

# Interactions with Specialty Pharmacies

Mini Summit IX

19<sup>th</sup> Annual

Pharmaceutical Compliance Forum

November 7, 2018

# Meet the Panelists



**Yogesh Bahl, CPA, MBA**  
Managing Director, Alix Partners



**Craig Clesson, JD, CIPP / US**  
Assistant General Counsel and Global Privacy Officer,  
Syneos Health



**Sarah diFrancesca, JD**  
Partner, Cooley



**Richard Liner, JD**  
Senior Counsel, Compliance & Investigations, Bayer



**Katherine Norris, MPA**  
Director, BRG

# Disclaimer



*In the interest of providing robust continuing professional education to conference attendees, this panel is comprised of legal and compliance professionals from several firms and companies representing different aspects of the pharmaceutical industry.*

*The panelists' views are their own and do not necessarily represent views of their respective employers.*

# Discussion Topics



- Specialty Drugs, Specialty Pharmacies
- How does it work with industry?
- Evaluating the Risks?
- The Current Enforcement Environment
- Q & A

# What is a Specialty Drug?



“**Specialty Pharmaceutical**” products typically meet the following criteria:

- ✓ Used for the treatment of complex, chronic, and/or rare conditions
- ✓ High cost, often exceeding \$10,000, with some costing more than \$100,000 annually
- ✓ Availability through exclusive, restricted, or limited distribution
- ✓ Special storage, handling, and/or administration requirements
- ✓ Ongoing monitoring for safety and/or efficacy
- ✓ Risk Evaluation Mitigation Strategy
- ✓ Historically infusion and injectable; increasingly oral administration as well

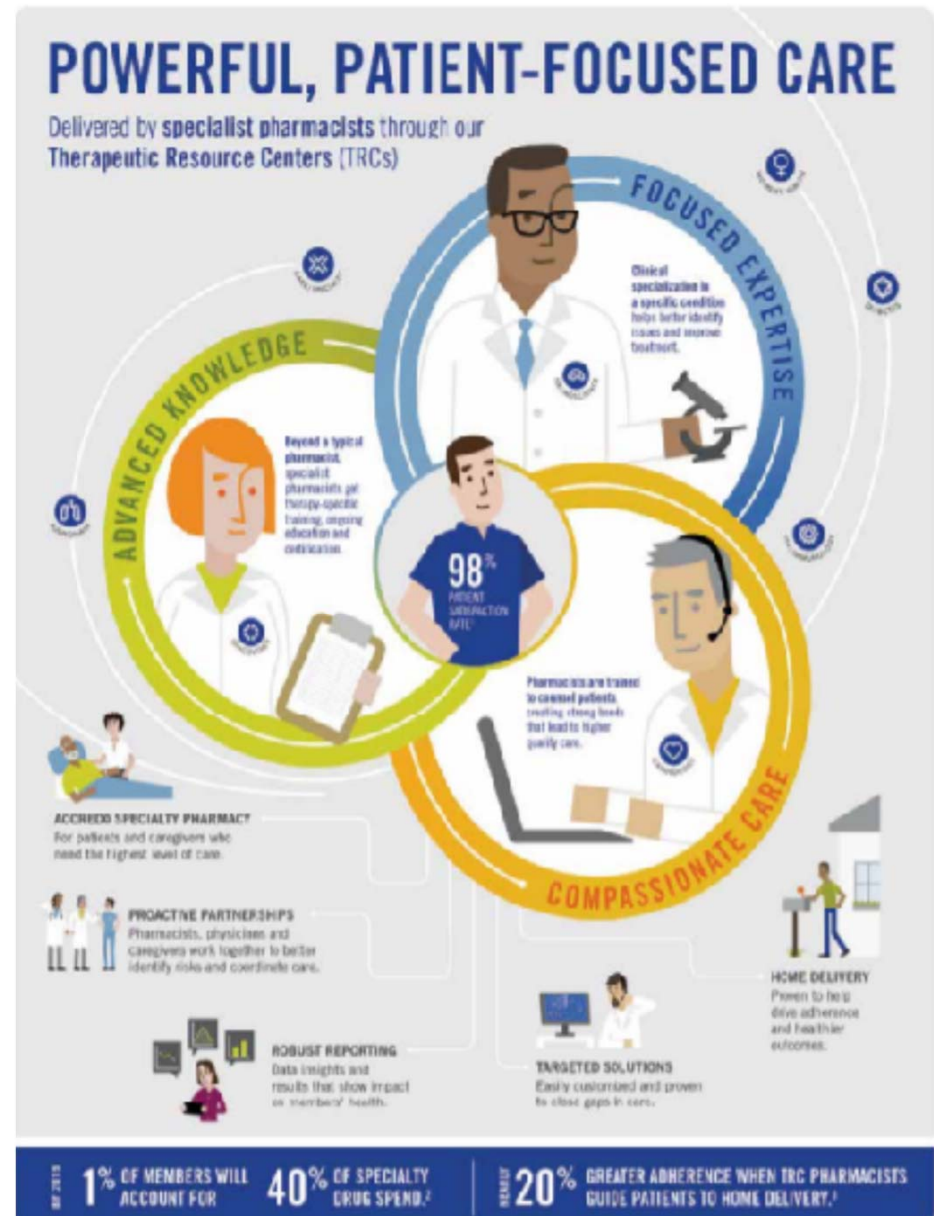
Hagerman, Jennifer, PharmD, AE-C. et al. “Specialty pharmacy: A unique and growing industry” *American Pharmacists Association*. July 1, 2013. Available online at: [www.pharmacist.com](http://www.pharmacist.com).

