

- Enhancements to pricing and contracting systems and processes
- Deployment of advanced technology (e.g., machine learning) to support monitoring activities
- Increased coordination between compliance, legal, and business stakeholders

> *We will continue to aggressively pursue these violations of the Anti-Kickback Statute and the False Claims Act and obtain significant recoveries.*
>
> *– Acting U.S. Attorney Jennifer Arbittier Williams for the Eastern District of Pennsylvania* [8]



Shining a light on Medicaid and Medicare regulatory updates

Uncovering three updates in 2022 you might have missed

1

What changed: Inflation Reduction Act—Aimed to reduce costs to Medicare beneficiaries, the legislation will:

- Allow Centers for Medicare & Medicaid Services (CMS) to negotiate prices for select high-cost drugs in Part D and Part B (effective 2026);
- Require manufacturers to pay inflation rebates to Medicare (effective 2023) if the price of Part D and Part B drugs increase faster than inflation; and
- Redesign Medicare Part D to cap out-of-pocket costs for Medicare beneficiaries to $2,000 (effective 2025).

Why it's important

Manufacturers need to identify which products and future pipeline assets may be affected:

- Model potential **financial implications**
- Consider **strategic planning for pipeline assets** including launch price strategies

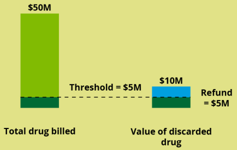
2

What changed: Medicare Part B wastage: REFUND Act—Effective January 1, 2023, the REFUND Act requires manufacturers to pay CMS a refund based on the discarded volume of Part B drugs.[9]

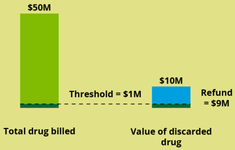
Why it's important

- **All single source drugs**, biologicals, or biosimilar biological products payable under Medicare Part B are included
- **10% threshold will be applied** to the estimated allowed charges for drug billed in a quarter
- **Manufacturers will potentially owe** significant amounts of money to CMS
- **Significant impact to therapies** with weight-based dosages

Base case interpretation: 10% of total amount



Alternate interpretation: 10% of discarded amount



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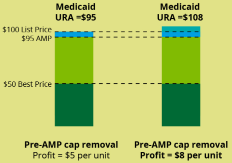
What changed: AMP cap removal—In 2024, the statutory cap on rebates that drug manufacturers pay to Medicaid (previously capped at 100% of the drug's average manufacturer price (AMP) will be eliminated due to the American Rescue Plan Act of 2021.

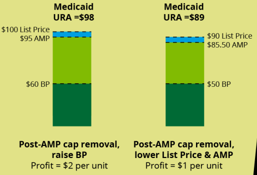
Why it's important

- **Drugs with price increases that exceed the inflation rate** can significantly increase manufacturer Medicaid rebate liability and could even result in rebates that exceed sales price.
- **There is uncertainty around the actions and reactions** of customers and competitors in this new environment.
- **Removal of the Medicaid Unit Rebate Amount (URA) liability cap** at AMP will impact Medicaid-covered outpatient drugs

In some cases, rebates may exceed sales prices.



To mitigate, drug manufacturers can raise the Medicaid Best Price (BP) and lower the List Price to decrease AMP.



The Life Sciences Regulatory Compliance team at Deloitte is focused on helping our clients identify industry trends, navigate regulatory challenges, and seize digital opportunities to grow and protect the business. Please reach out to us if you have any questions about how these updates and changes may impact your organization.

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Endnotes

[1] Deloitte, "A summary of the updated PhRMA Code," 2021.
[2] Deloitte, "Office of Inspector General releases special fraud alert for speaker programs," 2021.
[3] Centers for Medicare & Medicaid Services (CMS), "Open Payments – Data overview," accessed October 19, 2022.
[4] US Department of the Treasury, "Sanctions List Updates" webpage, accessed October 19, 2022.
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[8] US Department of Justice, "Pharmaceutical companies pay over $400 million to resolve alleged False Claims Act liability for price-fixing of generic drugs," press release, October 1, 2021.
[9] REFUND Act of 2021, S.1287, 117th Cong. (2021–2022).