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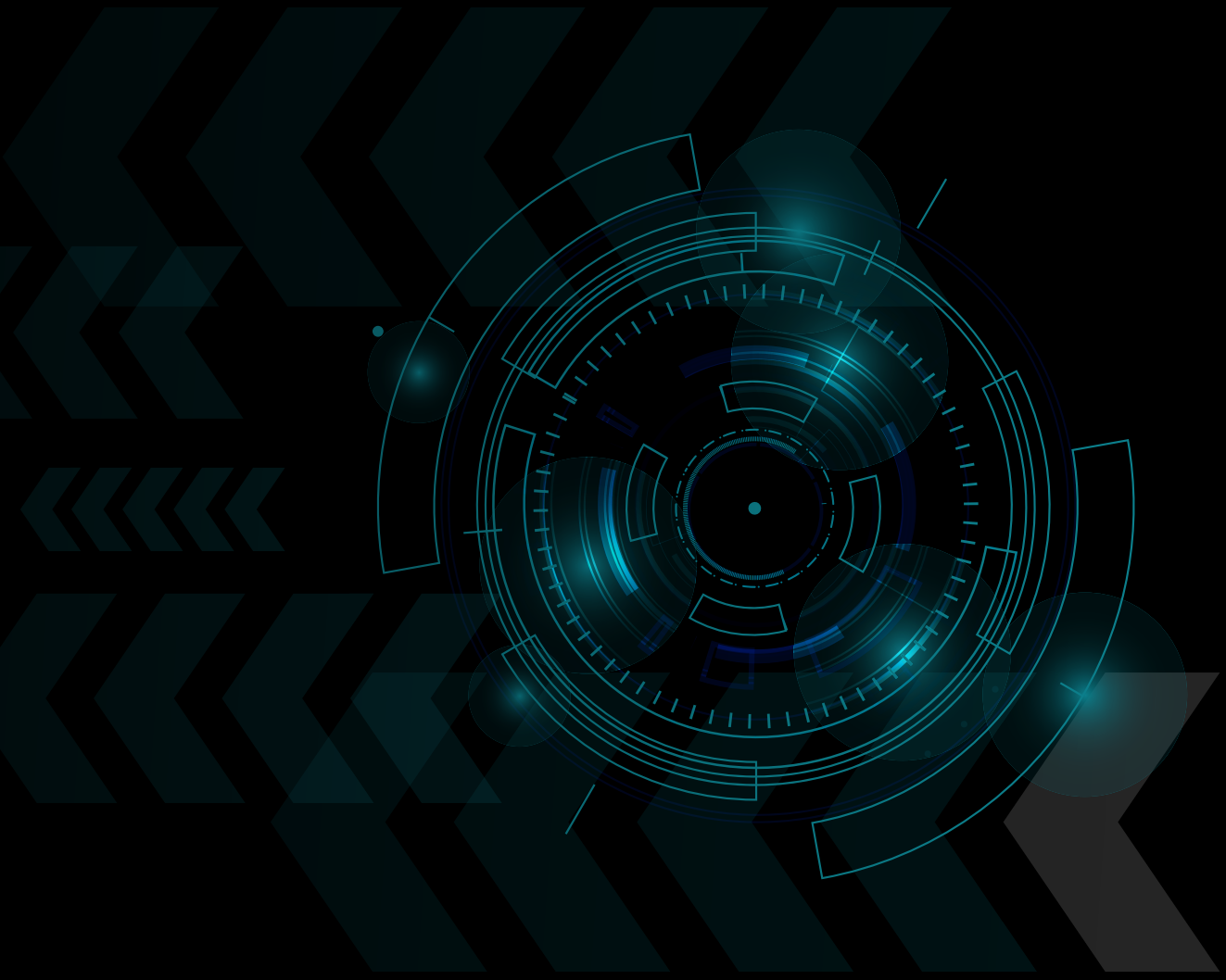


Life sciences companies:

Are you managing your contracts with health care providers effectively?

When it comes to information about their care, consumers trust physicians and provider groups more than any other resource.[1] That's a powerful opportunity for Pharmaceutical, Biotech, and MedTech companies to invest in capabilities to help manage Healthcare Professional (HCP) contracts.

