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When Health Care Systems and Life Science Companies Collaborate: Benefits and Key Issues

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In today's dynamic health care industry, health care providers are pressed to constantly adapt and innovate at an unprecedented rate while facing major changes in the applicable reimbursement systems. In such an environment, collaboration between health care systems and life science companies could provide health care providers a competitive advantage in the health care market, while simultaneously providing the life sciences companies with new opportunities to test their product and technology and create market demand. The ongoing COVID-19 pandemic has provided the most recent evidence of the benefits of collaboration between health care systems and the life sciences industry, as collaboration between life science companies and health care systems enabled these parties to jointly expedite medical research and combine technological and financial resources to quickly produce and distribute an effective vaccine to the general public, and to improve therapeutic treatments for COVID-19. Those collaborations not only contributed to financial success of the parties involved, but it provided an enormous health benefit to the general public.

This collaborative approach, however, can also be beneficial beyond the context of a global pandemic. Collaboration between health care systems and life science companies would enable these entities to combine extensive research, independent industry expertise, and financial resources together in pursuit of medical improvements and innovation within the health care industry. The willingness for these entities to combine clinical and technological information and financial resources would likely contribute to individual success in the industry and provide medical innovation and treatment to a wide variety of patients in need.

While there are many potential benefits to collaboration, health care systems and life science companies need to consider a variety of important regulatory and legal issues before they begin a collaboration. The health care and life sciences industries are both highly regulated and the impact of this type of scrutiny should be considered. There are several key issues

that health care systems and life science companies should consider when evaluating a potential collaboration. Here we'll examine these key issues:

- Intellectual Property – If the collaboration involves the potential creation of new technology devices, drugs, or new methods of performing or improving operations, it is imperative that any collaboration identify and document which entity controls and owns which intellectual property, including any new technology developed during the collaboration. This typically occurs through a joint development agreement or other agreement that delineates ownership rights. Further, any joint development should also cover duties of confidentiality and trade secrets so as to preserve the rights for future intellectual property filings.
- Who Owns/Controls the Clinical Data – Because clinical data is very important to the patient and to the development of the applicable technology, a device, or drug, it is critical to clearly define how the clinical data will be obtained and maintained and who owns it before a collaboration begins. Additionally, any third-party processing entity, such as storage vendors, must be identified and examined to identify a clear understanding of how the data will be managed. The parties will also need to obtain applicable patient consents and authorization about how the data will be used, and be sure any applicable HIPAA regulations are being followed.
- Federal Regulatory Issues – There is a well-established system of federal statutes and regulations that apply to health care providers and potentially life sciences companies which must be complied with.
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    - Stark and Anti-Kickback Statutes - The federal regulatory framework includes laws like the federal Anti-Kickback Statute ("AKS") and Provider Self-Referral Act (the "Stark Law") that deal with financial relationships between individuals and entities that refer patients and services to physicians or health care systems that are paid for by Medicare, Medicaid, Tricare or Medicaid Managed Care and Medicare Advantage plans. If collaboration between health care systems and life sciences companies implicate potential referrals of patients or services paid for by federal government, then the relationship should be carefully structured to be within applicable AKS Safe Harbor or Stark exceptions.
    - EKRA - The Eliminating Kickbacks on Recovering Act ("EKRA") is a statute created in 2018 that was designed to help restrict patient brokering and recovery profiteering. EKRA prohibits accepting or paying kickbacks for referral to recovery houses, clinical treatment facilities or laboratories. In the health care and life sciences industry, this statute has raised questions about how entities pay their sales or marketing forces in a compliant manner. The stakes are high because EKRA is a criminal statute. In addition, there has not yet been a lot of case law interpretation of EKRA which means there are still questions on how to maintain compliance with this law. In the life sciences industry, clinical laboratories are most impacted by this statute, as it impacts how these entities market their services.
    - Federal False Claims Act - If health care providers or life sciences companies are submitting claims for payment to the federal government whether it be to Medicare, Medicaid, Tricare or to the Department of Defense, or another federal agency, if the submitted claim was false or improper, it could implicate the federal False Claims Act which could result in draconian financial penalties and exclusion from the federal health programs. These disciplinary actions, specifically exclusion from CMS, can prohibit a health care provider or life sciences company from treating any Medicare and Medicaid beneficiaries, which would be a crushing blow to any health care provider or life science company.

- Sunshine/Open Payment Laws - The Federal Physician Payment Sunshine Act was enacted in 2010. The intent of this act was to increase transparency of financial relationships between life sciences companies and health care providers including physicians and teaching hospitals. This act requires that payments and transfer of value made by life sciences companies to physicians and teaching hospitals be reported in a public database.
- S. Food and Drug Administration ("FDA") laws, including the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and related regulations - FDA is responsible for, among other things, regulating the manufacturing, marketing, and distribution of drugs, medical devices, and biologics. The products manufactured, marketed, or distributed by life science companies many times implicate FDA laws.

- Clinical Research Rules – To the extent the collaboration includes clinical research, the parties should ensure that the applicable clinical research protocol complies with the applicable FDA requirements, including approval by the appropriate Institutional Review Board ("IRB"). To the extent that the clinical research program requires use of health systems services, people or space, the parties should negotiate and enter into written agreements that are compliant with any applicable federal regulatory laws, like AKS or the Stark Law.
- Due Diligence and Documentation of Business Deal – When health systems and life science companies collaborate on a matter, due diligence between the parties is critical to ensure the collaboration is a good, safe fit. The parties should initially execute a term sheet that reflects the business deal. After executing the term sheet, the parties can will develop applicable transaction documents that memorialize the nature and scope of the agreement. These transactional documents will also define any applicable regulatory requirements that will need to be addressed.

CONCLUSION

Collaboration between health care systems and life science companies presents intriguing opportunities and can provide a range of benefits to both parties, but there are a diverse set of key issues both parties must be aware of before entering into such agreements. It is critical that the involved parties consider the different legal and regulatory obstacles a collaborative effort will face and take the proper steps to ensure each is adequately protected and in compliance with the applicable laws. If done properly, the parties can capitalize on the immense potential that collaboration between life sciences companies and health care systems can generate.

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