# Unique Drugs, Unique Market Factors

- SP delivery model is increasingly popular
- Corresponds with advancements in medicine, particularly in oncology
- Shifts in the industry toward personalized regimens that require individualized treatment plans; medication adherence
- Rare disease markets = smaller patient populations

## Coinciding with these shifts:

- Specialty Pharmaceuticals grew 24% from 2011 – 2014
- Specialty Pharmacy “Boom” is expected to continue.
  - 2011 - \$ 299B
  - 2016 - \$ 412B
  - 2025 - \$ 572B
- *“20% greater adherence when the TRC pharmacists guide patients to home delivery.”*



# What is a Specialty Pharmacy?



There is no formalized or fully agreed upon definition of a “Specialty Pharmacy”; however, the primary objective is to **dispense product directly to a patient or provider**, as appropriate, **as soon as possible**. Specialty pharmacies generally focus on **key disease states** and work hard to provide the **best service possible** on the drugs that best meet the patient’s needs for those disease states. The level of care typically exceeds that of a brick-and-mortar pharmacy:

- **24-hour access to pharmacists**
- **Adherence management**
- **Benefits investigation**
- **Communication and follow-up with the physician/staff**
- **Dispensing of specialty pharmaceuticals and shipping coordination**
- **Enrollment in patient assistance programs**
- **Financial assistance**
- **Patient education and medication adverse effect counseling**
- **Patient monitoring for safety and efficacy**
- **Payor and/or manufacturer reporting**
- **Proactive patient outreach for prescription refill and renewal**
- **Prior authorization assistance**
- **....the list goes on...**

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# What Could Possibly Go Wrong?!



