

COMPLIANT INTERACTIONS WITH SPECIALTY PHARMACIES

**20th Annual Pharmaceutical and
Medical Device Compliance Congress**

November 7, 2019

THE PANEL



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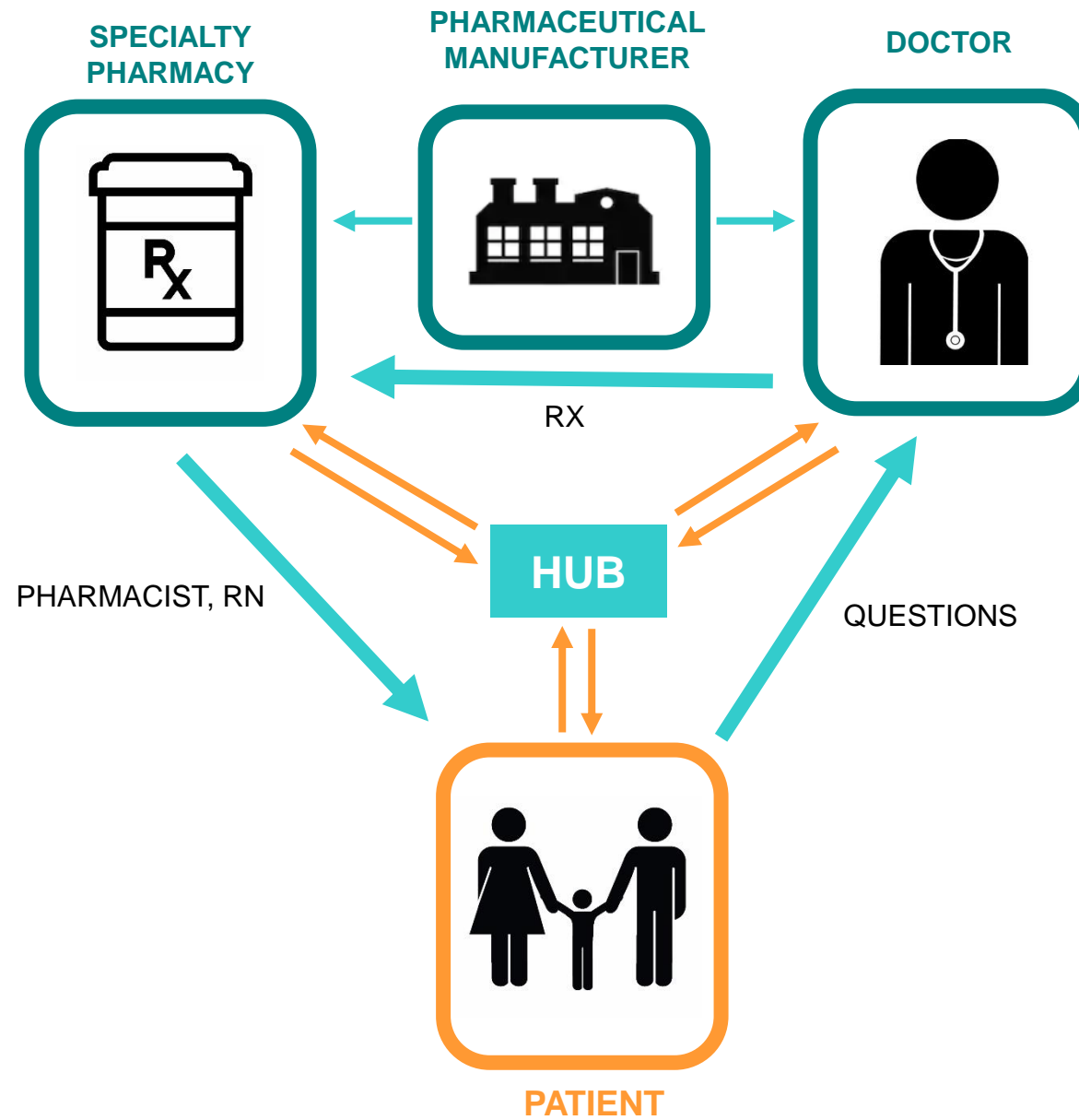
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SPECIALTY PHARMACY BUSINESS MODEL



INDUSTRY ENFORCEMENT EXAMPLE

- Novartis \$390M civil settlement to resolve FCA allegations that it paid kickbacks to specialty pharmacies
 - Incentivized and pressured the pharmacies to emphasize Exjade's benefits to patients while understating the drug's serious side effects
 - Rebates used to induce the pharmacies to recommend to doctors that they switch patients to Myfortic from competitor drugs
- 3 parallel settlements:
 - US Bioservices: \$13.4M
 - Accredo Health Group: \$60M
 - BioScrip: \$15M

“Novartis turned pharmacies that should have been disinterested healthcare providers into a biased salesforce for the drug-maker.
Drug-makers and their relationships with healthcare providers – whether they are doctors, pharmacists, or nurses – must comply with the Anti-Kickback Statute.”
- *Manhattan U.S. Attorney Preet Bharara*

EVOLVING ROLE OF SPECIALTY PHARMACIES

- Defining “specialty pharmacy”
- Evolving list of services provided by specialty pharmacies
- Exclusive vs. non-exclusive specialty pharmacies
- Specialty pharmacy interactions with HUB
- Specialty pharmacy interactions with patient support programs / charitable foundations
- Specialty pharmacy interactions with manufacturer sales team

OTHER KEY COMPLIANCE RISKS AND RISK MITIGATION

- Privacy / HIPAA
- Contract negotiations
- Performance metrics / ROI
- Auditing and monitoring