These contractual relationships require focused diligence to help avoid the potential to undermine the integrity of the HCP and company relationship. A subpar contracting process may cause life sciences companies to inadvertently stray from legal and regulatory compliance guidelines and policies. It may also result in inadvertent overpayments to HCPs. An enhanced capability can help avoid unwanted scrutiny from regulators and the public, who may view payments to HCPs as an inducement to prescribe the company's products if they are not in line with Fair Market Value (FMV) standards.

In this article, we'll explore HCP contracting processes and their associated potential risks to be considered. We will also share considerations to streamline the process that allows life sciences companies to potentially improve compliance, reduce their operational burden, and maximize the value they get from the HCP relationships.

HCP contracting in life sciences

Let's start with a definition. HCP contracting refers to the processes by which Life Sciences companies engage and contract with HCPs and Healthcare Organizations (HCOs).

What these processes look like depends on the type of engagement. HCPs play a number of different roles in the life sciences industry. **Examples include:**

Research and development
Early on in life sciences companies' therapy development, or product development, HCPs advise on disease mechanisms as well as the patient needs and treatment gaps they see in practice. At the clinical trial stage, HCPs recruit and monitor patients, keeping track of outcomes and providing insights into treatment preferences.

Advisory boards and consulting
HCPs can also be strategic in helping life sciences companies to gain real-world insights on how therapies are working in practice, and the potential expansion of indications and patient populations. These engagements can also allow for education, calculated planning, thought leadership and advocacy, and product development and improvement.

Education and training
HCPs educate patients and peer healthcare providers on the therapies and devices that support the treatment of patient needs. They also share their knowledge about these treatments with colleagues at medical seminars, conferences, and speaker programs.

Public advocacy
HCPs advocate for patient access to drug therapies. They may share their viewpoints with courts, lawmakers, regulators, medical payors, and the media.

A brief history of HCP payment regulation

Such relationships are highly regulated today, but that wasn't always the case. Most recently, in 2010, Congress passed the Physician Payments Sunshine Act as part of the Affordable Care Act. The law required life sciences companies covered by federal health care programs to publicly disclose payments and value transfers to HCPs.[2] California later followed up with its gift ban bill.[3] Since then, many other states have enacted similar laws detailing payments to HCPs.

The life sciences industry's financial ties with HCPs have continued to grow, likely necessitated by increases in patient needs and the complexity of therapies. A 2016 study found that two-thirds of hospital doctors took payments from pharmaceutical companies.[4] Without greater transparency and control from life sciences companies, authorities in the United States and around the world are responding with further measures to help confirm HCPs continue to prioritize the interests of their patients.

HCP contracting potential risks

Against that backdrop, what may be potential risks associated with HCP contracting? **Here are some of the most common ones:**

Compliance and legal

Life sciences companies have to manage HCP contracting within a range of global and regional statutes—think anti-bribery and corruption, anti-kickback, conflict of interest, and data privacy. Noncompliance raises the potential for legal actions and penalties and will likely trigger greater scrutiny that may lead to Corporate Integrity Agreements or similar actions. In addition, the Physician Payments Sunshine Act "requires any manufacturer of a covered drug, device, biological, or medical supply that makes a payment or another transfer of value to a physician, a physician medical practice, or a physician group practice to report annually, in electronic form, specified information on such transactions to the Secretary of Health and Human Services."[5] As of 2024, companies that fail to do so can incur as much as $1.5 million in civil monetary penalties.[6]

Reputational

Industry payments to physicians have become common. Over the last decade, 57% of physicians in the United States received at least one payment from a life sciences company.[7] However, the average payment was $48 whereas some doctors were paid millions, and there was a significant gap between the products associated with the greatest sum of payments and all other products.[8] In one recent case that attracted negative public and media scrutiny, it wasn't the total amount of payments that stood out, but the small number of physicians who received the payments and the high cost of the product. An effective HCP contracting policy can help prevent such outliers and other conditions that could create the perception of undue influence or bias in HCPs' recommendations.