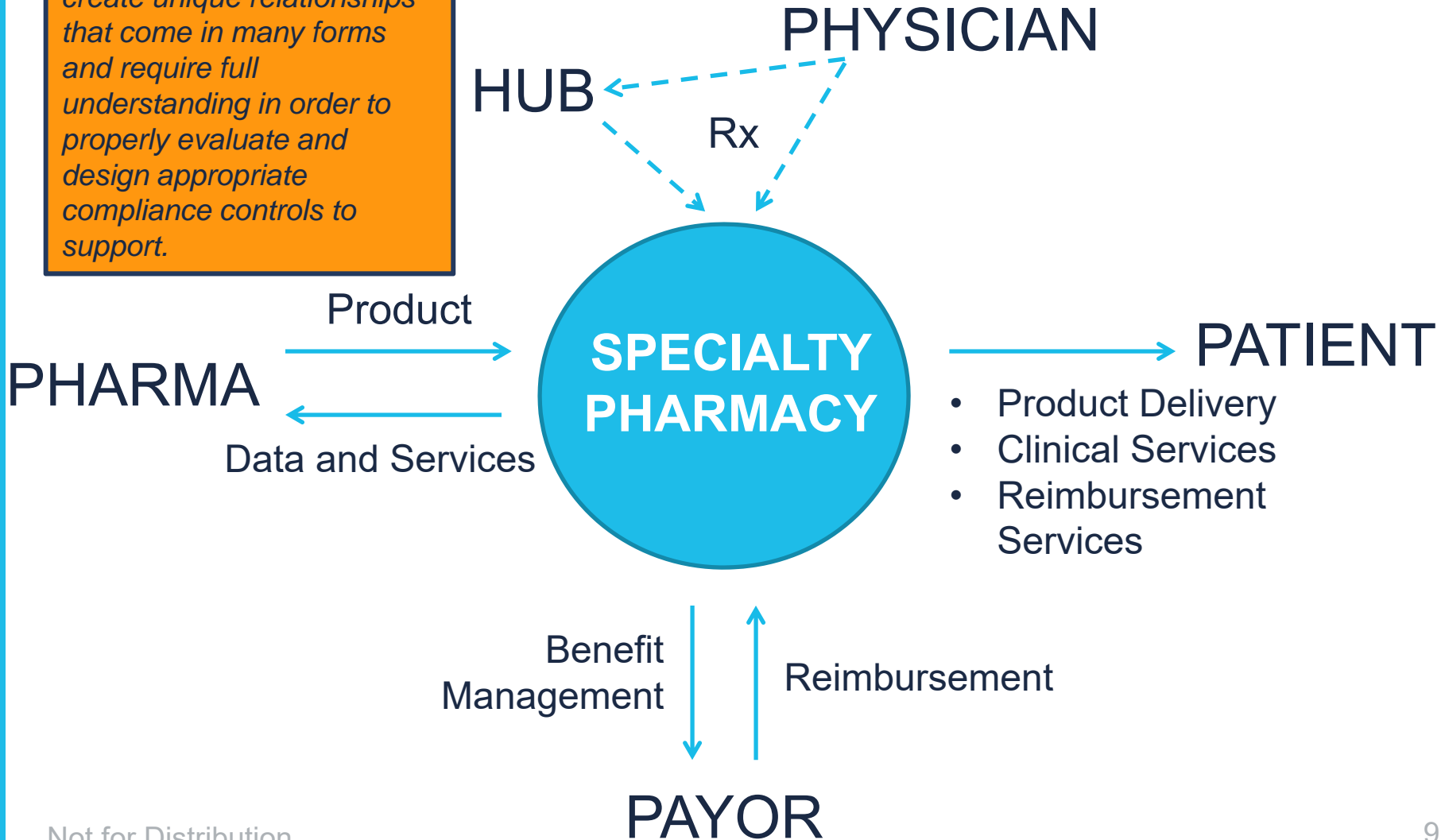
## PHARMA / SP INTERACTIONS CAN TRIGGER CONCERNS PERTAINING TO:

- **Federal Anti-Kickback Statute**
  - Provision of *legitimate* items or services of value
  - Provision of services at FMV
  - “Arm’s Length” Transactions
  
- **False Claims Act**
  - Discounts / Price Reporting
  - Provision of Services that Lack Medical Necessity
  
