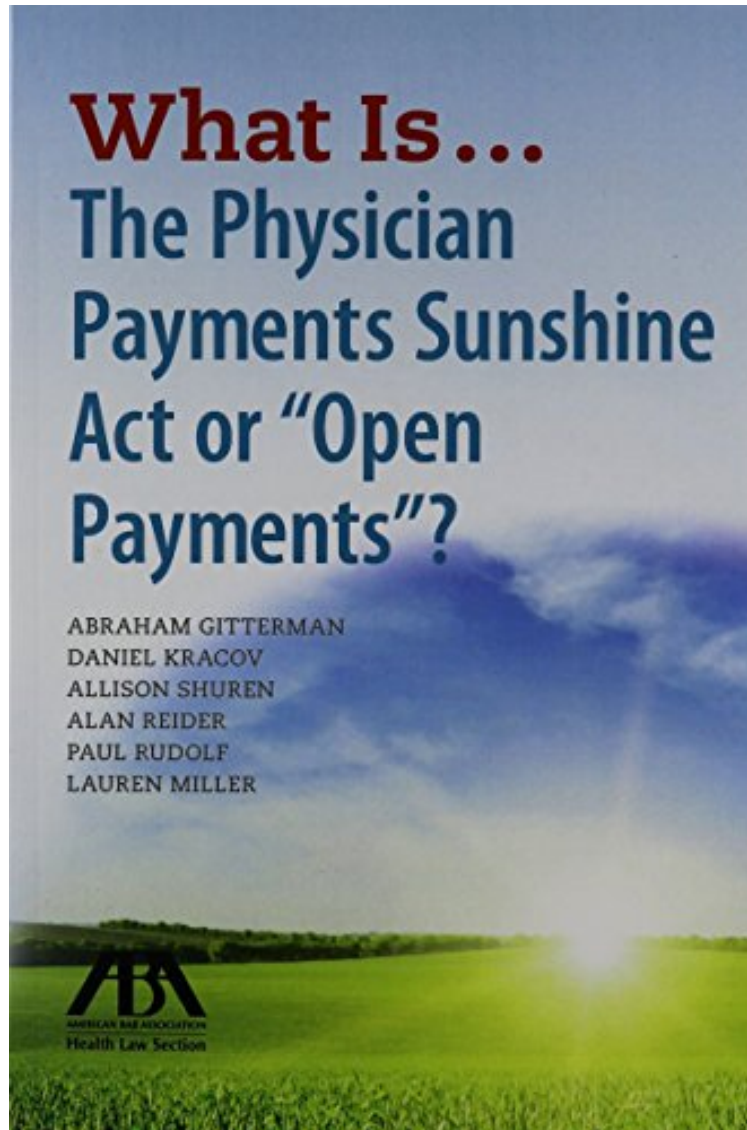


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What Is...The Physician Payments Sunshine Act or "Open Payments"?

*Abraham Gitterman, Daniel Kracov, Allison Shuren, Alan Reider, Paul Rudolf
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This guide provides a detailed overview of the Sunshine Act, transparency initiatives, and related implications associated with increased attention on physician-industry relationships. Section II provides background and the legislative history of the Sunshine Act. Section III provides a detailed summary and analysis of the technical statutory and regulatory requirements manufacturers and group purchasing organizations must abide by to comply with the law. Section IV analyzes the Sunshine Act's regulatory requirements as they may impact other healthcare fraud and abuse and compliance obligations and requirements, including the Anti-Kickback Statute and the False Claims Act. Section IV.C provides an overview of related state transparency laws and gift ban laws, including how such provisions are preempted under the Sunshine Act. Section V offers a brief overview of CMS's first data release on the Open Payments website and discusses potential issues and future concerns for all stakeholders moving forward. As a bonus at the end of this guide you will find: Appendix A - Table of U.S. Transparency, Gift Ban Requirements Appendix B - District of Columbia Appendix C - Massachusetts Appendix D - Nevada Appendix E - Vermont

About the Author Abraham Gitterman is an associate in Arnold Porter's FDA and Healthcare Group in the firm's Washington, DC office, where his practice focuses on FDA and health-care regulatory matters involving pharmaceuticals, medical devices, medical technology and software, and mobile apps. Daniel Kracov is co-chair of Arnold Porter, LLP's FDA and Healthcare practice. He assists clients, including start-up companies, trade associations, and large manufacturing companies, in negotiating the challenges relating to the development, approval and marketing of drugs, biologics, and medical devices. Allison Weber Shuren is co-chair of Arnold Porter, LLP's FDA/Healthcare practice group, where she focuses her practice on a variety of regulatory and legislative healthcare issues involving Medicare coverage, reimbursement and coding issues; fraud and abuse counseling and investigations including defense of allegations of False Claims Act, Anti-Kickback, and Stark Law violations; and implementation and audit of corporate compliance programs and government imposed corporate integrity agreements. Alan Reider is a Partner in the FDA and Healthcare practice group in Arnold Porter, LLP's Washington, DC office, with more than 30 years of experience representing national healthcare corporations, pharmaceutical and medical device companies, as well as institutional providers and individual practitioners and suppliers. Paul Rudolf is a partner in Arnold Porter, LLP's Washington, DC office. Dr. Rudolf has significant experience in both Medicare and FDA legal, regulatory and policy issues, particularly those relating to counterfeit drugs and radio-frequency identification technology as applied to pharmaceuticals and medical devices. Lauren Nicole Miller is an associate in Arnold Porter LLP's FDA and Healthcare practice group, where she provides counseling on regulatory and public policy issues for clients in the drug, food, medical device, and healthcare sectors.