This publication is part of the Deloitte Center for Regulatory Strategy Americas' cross-industry series on the year's top regulatory trends. This annual series provides a forward look at some of the regulatory issues we anticipate will have a significant impact on the market and our clients' businesses in 2017. The issues outlined in each of the reports provide a starting point for an important dialogue about future regulatory challenges and opportunities to help executives stay ahead of evolving requirements and trends. For 2017, we provide our regulatory perspectives on the following industries and sectors: banking, securities, insurance, investment management, energy and resources, life sciences, and health care.

We hope you find this document to be helpful as you plan for 2017 and the regulatory changes it may bring. Please feel free to contact us with questions and feedback at centerregstrategies@deloitte.com.
Contents

Introduction 2

1. Pending changes to the EU regulatory requirements for medical devices 4
2. Medical devices: FDA cybersecurity regulatory update 5
3. Use of next-generation sequencing in-vitro diagnostics 6
4. Quality metrics for pharmaceuticals 7
5. Identification of medicinal products (IDMP) 8
6. Fair market value (FMV) 10
7. 340B Drug Pricing Program pending regulatory changes 11
8. FDA’s Office of Prescription Drug Promotion (OPDP) and off-label 13
9. Pricing and market access: Patient assistance programs (PAP), copay, copay donation, and specialty drugs 14
10. Global and US transparency 15
11. Simplify compliance, focusing on strategic risks 17

Looking ahead 18

Contacts 21
Introduction

The 2016 election results may, over time, reshape the life sciences industry’s regulatory landscape. Key regulatory areas, such as insurance coverage, Medicare reimbursement, regulatory inspection, and user fees face uncertainty, and no one knows for sure how things will turn out. Also, regulatory-driven trends in health care, such as an increased focus on patient outcomes and value-based contracting, have a significant downstream impact and reveal regulatory priorities that could eventually lead to related regulations in life sciences.

As companies look for clues and direction to help guide their compliance strategies, actions, and investments in 2017 and beyond, they should be proactive and pay extra attention to regulatory changes as they unfold, as the industry’s regulatory trajectory may shift. Yet they would be wise to be careful about engaging in undue speculation. After all, most of the boldest ideas to amend or repeal existing statutes would need to go through the full legislative process, starting with bills in Congress. Revising other regulations or guidance would be somewhat easier, but there’s still a process to follow and the scope of change would be narrower.

On the other hand, companies should also make a conscious effort to avoid being paralyzed by uncertainty. With so much change in the air, it can be tempting to just sit back and wait for things to settle down. But until changes are officially announced and approved, compliance with existing regulation is paramount.

Also, it’s important to note that firms have invested considerable money and effort in key regulatory-related activities—such as enhancements to risk management and compliance frameworks. These investments can be expected to deliver long-term business benefits regardless of the specific regulations that are enacted.
Taking all these factors into account, here are the regulatory trends we believe may have the biggest impact on life sciences companies in 2017:

- Pending changes to the European Union (EU) regulatory requirements for medical devices
- Medical devices: Food and Drug Administration (FDA) cybersecurity regulatory update
- Use of next-generation sequencing in-vitro diagnostics
- Quality metrics for pharmaceuticals
- Identification of medicinal products (IDMP)
- Fair market value (FMV)
- 340B Drug Pricing Program pending regulatory changes
- FDA’s Office of Prescription Drug Promotion (OPDP) and off-label
- Pricing and market access: Patient assistance programs (PAP), copay, copay donation, and specialty drugs
- Global and US transparency
- Simplify compliance, focusing on strategic risks

In this report, we explore each of these trends based on what we know now, with additional insights about high-level views on potential regulatory changes. However, in 2017, we may very well find that nothing is certain until it actually happens.

To stay on top of the latest regulatory news, trends, and insights, we invite you to visit our website at www.deloitte.com/us/about-dcrsamericas.
Pending changes to the EU regulatory requirements for medical devices

The EU will soon be finalizing new regulations for medical devices, as well as separate regulations for in-vitro diagnostic devices. These regulations will increase the compliance requirements for manufacturers. In particular, there will be tougher requirements for quality systems, post-market surveillance, and device submissions. Specifically:

- All medical devices will have to undergo an independent assessment of safety and performance before they can be marketed in the EU.
- There will be greater transparency of information about the patient benefits and residual risks, and a thorough assessment of the overall risk/benefit ratio will be necessary.
- Additional clinical evidence will be required for new regulatory submissions, as well as for products already on the market.
- There will be a mandatory inclusion of data sourced from clinical investigations for new Class III or implantable medical device applications.
- New requirements will be added for post-market surveillance reporting requirements, and companies will be given less time to report.
- There will be a general strengthening of controls around traceability and transparency across the entire supply chain.
- There will be additional requirements around unique device identifier (UDI) and better alignment with US requirements.