- **Government Price Reporting**
  
- **HIPAA / Patient Privacy**
  
- **Adverse Drug Event Reporting**
  
- **Integrity of the Patient / Physician Relationship**
  
- **“White Coat Marketing”**
  
- **Truthful & Accurate Presentation of Product Safety Profile**



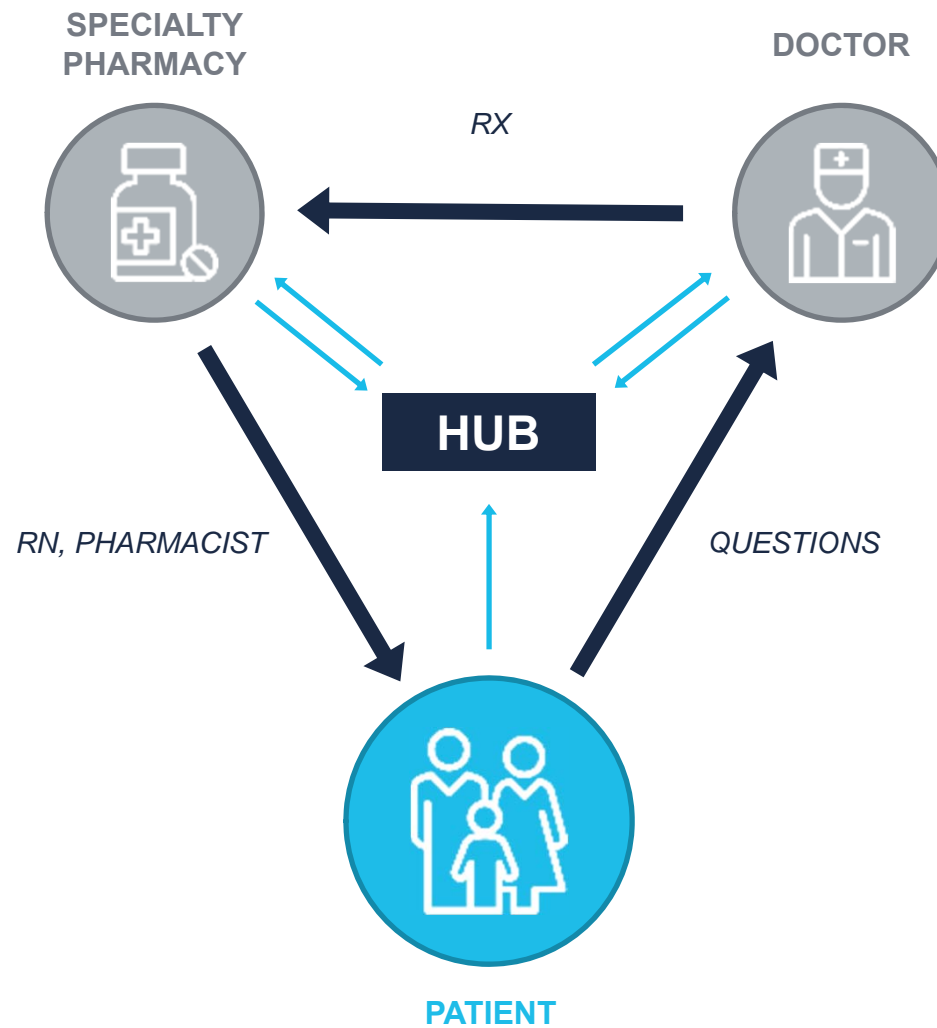
# Specialty Products Support and Delivery

*These unique products create unique relationships that come in many forms and require full understanding in order to properly evaluate and design appropriate compliance controls to support.*