Financial

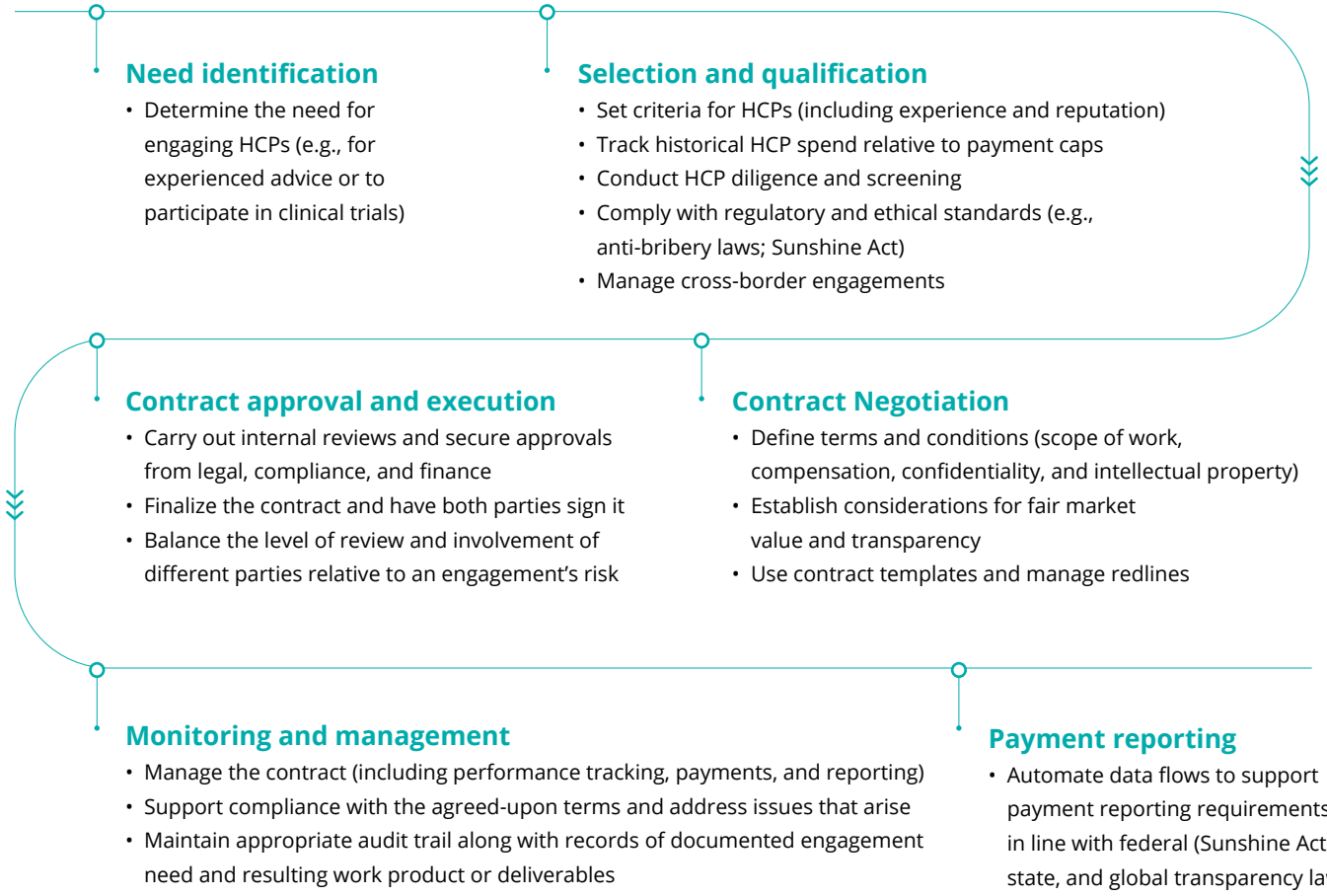
A faulty HCP contracting process can give rise to legal disputes and possible financial penalties. It can also increase the risk of overpaying for HCP services or otherwise misallocating resources. In large companies, even small percentage errors in payments can yield millions of dollars in unsupportable payments each year. A study by the Health Care Compliance Association (HCCA) found that errors in FMV assessments can lead to overpayments ranging from 5% to 20%. For large companies, this can translate to millions of dollars annually.[9] Furthermore, ineffective analytics of engagements with HCP can result in duplicative speaker programs, advisory boards, and similar arrangements.