These changes may make it more difficult to bring medium- and high-risk devices to market in the EU. They may also increase the cost of maintaining quality systems and overall compliance post-approval.

In addition, the EU Medical Device Regulation (MDR) will place further responsibilities on notified bodies (NBs), the independent third parties that perform conformity assessments for medium- and high-risk devices. The NBs will be subject to heightened scrutiny from competent authorities—and will need to be designated under the EU MDR—with the process of designation coordinated at a European level. This will likely lead to a reduction in the number of NBs, which would add to the workload for the remaining NBs. This could increase the lead time needed for pre-approval and “for change” audits. The transition of the NBs from “partners to police” may also result in an increase in the quantity and severity of non-conformances identified during routine audits, as well as less collegial interactions between the NB and the audited entity during the resolution phase.

Manufacturers should evaluate these pending changes from both a compliance and commercialization perspective. These changes might make it more attractive to launch products in other markets—such as the US, which has traditionally been seen as a more difficult market in which to obtain regulatory approval. Specifically, the new regulations could:

- Change commercialization strategies for new products.
- Require more investment and maintenance of quality systems.
- Make it prohibitive to keep older and/or lower margin products on the market.
- Provide opportunities for some companies as other companies exit the market.

To prepare for the changes, companies should review the pending regulations, which are expected to be finalized in the first quarter of 2017 and have a three-year phase-in period (five years for in-vitro diagnostic (IVDs)). Also, they should evaluate the potential impact on their quality management systems (QMS) and commercialization strategies. They can then start planning the required QMS changes immediately in order to reduce disruptions to their ongoing business processes and operations.
Medical devices: FDA cybersecurity regulatory update

Medical devices have evolved tremendously over the past 50 years, resulting in an enhanced threat landscape that affects both patient safety and information security. To address this growing issue, the US FDA has released and is enforcing guidance on medical device security.

On June 14, 2013, the FDA issued a guidance document titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." In the document, the FDA signaled a significant paradigm shift that’s relevant for many stakeholders in the connected medical device arena. As medical devices are increasingly interconnected—via the Internet, hospital networks, other medical devices, smartphones, electronic health records, and third-party cloud solutions—there’s an increased risk of cybersecurity attacks. Such an attack could affect how a medical device operates and, ultimately, endanger human health or—even worse—human life.

In January 2016, the FDA released a follow-up document with new cybersecurity guidance. The document outlines the FDA’s cybersecurity expectations for medical device manufacturers regarding “post-market surveillance” of their products. These “pre” and “post” market guidance documents are affecting how medical device manufacturers are thinking and addressing cybersecurity issues, both with devices that are in the pipeline as well as “legacy” devices that are already in the field.

In addition to the above pre- and post-market guidance, the FDA has published guidance on a variety of topics, including the requirements for submitting device packages for approval following software changes.

In order to improve patient care, maintain a competitive advantage, and extend the remote reach of physicians, medical device manufacturers are increasingly connecting their products to the Internet, hospital networks, mobile products, and other medical devices. Although there are clear benefits to using such connected devices, the associated cybersecurity risks are exponentially higher.

As such, connected medical devices are becoming heavily regulated and many manufacturers are struggling to address the FDA’s pre-market guidance for receiving the approvals necessary to market a device. What’s more, for connected devices that are already on the market, many manufacturers and health care providers aren’t sufficiently incorporating the security processes outlined by the guidance.

Manufacturers today have an opportunity to develop efficient security processes that align with the guidance. This would enable them to address security issues early in the design phase and get to market more quickly than companies that retroactively address security. In addition, having a robust product security organization that aligns with regulatory guidance is a valuable differentiator that could lead to increased sales and an improved reputation.

Moving forward, here are some recommended action items for consideration:

• Conduct security awareness training on the FDA’s pre- and post-market guidance, as well as supporting artifacts

• Ensure the cybersecurity team has a seat at the table with decision makers from product development, procurement, and sales throughout the product lifecycle

• Establish a product-focused corporate cybersecurity organization to help implement cybersecurity processes universally across the organization

• Adopt TIR57 risk management principles for medical device security into the organization’s product security program

• Embed security requirements from pre-market and post-market guidance into the QMS or equivalent document hierarchy, with appropriate governance and oversight

• Assign people to implement and execute security processes and train them appropriately

• Consider working with outside security experts for medical device security risk assessments and technical security testing
Use of next-generation sequencing in-vitro diagnostics

As part of the White House’s Precision Medicine Initiative (PMI), the FDA recently issued two draft guidance documents on next-generation sequencing (NGS) in-vitro diagnostics (IVDs) and the use of publicly accessible genetic variant databases.

