

IMS Health & Quintiles are now



Mini Summit XII

Patient Support Programs: Helping Patient Access Products

*The Regulatory and Compliance
Challenges to Consider Today*

7 November 2019

Today's speakers



Darren Jones

Senior Principal & Global Consulting Practice Leader
IQVIA Commercial Compliance



Elizabeth Weiss

Chief Compliance Counsel for Patient Support Services and Payer Access
Pfizer



Timothy Ayers

Life Science Compliance Consulting, LLC; Former VP, Chief Compliance
Officer, Horizon Pharma plc.



Samantha Badlam

Counsel, Ropes & Gray

DISCLAIMER

Views, thoughts, and opinions expressed today belong solely to the speakers and do not represent, and are not necessarily endorsed by, their employers.

Agenda

- + Patient Treatment Journey Engagement Considerations
- + The 3 Main Areas of Patient Support Programs (PSPs)
- + PSP as a Necessary Tool to Help Patients Navigate the Treatment Journey
- + Patient Advocacy Group Engagement Action

Terminology

- PSPs
- PAPs
- ICPAPs/Co-pay Foundations
- Hubs
- SPPs
- Copay cards/vouchers/coupons

Increased Scrutiny Demonstrated by Cases Nationwide

THE WALL STREET JOURNAL.
U.S. Edition | July 11, 2019 | Print Edition | Video

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U.S. Probes Drugmakers Over Free Services

Companies say the services, such as nurses and copay assistance, help doctors and

By Peter Loftus
Updated Sept. 21, 2018 3:23 pm ET

Federal prosecutors are probing whether big drugmakers including Sanofi SA, Gilead Sciences Inc. and Biogen Inc. potentially violated laws by providing free services to doctors and patients, according to a Wall Street Journal review of securities filings.

Drug companies say the services, such as nurses and reimbursement assistance, help doctors and patients. But the practices, which have

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Markets

California Sues AbbVie Over Alleged Arthritis Drug Kickbacks

By Robert Langreth

Sept 11, 2018

REUTERS

Business Markets World Politics TV

MARKET NEWS MARCH 11, 2014 / 12:45 PM / 5 YEARS AGO

Teva settles Medicaid false billing case tied to Chicago doctor

Jonathan Stempel

March 11 (Reuters) - Teva Pharmaceutical Industries Ltd. agreed to pay more than 100,000 dollars to settle charges that it induced a Chicago doctor to prescribe its generic drug at inflated prices.

BREA

What's News

Drugmakers' Free Services Trigger Anti-Kickback Probe

Federal prosecutors are probing whether big drugmakers including Sanofi, Gilead Sciences and Biogen potentially violated laws by providing free services to doctors and patients.

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By JAMES RUFUS KOREN SEP 18, 2018 | 3:55 PM

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The New York Times

Another Alleged Drug Kickback Scheme

By The Editorial Board

April 27, 2013

Two federal lawsuits charging a prominent drug company with making fraudulent kickbacks to promote sales of its drugs raise disturbing questions about how to control fraudulent behavior in the pharmaceutical industry, behavior that appears to be on the rise. The company is Novartis Pharmaceuticals, the American subsidiary of a Swiss-based multinational. Novartis denies any wrongdoing and vows to defend itself in court.

Less than three years ago, Novartis settled criminal and civil

PSP Compliance Landscape

Regulatory Focus Areas and Key Legal Risk	
Regulatory Focus Areas	Importance
Federal Anti-Kickback Statute (“AKS”) (42 USC 1320a-7b)	<ul style="list-style-type: none"> Prohibits the knowing and willful offer, payment, solicitation or receipt of “remuneration” to induce or reward the referral or generation of business that is paid for by a federal healthcare program.
False Claims Act (“FCA”)	<ul style="list-style-type: none"> Prohibits presenting a false or fraudulent claim resulting in payment through a federal healthcare program
Beneficiary Inducement Statute	<ul style="list-style-type: none"> Prohibits transfer of value to a healthcare program beneficiary that is likely to influence a beneficiary’s provider selection
FDA Regulations	<ul style="list-style-type: none"> Prohibits the promotional advertising of pharmaceutical products off label by pharmaceutical companies in certain cases
HIPPA/Privacy Laws	<ul style="list-style-type: none"> Prohibits certain access to and dissemination of patient information and privacy data to safeguard (e.g., PHI authorization, marketing opt-ins, etc.)

PSP are meant as a necessary tool to help patients navigate the treatment Journey

Why should we be concerned?