Potential Improvement opportunities in an HCP contracting process

HCP contracting improvements aren't just an exercise in risk management. Often, there are opportunities to help capture value and do more with less.

Consider the typical HCP contracting process (Figure 1). It looks straightforward—and conceptually, it is. But a lack of process design can introduce a host of operational challenges.

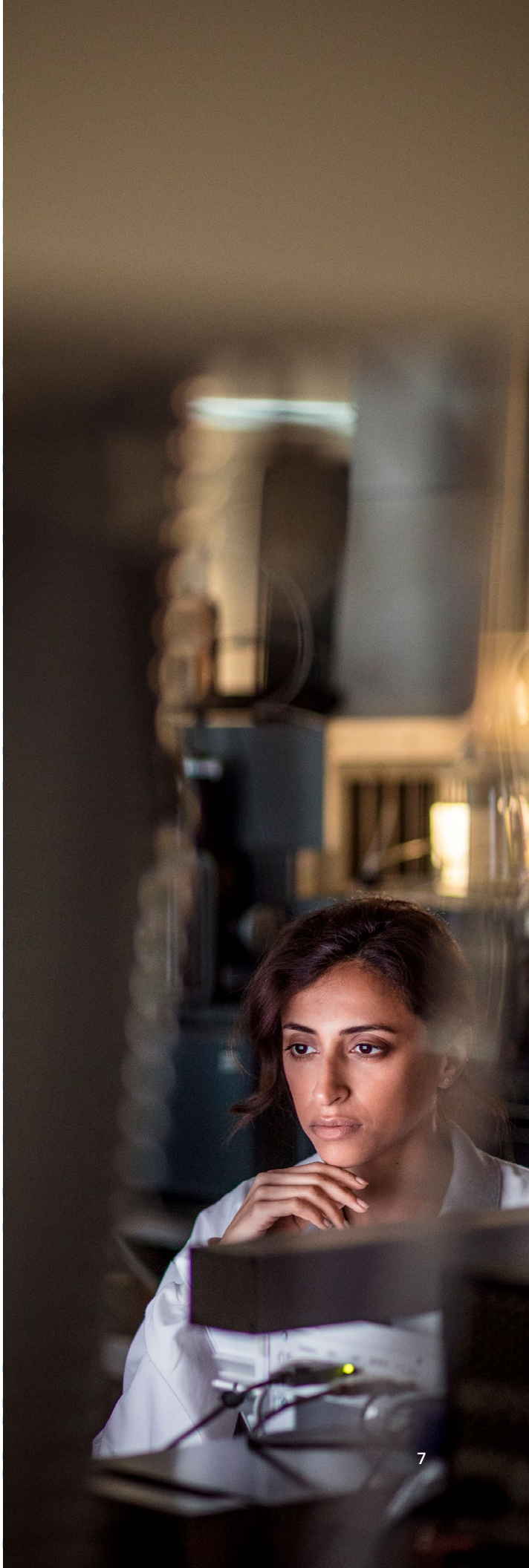
Figure 1: Illustrative HCP contracting process



Let's start with the inefficiencies. HCP contract management is often fraught with time-consuming processes, redundant steps, and a lack of standardization. Contract performance can be hard to track and report. All this can add up to delays in contract execution, which in turn can affect project timelines and outcomes.

Then there's the potential impact on growth. For instance,, hurdles can result in missed opportunities to engage with key HCPs. Aligning the roles of HCP contracting teams relative to medical and compliance, for example, is a common challenge if not well defined.

Finally, cross-border challenges can come into play. Multinational companies may be challenged to harmonize global processes, systems, and FMV compensation rates. Contract templates may vary and cross-border redlines may be tough to manage. Reviews and approvals may slow due to unclear roles, responsibilities, and timelines. At the global level, a poorly designed process can impede visibility into who the company is engaging with, including tracking and management of compensation caps.