The first guidance outlines “a flexible and adaptive regulatory oversight approach that fosters innovation and simultaneously assures that patient test results are accurate and meaningful.” The guidance includes considerations for possibly recategorizing certain NGS-based tests for germline (heritable) diseases as Class II (moderate risk), rather than their current categorization as Class III (highest risk)—potentially exempting them from pre-market notification requirements. This could have a huge impact on the commercialization of NGS-related devices by enabling a much faster regulatory path to market since Class III devices require proof of safety and efficacy via controlled clinical trials. Controlled clinical trials are extremely expensive and take years to conduct, whereas an exempted Class II device doesn’t even require the submission and FDA review of a 510(k).

The second guidance provides recommendations to support FDA-recognized publicly accessible databases of human genetic variants as acceptable sources of scientific evidence for supporting the clinical validity of NGS tests. This would allow test developers to use FDA-recognized genetic variant databases to establish, at least in part, the clinical validity of their tests. For pre-market submissions that rely upon genetic variant databases recognized by the FDA, the agency may determine that submission of additional scientific evidence for certain variant assertions isn’t necessary, depending on the sufficiency of the evidence for the assertions. Such information could preclude the need to provide additional clinical data in the submission.

If finalized, this guidance could greatly simplify the submission, review, and approval process for new IVD tests that use NGS sequencing technology and/or can leverage FDA-recognized genetic variant databases.

Firms in this space should review the new draft guidance to determine if the outlined approach is suitable for products in their development pipelines. NGS IVD device developers should identify potential vendors with FDA-recognized databases, while database holders should evaluate the quality criteria to determine if compliance is feasible, as it could significantly increase the value of their databases. It’s important to reiterate that these are draft guidance documents. Therefore, they may be subject to significant changes before the final versions are issued (or the final versions may never be issued at all). However, they do reflect the FDA’s latest thinking on this subject, and they fit nicely with the intent of the PMI which is—in part—to provide policies that allow for the rapid and safe development of individualized patient care.
Quality metrics for pharmaceuticals

The FDA plans to request data on quality metrics and has proposed guidance on data collection and submission. The proposed guidance would bring a paradigm shift in how the FDA schedules its inspections, helping to promote modernization of the pharmaceutical industry and prompting companies to use data analysis to drive process improvement.

According to the proposed guidance, the FDA would request data from companies and calculate metrics based on that data, which might be used for peer benchmarking. This would help the agency evaluate risk and focus on establishments/ processes that pose the greatest risk to patient safety and product quality.

Traditionally, pharmaceutical companies may have focused more on complying with regulatory requirements than on improving their manufacturing processes. At times, this has resulted in drug shortages due to substandard manufacturing facilities.

To address the situation, the FDA is moving toward a science- and risk-based approach for scheduling its inspections. Key goals include avoiding drug shortages, catalyzing the modernization of pharmaceutical manufacturing, and making efficient use of FDA resources.

Pharmaceutical companies should conduct an assessment of their existing systems and processes to ensure they are ready to comply with the FDA’s requirements. Areas that will likely need to be addressed include:

**People**
- Management responsibility and commitment to compliance—and to driving the required changes across the organization
- Organizational changes and allocation of resources to implement and run the quality metrics program
- Training to raise awareness of the issue and create an effective resource pool to support the program

**Process**
- Metrics identification, collection, and standardization (including consistent definitions across the enterprise and separate metrics and tracking for non-US sites)
- Continuous improvement and monitoring, not just focusing on compliance as the end goal
- Validation of IT systems used for data storage and reporting

**Technology**
- Dealing with a complex IT environment, which includes data on multiple systems in different formats
- Automating data collection and ensuring that data is accurate and complete
- Establishing a single platform to consolidate data from multiple systems and locations
- Calculating metrics and presenting the results as a dashboard for continuous monitoring

The proposed guidance is designed to drive manufacturing modernization and also reduce the compliance burden. Companies that have standardized processes and are able to maintain the required quality standards would be subject to less frequent inspections, giving them a strong incentive to focus on process improvement.
Identification of medicinal products (IDMP)

The IDMP regulation is a set of five International Organization of Standardization (ISO) standards with the purpose of facilitating the exchange of medicinal product information in a robust and reliable manner. These standards together allow for the definition, characterization, and unique identification of regulated pharmaceutical products during their entire lifecycle, from development to authorization to marketing. The scope, which is cross-functional in nature, includes more than 400 attributes and more than 1,000 data elements.