# Patient Support Services:

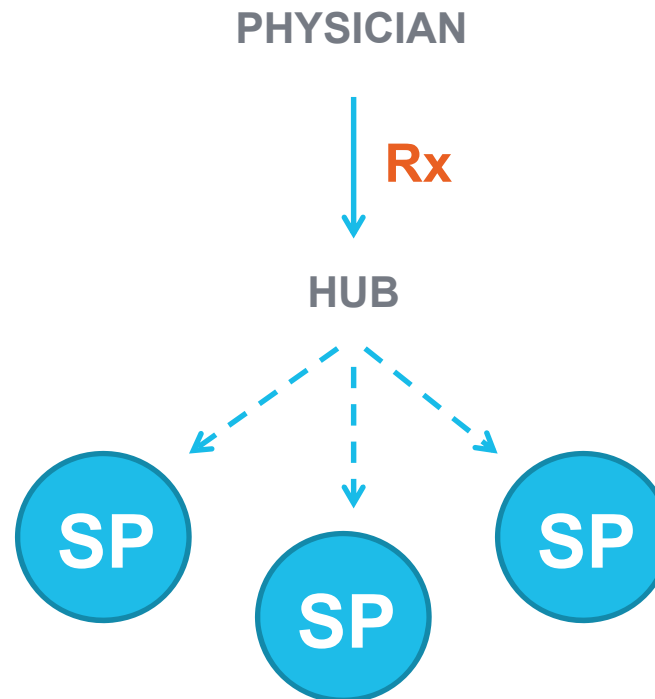
## TYPICAL COMMUNICATION FLOW



# Working with Specialty Pharmacies



If no payor, physician or patient preference for an SP, then Rx is “open”. Most hubs use a referral method to rotate open Rx referrals to avoid disproportionate referrals to any one SP. These relationships have been scrutinized where referrals are targeted to certain SPs in conjunction with additional services, or benefits, a Company derives (e.g. product marketing by the SP to patients).



