ML STRATEGIES

Examining Charitable Patient Assistance Programs: Careful Due Diligence Yields Responsible Investment Decisions

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In today's challenging health care environment, nearly 30 million Americans suffering from various chronic and life-threatening illnesses are underinsured and have difficulty paying their out-of-pocket medical costs. Charitable Patient Assistance Programs (Charitable PAPs) have emerged over the past decade to help fill this critical need. This need will be great even after full implementation of the Affordable Care Act (ACA). Several holes in coverage have not been addressed and Charitable PAPs will continue to play an important role.

As the biopharmaceutical industry and other potential donors make strategic decisions to fund Charitable PAPs, there are many important elements which must be considered to ensure compliance with all applicable laws and regulations. This is the first of a multi-part series that outlines the important issues that prospective donors need to consider.

- **Review the organization's official opinion from the Office of the Inspector General (OIG):**OIG opinions are available on the website of the Inspector General or can usually be obtained upon request of the Charitable PAP organization. OIG opinions are written considering specific details provided by individual organizations. This means that the opinions are not necessarily applicable from one organization to the next. Therefore, it is important to understand if an organization has sought and received its own OIG opinion, or if it is relying on that of another Charitable PAP. The OIG opinion is the roadmap the Charitable PAP should be following and provides the assurance that the organization is complying with the law.
- **Request copies of the organization's IRS forms 990 for the past several years** It is important to understand if the organization is being operated as a bona-fide 501(c)(3). The 990 form provides a quick glance of the organization in terms of revenue and how much it, in turn, spends promptly and directly on patient grants. It also provides a record of whether the organization is operating under the management and operating restrictions imposed on nonprofit organizations. All of these are critical considerations when donation decisions are made.
- **How long has the organization been in existence?** While new organizations can be successful in providing assistance to their clients, a demonstrated track record of success over several years provides a measure of assurance to potential donors.
- **Is the organization financially stable?** A Charitable PAP that has demonstrated financial stability means that new donations are more apt to reach those in need and they are leveraged by the donations of others.

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Alex Hecht is a trusted attorney and policy strategist with over 20 years of experience advising clients across a broad range of industries on how to navigate complex policy environments. His strategic insight and hands-on experience in both legislative and regulatory arenas empower clients to advance their priorities with clarity and confidence in an evolving policy landscape.