1-on-1 Healthcare Professional Consultation

- Off-label advertising
- Unduly influence of therapy choice
- Risk of fraudulent claim
- Abusing patient trust



Financial Services

- Risk of fraudulent claim for special access or special authorization
- Risk of kickbacks paid through Co-Pay Assistance Foundations



Pharmacy Services

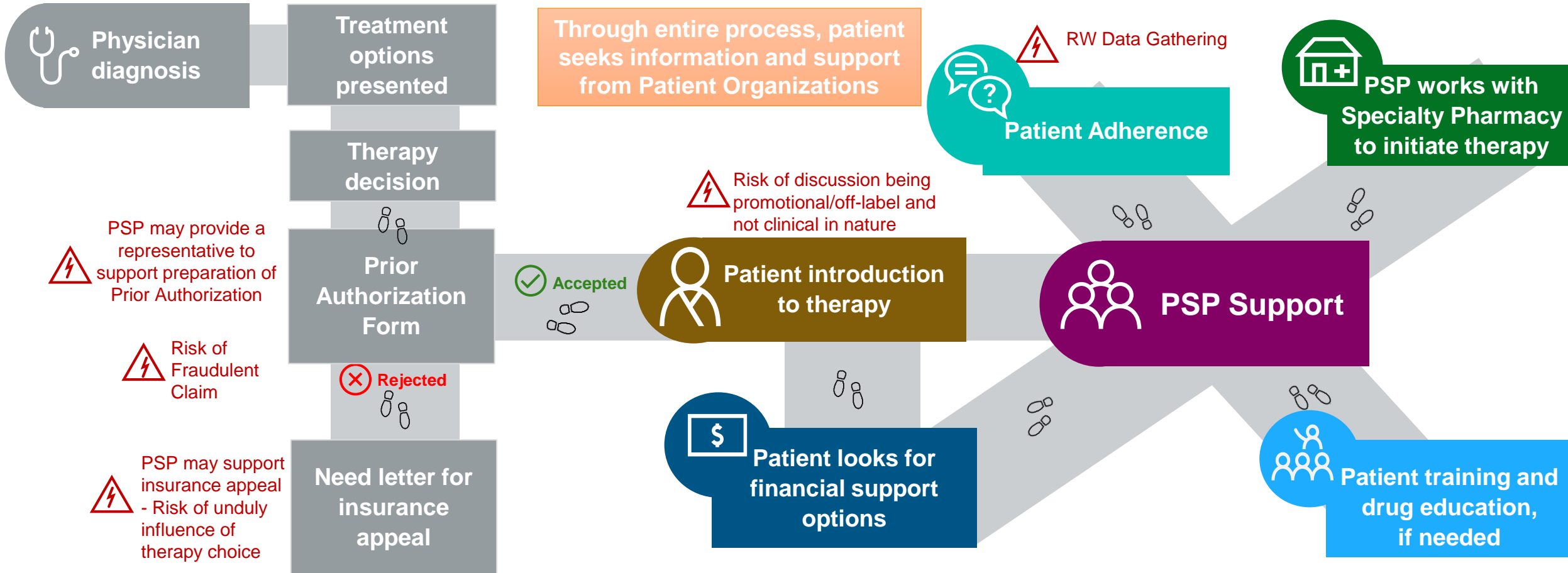
- Unduly influence of therapy choice
- Risk through free drug patient assistance programs



Patient Education & Disease Management

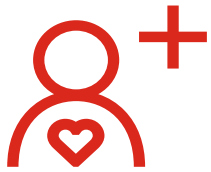
- Off-label advertising
- Unduly influence of therapy choice

Key Considerations Throughout the Patient Treatment Journey



Indicates increased risk

The Role of PSPs has been expanding



Patient Identification

- Programs to support the identification of rare disease patients, including covering the costs for clinical diagnostics and testing
- Engagement with Patient Advocacy or other organizations to support the development of or access to patient registries



Ongoing Patient Support

- Patient case managers and nurse educators
- Treatment and disease education
- Patient Transportation
- Adherence/ Treatment reminders
- Community Support
- Lifestyle/ treatment support



Patient Affordability

- Benefits Verification
- Appeals Support
- Financial Assistance
- Co-pay support
- Foundation referrals
- Samples/ Free product (e.g., PAP)

Best Practices to Minimize Risk



Ensure the integrity of the patient-physician relationship is maintained.



Avoid interference with physician decision making.



Ensure engagement structure reflects HCP as playing the role of an educator rather than a company representative.



Program is tailored to patients who are already on a prescription rather than potential targets for prescriptions.



Services are provided equally regardless of value added to the business.