Discussion

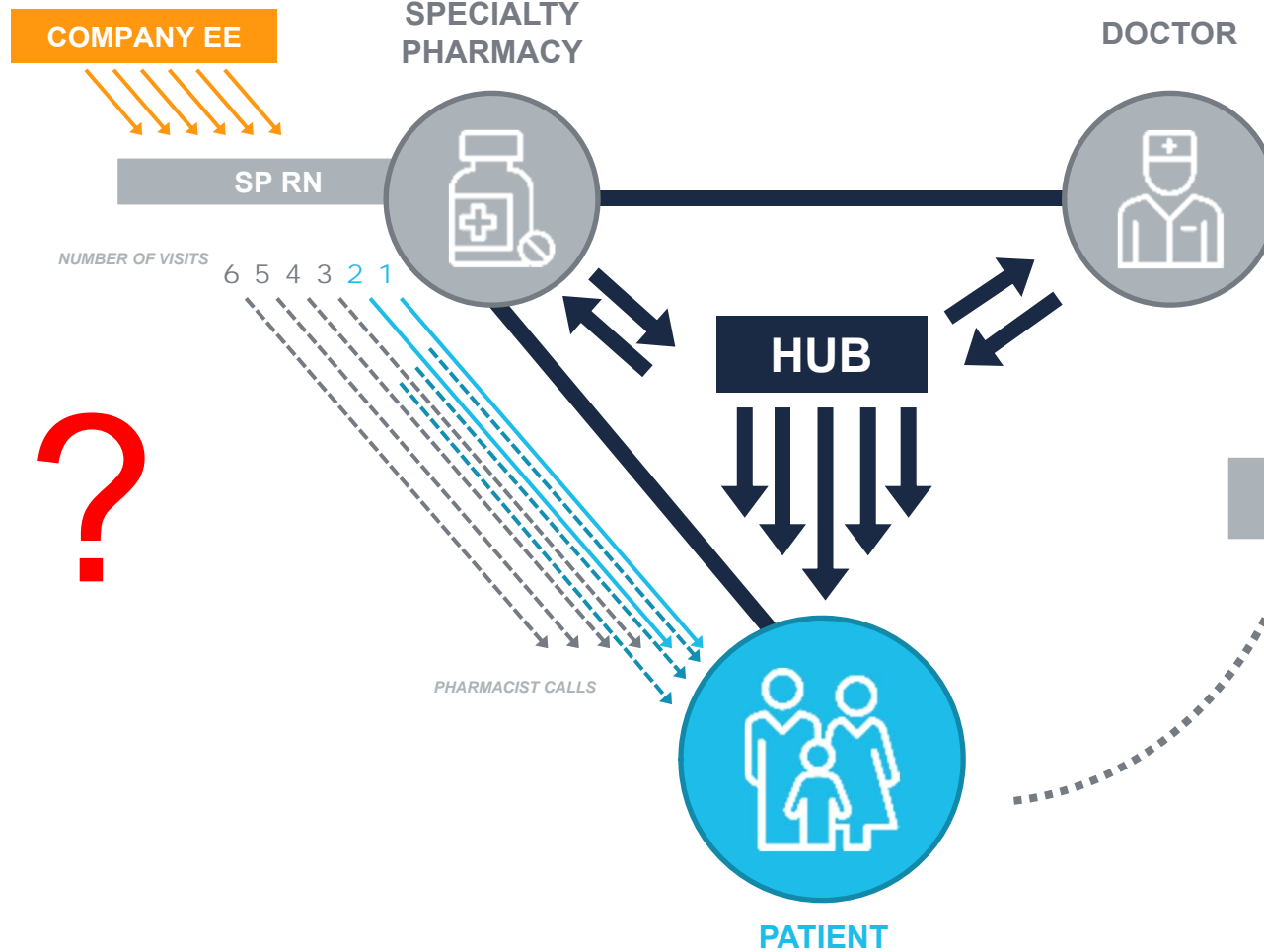
# **COMPLIANCE CONSIDERATIONS**

# Patient Support Services:

## MANAGING COMPLIANCE CONCERNS



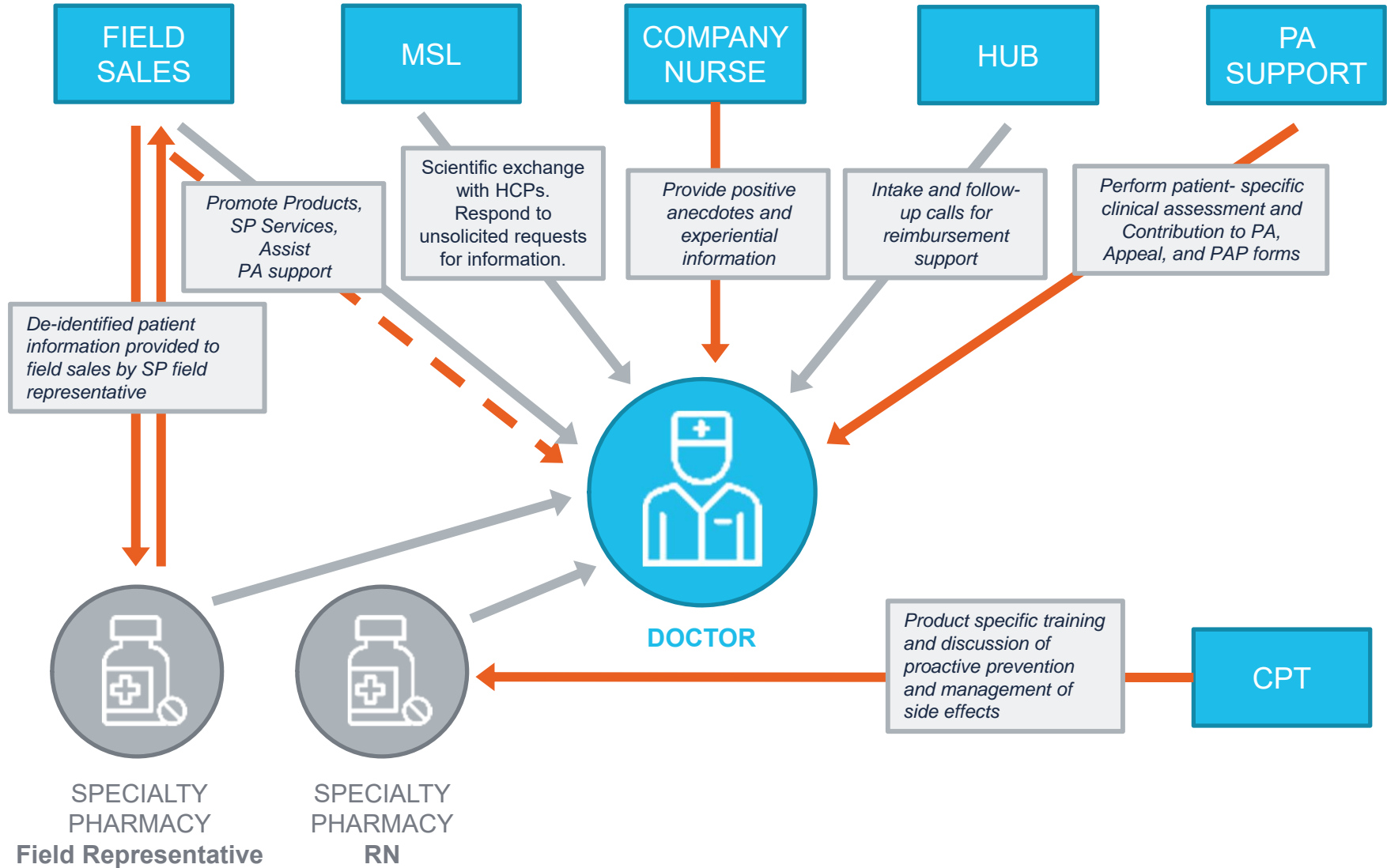
PATIENT EDUCATION AND SUPPORT  
RN HOME VISITS +  
ADDITIONAL PHARMACIST PHONE CALLS



