

# **MINI SUMMIT IV: PATIENT PROGRAMS -- MANAGING THE VARIOUS RISKS OF GETTING CLOSER TO THE PATIENT**

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# Patient Support Programs

- Typically involves telephone support and nursing home visits with patient interaction, or nursing education provided to hospital nurses on treatment issues
- May also include
  - assistance with payment determinations and coverage appeals under applicable healthcare delivery systems
  - counseling or related advice
  - Receipt of items such as medication carrying bags, product related items, OTC medications, or disease state information
- Key compliance risks include:
  - Privacy
  - Transfer of value to HCPs by giving support to their patients that would otherwise be borne by the HCP
  - Having direct contact with patients and seeking to influence their decisions
  - Diverting the use of nursing support to the personal use of the HCP for work unrelated to the patient support program
  - Pharmacovigilance

# Patient Assistance Programs

- Programs focus on improving access to treatment and may:
  - improve patient access to company products before reimbursement decisions are made
  - enable patients to secure treatment which might not otherwise be available under government healthcare programs
  - provide additional product with co-payment of other price concessions
- Key compliance risks include:
  - Programs that have mixed medical and commercial goals
  - Providing company products in a way that HCOs or HCPs can receive product without cost, but are able to obtain payment from the government for the product
  - Accessing and using private patient information without consent, or using it for commercial purposes even when consent is obtained
  - Providing benefits to HCPs by giving support to their patients that would otherwise be borne by the HCP
  - Having direct contact with patients and seeking to influence their decisions
  - Pharmacovigilance

# Patient Screening, Disease Awareness and Outreach Programs

- May include:
  - screening for basic health conditions such as diabetes, gout, bone density or lipid screening or the provision of disease state information
  - laboratory testing or use of diagnostic tools such as EKG machines, ultrasound or other imaging technologies which may be provided through issuance of a voucher to the patient
  - limited patient assessments though, for example, blood pressure reading or heart function evaluation using a stethoscope or other diagnostic tool or application
  - initial physical evaluations by HCPs
  - disease state education to patients
- They are typically made available to a community at large, where the underlying population may not have ready access to basic health services; the focus is on underserved health populations
- Typically local HCPs are used as staffing of the program, either directly or engaged by a third party retained by the sponsor to conduct the screening
- The location of the program varies; they may be held at HCP offices, public facilities, hospitals, or other public sites
- Key compliance risks involve using these activities to benefit participating HCPs or HCOs for commercial purposes, increasing the number of new patients for “loyal” HCPs, and gathering personal information from participants

# Patient and Patient Organization Interactions

- For patients interactions may include:
  - Subject to applicable laws and codes, provision of gifts or other items directly to patients through HCPs
  - Engagement of patients for speaking and consulting services
  - Patient assistance
  - Disease state education
- For patient organizations interactions may include:
  - Provision of support
  - Provision of gifts or other items
  - Engagement for speaking and consulting services
  - Holding events and providing hospitality
- Key compliance risks involve: direct to consumer advertising, impermissible items and gifts, improper inducements, using these activities to benefit participating HCPs or HCOs for commercial purposes, gathering personal information from participants, lack of independence, and transparency issues