IDMP is supported by European legislation and regulation and is required for all companies that market and sell biopharmaceuticals in Europe. In the coming years, other major health authorities are expected to also adopt the IDMP standards. Because most major US-based biopharmaceutical companies market and sell products in the EU—and because they generally have global processes for research and development (R&D), manufacturing, and regulatory affairs—many companies will likely implement IDMP as a large, multi-year business process transformation initiative.

The original mandate called for IDMP to go live in July 2016; however, an iterative approach is now planned, with the first iteration expected to go live in 2018. The life sciences industry is currently waiting for the EU Implementation guidelines (expected in Q1/Q2 of 2017) to prescribe the specific data and process rules that must be followed. Meanwhile, much preparation is needed. Many medium to large biopharmaceutical companies conducted assessments in 2016 to understand the scope and timeline of complying with IDMP. Key conclusions:

• Comprehensive data collection and curation should to begin in 2017 to meet the EU iteration 1 timelines
• Much of the required data exists in unstructured documents, so document parsing capabilities will likely be needed
• Master data management (MDM) will be necessary since the data required for IDMP is distributed across multiple departments and systems within R&D, manufacturing, and regulatory affairs.
• Companies should plan for cross-functional process changes and expanded governance
• Managing product data centrally—using a central repository of product information with controlled vocabularies—will produce a variety of business benefits
The business case for IDMP implementation should extend beyond what’s normally associated with a regulatory compliance initiative. IDMP is an opportunity to implement a leaner, more integrated operating model that supports business transformation and improved patient health. Biopharmaceutical companies should develop a roadmap of strategies to leverage IDMP’s value-added opportunities and synergies with other regulatory drivers that can also make use of IDMP data.

Key challenges:
- Develop and gain alignment on a product master data governance model across R&D, manufacturing, and regulatory affairs
- Define and implement efficient processes to manage the one-time collection and maintenance of IDMP data
- Select and implement the correct set of technologies to enable IDMP processes

Opportunities to achieve operational efficiencies:
- Leverage the IDMP mandate to improve corporate-wide data management practices, processes, and tools
- Improve data governance and optimize information flow to create data once and reuse it across processes, reducing data duplication and inconsistencies
- Improve data aggregation and insights by establishing standards and reusing more controlled vocabularies
- Develop the ability to leverage and reuse structured content/data during the document creation process through structure content authoring; this concept has been piloted on a small scale in biopharmaceutical companies, but is now being more widely considered

A company can start preparing for the IDMP transformation by conducting a detailed product data assessment and by identifying, documenting, and communicating the business benefits associated with better management of product master data (beyond the benefit of IDMP compliance). Other key steps include developing a roadmap of activities required to meet data strategy and IDMP compliance needs; creating a product master data governance council; and understanding the IDMP vendor landscape.

As part of the implementation, the company should assess and design a new process and operating model for one-time IDMP product data collection and maintenance. It should also develop technology requirements and implement tools to assist with the collection, maintenance, and submission of IDMP data to regulators.

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Fair market value (FMV)

FMV is a concept that applies to fee-for-service relationships with third parties, including health care professionals and other experts, as well as third-party providers.

Engaging in such relationships is a common business practice and something regulators expect. However, fee-for-service engagements that aren’t priced at FMV may have the real or perceived risk of leading to inappropriate influence or inducement. Regulatory risks related to payments outside of FMV include allegations of kickbacks and/or illegal remuneration, bribery, and violations of the Foreign Corrupt Practices Act (FCPA).

Increased attention on FMV is being driven by many market factors, including the growth of specialty drugs, globalization, and the increased use of third parties. Furthermore, regulatory actions seem to indicate that the application of FMV may extend beyond its traditional scope. For example, recent actions in a variety of business functions—from clinical trial to reimbursement hub relationships—have signaled the broad expectation that FMV applies to all relationships and engagements across the company.

Manufacturers face the challenge of documenting, maintaining, and monitoring FMV globally. Establishing FMV methodologies that can support global markets is difficult and complex, as markets vary greatly—not only in terms of data availability but also in factors that affect FMV. Regulators have indicated that FMV must be based on a clear and appropriately consistent methodology and that manufacturers must take these considerations into account when establishing their FMV methodology (both for expert engagement and third-party fee-for-service).