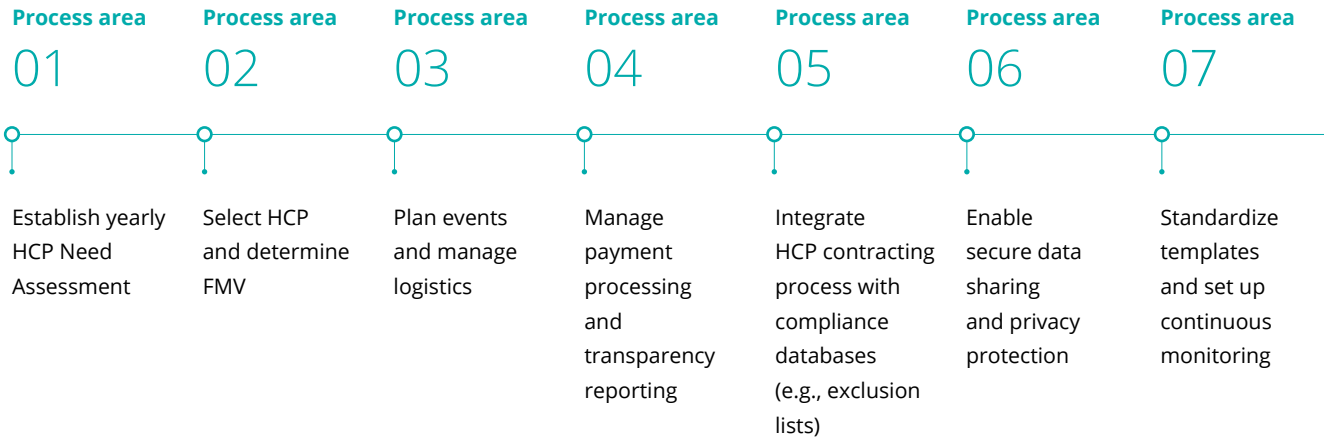


Streamlining the HCP contracting process

Incompatible systems and manual workarounds may accompany a challenged HCP contracting process, which is why many companies look to technology for a fix. Technology—specifically cloud-based solutions and integrations— can be an important part of the answer. But the first step is to get the process right.

Streamlining an HCP contracting process may seem like a daunting task. But it can become more manageable when broken down into smaller tasks along two dimensions. The first dimension is by process area (Figure 2).

Figure 2: Streamlining HCP contracting by process area



The other dimension to potential process improvement is to optimize the organization's capabilities around HCP contracting (Figure 3).

Figure 3: Streamlining HCP contracting by organizational capability

Capability 01	Capability 02	Capability 03	Capability 04	Capability 05	Capability 06
Collaborate with cross-functional colleagues	Create integrated teams (legal, compliance, finance) to streamline contract workflows	Establish clear communication channels and responsibilities	Set up controls to support transparency and compliance in FMV assessments and contracting processes	Train staff involved in HCP contracting to facilitate understanding of regulations and leading practices	Provide continuous education on evolving legal and compliance standards

Help reduce risk, increase reward

HCPs have become a pivotal fixture in the life sciences industry. They can be a trusted resource for patients and a key advisor to organizations that dedicate themselves to improving people's lives. At the same time, the industry's financial ties with HCPs have attracted growing scrutiny from lawmakers and regulators.

But regulatory compliance isn't the only potential risk of HCP contracting. Lifesciences companies should also manage the potential for reputational and financial setbacks. An effective HCP contracting process can help manage these potential risks while helping companies to potentially capture more value and reduce their operational burden. By streamlining HCP contract management along two dimensions, process area and organizational capability, life sciences manufacturers can potentially create a strong differentiator for efficient and compliant engagement with the medical practitioner community.

Contacts

Paul Silver
Principal
Deloitte & Touche LLP
psilver@deloitte.com

Brent Griffith
Managing Director
Deloitte Consulting LLP
bgriffith@deloitte.com

Jaspreet Anand
Vice President, Service Delivery
Deloitte Transactions and Business Analytics LLP
jaanand@deloitte.com

Juan Tessi
Senior Manager
Deloitte & Touche LLP
juatessi@deloitte.com

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