



specialty pharmacy summit. **2016**

Practical Review of Legal Issues in Manufacturer: Specialty Pharmacy Contracting

Ben DiMarco – Asembia

Michael Hess – Bass, Berry & Sims

Kirk Hunt – Eli Lilly & Company

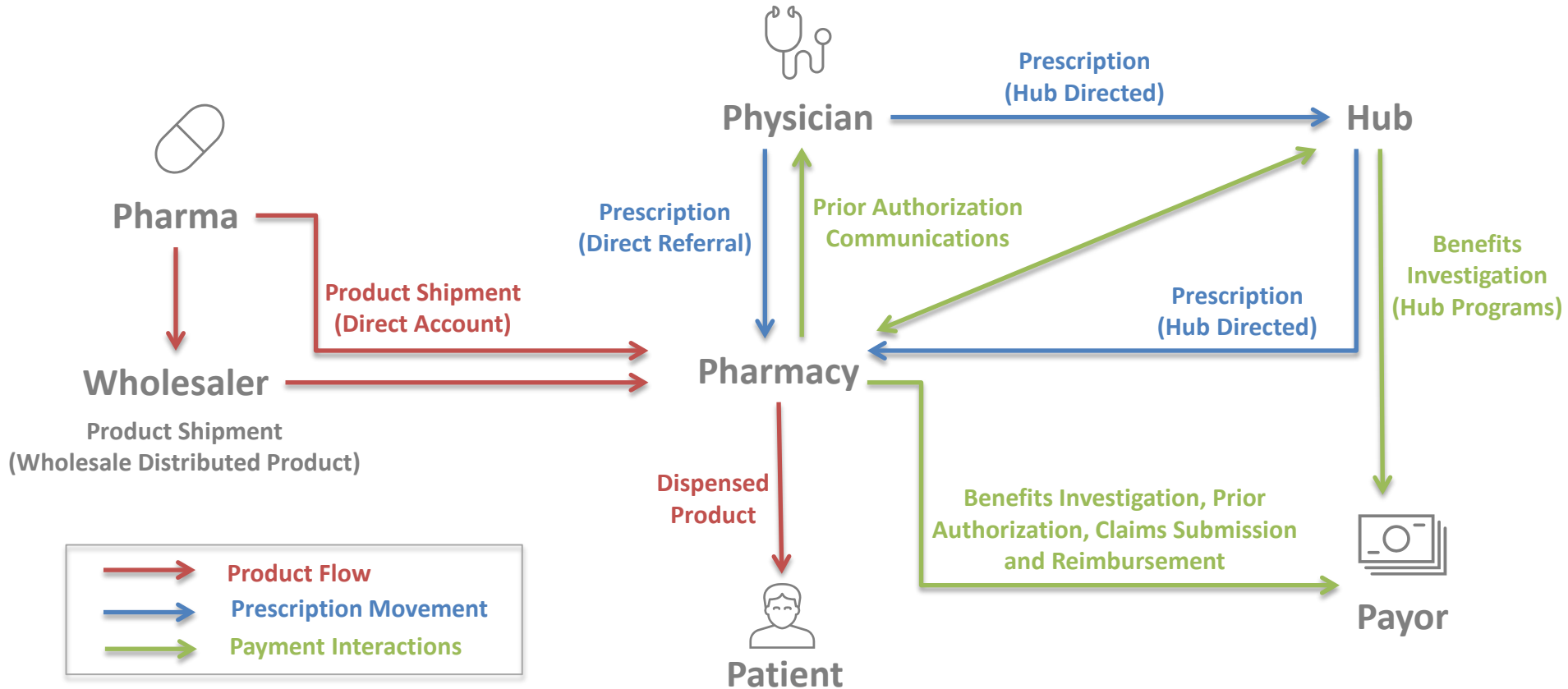
Dan Tardiff - Walgreens

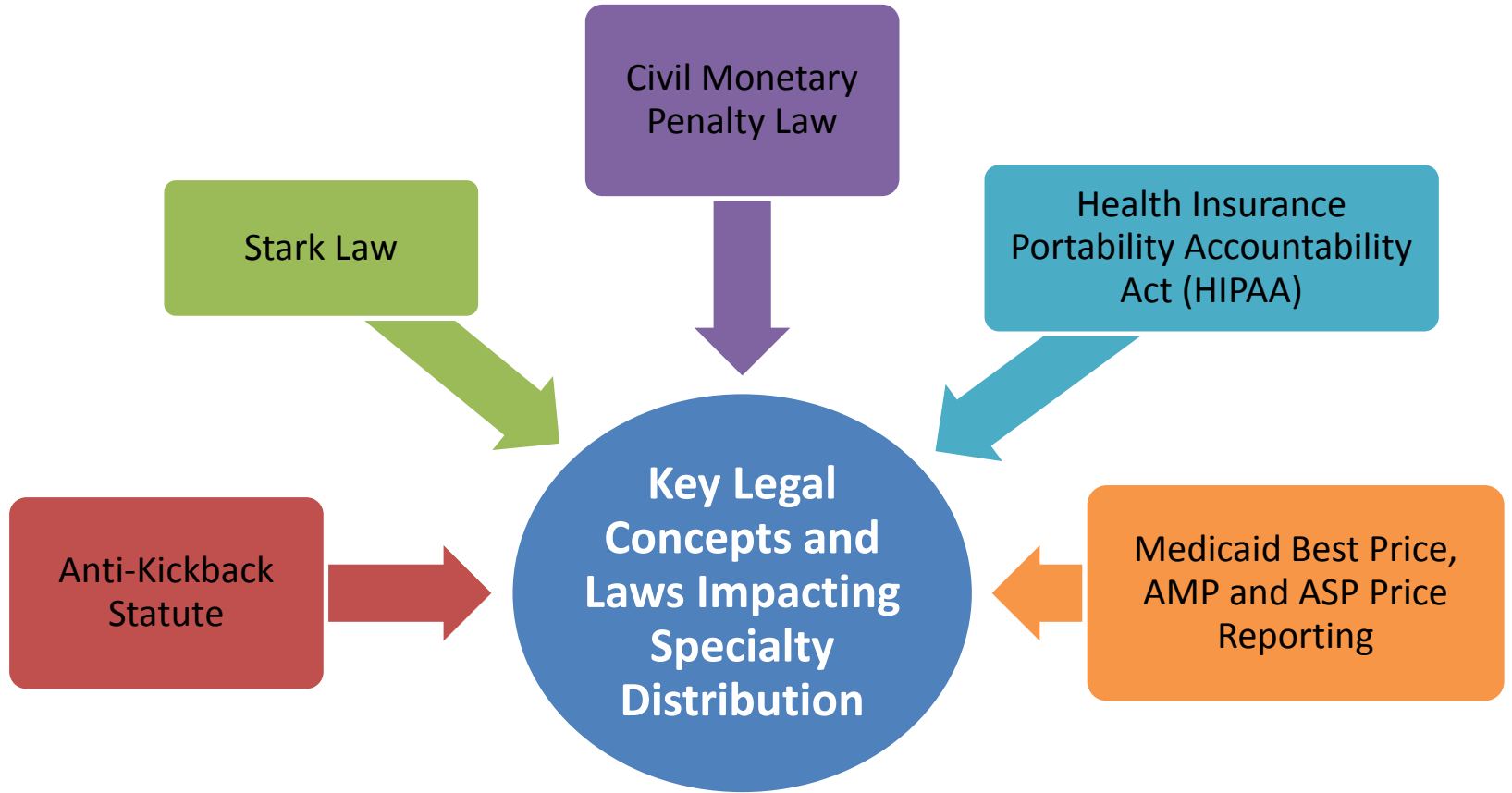


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Participants in the Specialty Distribution Channel





Prosecution and Investigation Trends Impacting Specialty

 <p>NOVARTIS</p> <p>Items beyond scope of contract as inducements, Incomplete communication with prescribers</p>	 <p>Johnson & Johnson</p> <p>Service fees as inducements to switch products</p>	 <p>AMGEN®</p> <p>Rebates as inducements to switch products</p>
 <p>CareMed Pharmaceutical Services</p> <p>Fraud in prior authorization process</p>	 <p>NPS PHARMACY</p> <p>Use of coupons on government recipients</p>	 <p>WC WARNER CHILCOTT</p> <p>Use of personal health information for improper purposes</p>