Regulators expect manufacturers to have clearly documented methodologies for FMV and to apply those methodologies consistently around the world, as appropriate. Leading practices across the industry are prompting companies to take a holistic view of FMV—from clinical through commercial expert engagement, and from distributor through managed markets partners. With no clear prescription from regulators about what constitutes FMV, manufacturers are left to ensure that their documentation and rationale for determining, applying, and maintaining FMV is defensible and consistent.
A number of federal programs have a direct impact on what drug manufacturers can charge for their products. In 2017, the program likely to face the most significant change and uncertainty is the Section 340B Drug Pricing Program (340B). This program requires drug manufacturers to provide outpatient drugs to qualified and participating health care organizations at significantly reduced prices. As a condition for participation, a drug manufacturer must enter into an agreement with the secretary of Health and Human Services to provide these discounted drugs to eligible entities.

- The 340B program provides one of the deepest discounts on biopharmaceuticals in the country
- In 2015, 340B entities accounted for over $12 billion in drug spend—nearly 3 percent of total spend across the United States
- The 340B program has specific requirements for how manufacturers calculate and report prices

The Health Resources and Services Administration (HRSA), which administers the program, continues to focus on integrity and enforcement activities for both manufacturers and participating health care organizations (“covered entities”). In 2016, which was a very active year for HRSA, the agency proposed several key regulations and guidance targeted for finalization by year-end. The government may extend the timelines into 2017. But once the regulations and guidance are finalized, they will have a direct and significant impact on drug manufacturers.

Key proposed changes include:
- **340B “Mega Guidance.”** The proposed 340B Drug Pricing Program Omnibus Guidance (“Mega Guidance”) was sent to the White House Office of Management and Budget (OMB) for final review in September 2016 and is awaiting publication. The OMB’s agenda as of November 2016 reflected a December 2016 targeted timeline for finalization. If released with no changes, the final version of the guidance could significantly affect the 340B landscape. For instance, clarification on the definition of an “eligible patient”—among other aspects of the Mega Guidance—could reduce the volume of sales eligible for purchase at 340B discounted prices by covered entities. Other provisions that have the potential to significantly affect manufacturers include:
  - Manufacturer restatements of 340B prices and refunds to covered entities for overcharges in cases of both one-time exceptional situations and routine instances of retroactive adjustment to 340B price inputs (e.g., Medicaid Best Price true-up)
  - Expanded requirements for manufacturers related to limited distribution plans
  - HRSA auditing of manufacturers
- **Congressional action.** Following the presidential election, congressional Republican leaders asked the Obama administration to put a hold on new regulations during the transition to the new administration. If the release of the Mega Guidance stalls, 340B may be
Navigating the year ahead Life sciences regulatory outlook 2017

discussed at the congressional level in 2017. After a contentious election cycle, it’s possible that the administration could seek to amend the 340B statute to allow the agency greater power and control over the 340B program.

• Pharmaceutical Pricing Agreement (PPA) addendum. Manufacturers participating in the 340B program are required to sign an addendum to their PPA that requires them to report 340B ceiling prices directly to HRSA on a quarterly basis. However, there’s significant confusion about when and how such reporting is expected to take place, especially since the planned online reporting system is unlikely to be up and running until well after the current agreement submission deadline of December 31, 2016. When submitting their signed PPA addendums, manufacturers should include a letter explaining that compliance is contingent upon receiving clear guidance about how to comply.

• Regulations on 340B ceiling price and civil monetary penalties. The proposed regulations that address manufacturer requirements regarding 340B ceiling price and civil monetary penalties for manufacturer non-compliance was sent to the OMB for final review in October 2016 and is awaiting publication. The OMB’s agenda currently reflects a December 2016 targeted timeline for finalization. These regulations propose to impose fines of up to $5,000 on manufacturers for each instance where they knowingly and intentionally overcharged a covered entity.

• Regulations on an administrative dispute resolution process. HRSA proposed regulations on a process for manufacturers and covered entities to resolve disputes over manufacturer overcharges, as well as covered entity duplicate discounts and/or diversion non-compliance. Comments on the proposed regulations were due to HRSA in October. The proposed process would require manufacturers to go through a series of steps to have disputes ultimately adjudicated by an Administrative Dispute Resolution Panel of federal employees. Such a process would presumably increase the time and effort involved for manufacturers to close out manufacturer audits of covered entities that are disputed by the covered entities.

To prepare for the changes, which could potentially be finalized very soon, manufacturers should review the pending regulations and guidance and evaluate the potential impact on their 340B program compliance and integrity policies, processes, finances, and commercial strategies. They should then start planning for the changes right away in order to reduce disruptions to their ongoing business processes and operations.
Pharmaceutical and medical device manufacturers face new and evolving challenges as they consider the issue of off-label promotion (i.e., promoting products using information that doesn’t align with the FDA-approved label and product indication). The key legal issue is whether companies must strictly adhere to government agency guidance and opinions or whether their promotional activities are protected by the first amendment right to free speech.