Potential disruption or delay in doctor patient communication, especially in re: adverse events

# Patient Support Services:

## MANAGING COMPLIANCE CONCERNS



Discussion

# **THE CURRENT ENFORCEMENT ENVIRONMENT**

# Novartis

(2015)

- \$390 MM in fines and penalties
- Make extensive disclosures regarding the nature of its relationship with specialty pharmacies
- Amend and extend the company's then-CIA by 5 years
- Specialty Pharmacies paid kickbacks in exchange for the SP's promotion of company products.
  - Improper discounts and rebates to SPs in exchange for recommending that HCP's switch patients to company products.
  - Rebates targeted 'medication adherence' metrics.
  - Increase patient referrals in exchange for recommending that patients refill scripts via direct-to-patient clinical education.
    - "Co-opt healthcare providers' independence"
    - "Closed circuit" distribution network
- Three parallel cases with SPs brought by the government:
  - US Bioservices settled a companion suit for \$13.4 MM
  - Accredo Health Group settled companion suit for \$60 MM
  - BioScrip settled its companion suit for \$15 MM



## Warner Chilcott (2015)

- \$125 MM criminal fine and civil settlement
  - Felony Plea
  - Indictment of Company President (conspiring to pay kickbacks; acquitted by jury in 2018)
  - 3 District Managers Convicted and Sentenced
    - Conspiracy to commit healthcare fraud
    - HIPAA violations
  - Physician conviction
    - Obstruction of justice
    - Wrongly providing patient info to a company sales representative
- **HCP prescription inducements through kickbacks**
    - Payments, honoraria, meals, snacks, and gifts associated with medical education events, which included speaker programs, speaker training, dinners, lunches, receptions, preceptorships, and in-office programs.
    - Mandatory minimum number of med-ed events, venue issues, program content / quality
  - **Prior Authorization manipulation**
    - WC assisted HCPs with PA requests, completed forms, provided forms coaching, non-formulary exception requests, coverage determination requests, and appeals documentation to ensure coverage and reimbursement and to overcome formulary restrictions that favored less expensive oral drugs.
    - Dubious tactics: Misleading or inaccurate patient information, coaching HCPs on ‘success factors’, HCP impersonation
  - **Payor coverage that may not have occurred, but for the PA manipulation**

# Aegerion Pharmaceuticals (2017)

- \$ 40.1 MM to DOJ and Victims
- Additional \$ 4.1 MM to SEC
- Initial Guilty Plea *rejected*; *judge later accepted two guilty please for misbranding and imposed a criminal sentence upon the corporation*
- CIA, DPA, Consent Decree (HIPAA)
- Independent monitor that must **submit reports to the presiding judge during a three-year probation period.**
- Sales reps and doctors charged, convicted of conspiracy to violate HIPAA



- **HCPs unlawfully disclosed PHI to patients**
  - Access EMRs, review patient records, identify potential patients for
- **Creation of false patient authorizations, used to obtain insurance payment for product.**
  - PHI obtained without patient consent; including minor patients.
- **Conspiracy to violate HIPAA**
  - “... with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm.”

Discussion

**Q&A**