 <p>VALEANT</p> <p>Aggressive pricing, use of coupons to override formulary</p>		 <p>QUESTCOR®</p>

Core versus Enhanced

**Establishing FMV and
commercial
reasonableness**

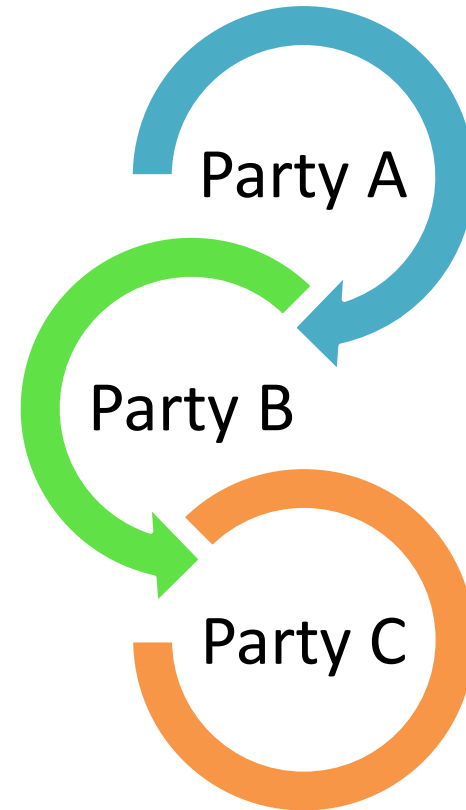
**Discounts versus
Payments**

**Evidencing Performance
of Services**



Data Sharing and Reporting

- **Various business models in use**
- **Determining who is a business associate**
- **Various methods of de-identification**



Manufacturer Funded Coupons and Financial Assistance

Government
Beneficiaries

Coupons versus
Financial Assistance

Trends in
Enforcement

Contracting Best Practices



Evidencing fair market value

Certifications from participants in process

Establishing key frameworks

Conclusion



Ben DiMarco
Armada Health Care
Benjamin.Dimarco@armada
healthcare.com



Michael Hess
Bass, Berry & Sims
MHess@bassberry.com



Kirk Hunt
Eli Lilly & Company
Hunt_kirk_russell@lilly.com



Dan Tardiff
Walgreens
Daniel.tardiff@walgreens.com