Many companies have recently been challenging the FDA’s authority over off-label promotion and have even taken the agency to court. And in at least one case (Amarin v. FDA), the court granted the company an exception to use off-label materials.

Such outcomes could lead to more FDA challenges, and they could make companies more willing to take on the risks of producing promotional materials once considered off-label. Also, they could expand companies’ ability to use medical and clinical information that isn’t part of a product’s approved indication. This has the potential to benefit patients and health care providers (HCPs) by bringing additional safety and efficacy information to their attention, leading to better use of prescribed therapies.

Case outcomes may also affect future FDA and OPDP decisions by redefining the boundaries of legal and regulatory authority for government agencies.

However, companies should weigh the risks carefully when evaluating changes to how they develop promotional materials. Recent cases apply to very narrow scopes of use and—overall—the FDA still maintains its prohibition on off-label promotion. Materials used by companies must be truthful and maintain fair balance between risks and benefits, and the FDA will continue to send warning letters for materials it perceives to be off-label. Companies risk additional regulatory actions if they persist in using materials that the FDA has classified as off-label.

Companies should carefully consider what information is being used to create promotional materials, verifying that there’s substantive clinical and medical data to support the materials and claims. Also, they may need to consider how materials are reviewed—and how internal policies are written—to ensure materials are used and disseminated appropriately.

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Pricing and market access: PAP, copay, copay donation, and specialty drugs

Product pricing and market access programs have been grabbing headlines lately, especially for high-priced specialty products. Major issues include significant price increases on existing products and questions about the mechanisms manufacturers use to support patient access and reimbursement.

Concerns related to the perceived high price of life science products have existed for years and have led to a variety of regulatory requirements. But recent headlines related to pricing and market access—and the resulting public outcry—have further invigorated these concerns.

The days of blockbuster, “simple” compounds are largely gone, replaced by complex products delivered for smaller patient populations. These specialty drugs often require special handling in terms of development, manufacturing, distribution, and reimbursement. This is driving a new landscape for pharmaceuticals and creating new areas of risk for manufacturers.

As manufacturers’ market approaches evolve in response to this new landscape, the resulting pricing and access mechanisms are being criticized by regulators and the public alike. Price is the biggest issue, along with the price-related issues of reimbursement and market access programs put in place by manufacturers to help defray some of the financial burden for patients.

Bipartisan support for further price controls on manufacturers is growing. Vermont and California have both passed legislation to increase transparency around manufacturer’s price increases, and a bipartisan bill has been introduced at the federal level.

Market access programs that provide free product to otherwise uninsured or under-insured patients are under increasing scrutiny. So are programs that help patients with the burden of copayments. Both are seen as mechanisms for manufacturers to continue increasing drug prices while maintaining sales volume through copayment coverage.

Greater regulation and scrutiny of pricing and market access programs is increasing the reporting burden and fines imposed on manufacturers. In Vermont, if a manufacturer fails to provide the information required, the attorney general may bring an action in civil court for injunctive relief and impose a civil fine of $10,000 for each violation.

Global regulatory participation is another potential issue for manufacturers. In particular, there’s a risk that reference pricing will come to the US.

For medical devices, increased transparency could affect the relationship between manufacturers and health care providers. Doctors often provide funding for device development.

In response to this trend, manufacturers need to establish pricing and patient access committees (and/or review the charter and effectiveness of existing committees). They also need to document their pricing. Manufacturers should be able to defend their prices and market access programs with well-documented policies, procedures, and processes.

Manufacturers should also work to improve how they manage third-party relationships. A good first step is to assess existing relationships between a manufacturer and its PAP or copay administrator, as well as the 501(c)(3) entities to which it donates.
Navigating the year ahead: Life sciences regulatory outlook 2017

Global and US transparency

The outcome of the 2016 election—and strongly voiced campaign promises to repeal the Affordable Care Act (ACA, or “Obamacare”)—have fueled much talk and speculation about the future of the law. Two related areas that have not received much attention are the Sunshine Act and FDA pharmaceutical sample disbursement reporting.

The Sunshine Act (Open Payments)

Open Payments (commonly known as the Sunshine Act) is part of ACA, as amended by the Health Care and Education Reconciliation Act of 2010. On August 1, 2013, “applicable” manufacturers were required to begin collecting detailed information about payments and “transfers of value” to health care professionals and health care organizations—with the first federal reports due on March 31, 2014.

Open Payments requires applicable manufacturers and group purchasing organizations (GPOs) to report certain payments and other transfers of value to physicians and teaching hospitals, and also to report any ownership or investment interest physicians (or their immediate family members) have in their company. This information must be reported every year, to be collected and displayed by the Centers for Medicare and Medicaid Services (CMS).

If the ACA is repealed, it remains to be seen if the Sunshine Act will be carved out and remain in effect. Transparency in the pharmaceutical and medical device industry is a growing trend, not only in the US but globally, and other countries are implementing or considering similar legislation.

Repeal of the Sunshine Act would affect US state reporting, sometimes referred to as aggregate spend. Today, reporting of spend activity (or a compliance declaration based on spend data collection and auditing) is required in six states: Vermont, Minnesota, Nevada, Massachusetts, Connecticut, and California, as well as the District of Columbia and Miami-Dade County in Florida. Reporting of payments and transfers of value to US states was taking place long before the Sunshine Act, so the biggest change would be the amount of data reported to the states. Today, under federal pre-emption, the states allow companies to not report data already submitted to CMS for the Sunshine Act. Thus, elimination of pre-emption would increase the volume of data companies send to the states, essentially reverting to pre-2013 status.

FDA sample disbursement reporting

Section 6004 of the ACA amended the Social Security Act to require the submission of certain drug sample information to the FDA no later than April 1 of each year, beginning on April 1, 2012. In particular, section 6004 requires manufacturers and authorized distributors of record (ADRs) for applicable drugs to annually report the identity and quantity of drug samples that were requested and distributed under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This information must include the name, address, professional designation, and signature of the practitioner making the drug sample request (or of an individual who makes or signs for the request on behalf of the practitioner).

Similar to the Sunshine Act, if the ACA is repealed in its entirety, companies would no longer be required to collect information on pharmaceutical sample disbursements and report that information to the FDA. State reporting for this type of information isn’t pre-empted and would thus remain unchanged. Vermont is currently the only state with pharmaceutical sample reporting requirements. However, Vermont’s requirements expand upon those in the ACA to include reporting of starter packs, coupons, and vouchers that enable a patient to receive a prescribed product free of charge or at a discounted price.

Global transparency

Globally, transparency requirements are increasing for life sciences manufacturers that interact with HCPs and health care organizations (HCOs).

• In Europe, HCP privacy is a hot topic, particularly as it relates to consent management for reporting value exchanges in compliance with transparency reporting regulations.

• In Canada and elsewhere, consideration is being given to implementing transparency reporting requirements (following the lead of other countries).

• In the US, CMS is considering changes to transparency reporting that could increase the burden on life sciences manufacturers and GPOs for tracking, recording, and reporting transfers of value to HCPs.

After several years of reporting transfers of value under the Open Payments program, life sciences companies are increasingly focused on preparing for Open Payments data audits by CMS (as well as by the Department of Justice (DOJ), Office of Inspector General (OIG), and the states). Senator Charles Grassley (R) and Senator Richard Blumenthal (D) have introduced a new bill—the US
Provider Payment Sunshine Act—that would expand reporting requirements to additional HCP types (such as advanced practice registered nurses (APRNs)) beyond those currently required by the Physician Payment Sunshine Act. Moreover, in Connecticut, new requirements for nurse practitioner reporting are to be implemented in 2017, with the first report due on July 1.

Evolving privacy laws and regulatory guidance around consent management affect a variety of areas, including obtaining consent, maintaining records of consent decisions, aggregate versus individual reporting, and evergreen contract terms.

Life sciences manufacturers face increasing potential for audits of the data submitted to the CMS Open Payments portal, which could lead to regulatory actions or requirements for improvements. Entering the third year of reporting, there seems to be a general feeling throughout the industry that CMS will soon begin taking action on companies that fail to report (or consistently report late), have a high number of outliers or failed records, or are believed to be involved in off-label promotion and/or kickbacks.

Additional reporting requirements imposed by CMS or the state of Connecticut increase the burden on manufacturers to ensure they collect accurate and complete data for their transfers of value to HCPs. This expanded reporting will give regulators greater insight into manufacturers’ interactions with prescribers, including those beyond the physician level, which could increase the risk of audits since authorities will have more data available to review.

There are significant challenges to capturing and verifying mid-level practitioner data through recipient master data providers, which are the traditional source of HCP and HCO information. In particular, recipient master data vendors may find it difficult to address the need for better recipient master data sources and to standardize information in order to increase reporting accuracy. Manufacturers will likely need to supplement their data with information from other vendors and/or create their own recipient master data records for affected individuals.

In the US, CMS has requested industry comments and feedback on a number of changes it’s currently considering, including:
• Defining different ways to identify teaching hospitals, which has been an ongoing challenge for manufacturers. To date, CMS hasn’t provided much guidance or direction
• Adding payment type categories beyond the current list to enable more precise classification of interactions
• Establishing a defined time period for manufacturers’ obligation to report transfers of value for past years
• Establishing a requirement for all manufacturers to register, regardless of whether they have reportable transactions or covered products
• Changing the information upload schedule from annual to ongoing throughout the reporting year
• Defining Physician Owned Distributors (PODs) and determining what data needs to be reported
• Expanding efforts to streamline data collection and reporting processes, including administrative changes to account management in the CMS Open Payments portal

These changes could increase the burden on manufacturers to identify, track, and report information to CMS. They could also increase the need to manage interactions appropriately from the start (via documented needs assessments, standardized and accurate FMV rates for payments to HCPs, and contracts for services) and to retain supporting documentation for future retrieval and use.

Potential negative audit outcomes include further investigation by the DOJ/OIG and/or imposition of a Corporate Integrity Agreement (CIA), as well as a Deferred Prosecution Agreement (DPA) or other penalties and high-dollar fines related to violations of the False Claims Act and anti-kickback statutes. In addition, negative findings could tarnish a company’s reputation.

Life sciences companies should carefully weigh the cost of reporting against the business value of engaging with HCPs and then provide adequate resourcing to manage compliance with all the requirements. They also should make sure there are documented processes for all steps, from engagement initiation and HCP selection to project close-out (including compliance auditing).

Companies may want to consider enhancing their recipient master data to include mid-level practitioners. This would create a need to train affected individuals about appropriate interactions and data capture. It may also create a need for updated systems to record the interactions and associated HCP data.
Simplify compliance, focusing on strategic risks

Businesses today need to move quickly and innovate. Yet compliance is often seen as a brake that slows the business down or, in some cases, as a barrier to innovation. In response to this concern, there’s an emerging trend to simplify compliance through process automation and to provide risk insights through advanced analytics.

Quality and compliance organizations are under pressure to add more business value by:

• Shifting from after-the-fact checks to real-time detection and resolution of compliance and quality events
• Providing the business with predictive risk insights
• Increasing visibility into non-US activities and quality events
• Empowering markets outside the US to take ownership of quality and compliance

In life sciences, compliance organizations have traditionally focused on ensuring quality and compliance after the fact. The business builds something and the compliance organization checks it, identifying problems after failures have already occurred—and then wasting precious time and resources on remediation. This approach is costly and no longer sustainable.

More and more, compliance is being embedded into business processes so that issues are detected in real time and fixed before they can continue downstream. As a first step to real-time compliance, organizations can start by standardizing quality and compliance processes across business lines to enable consistency. Next, they layer compliance automation algorithms on top of standardized processes to achieve real-time compliance surveillance and remediation.

Standardization and automation effectively allow compliance organizations to help the business achieve the goal of “right the first time”—without wasting time and resources. When compliance operations are standardized and automated, the compliance organization can shift unused employee creativity to tackle more challenging and strategic risks posed by emerging innovations, such as mobile, cloud computing, and additive manufacturing, among others.

Standardized processes and automation can also empower markets outside the US—markets that have even fewer resources to devote to compliance—and generate a wealth of data that can be mined with advanced analytics for visibility into these markets.

Today, more than ever, companies should think about emerging innovations and be ready to quickly harness them or risk falling behind the competition. To make the leap from perceived barrier to strategic risk partner for the business, compliance organizations should consider:

• Identifying opportunities to standardize compliance processes across business lines and markets
• Embedding automation into compliance processes
• Leveraging analytics to mine data for insights across business lines and markets
• Redesigning the compliance operating model to focus more on proactive risk management
Looking ahead

From a regulatory perspective, 2017 is shaping up to be a year with more than the usual uncertainty. In this dynamic and sometimes unpredictable environment, life sciences companies would be well-advised to focus extra attention on keeping up with the latest regulatory trends, while at the same time continuing to do all that’s needed to achieve compliance with existing laws and regulations.

At the Deloitte Center for Regulatory Strategy Americas, we will be continuously monitoring and analyzing new regulatory developments as they unfold throughout the year.

For the latest news, trends, and insights, please visit our website at www.deloitte.com/us/about-dcrsamericas.
Navigating the year ahead
Life sciences regulatory outlook 2017
Endnotes


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