

A Continued Examination of Charitable Patient Assistance Programs: Part Eight in a Series: What Products Say About Charitable PAPs

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In today's challenging health care environment, Charitable Patient Assistance Programs (Charitable PAPs) have emerged to meet the needs of the nearly 30 million Americans that are underinsured and have difficulty paying out-of-pocket medical costs. As potential donors make strategic decisions to invest in Charitable PAPs, there are many elements which must be considered to ensure compliance with all applicable laws and regulations. For the previous alerts in the series, please refer [here](#).

Charitable PAPs exist to assist as many eligible patients as possible with covering payments for their medical costs. It is important when assessing a Charitable PAP to ensure that the structure of the organizations' funds does not knowingly preclude certain patients by targeting a single product or service.

- **What type of products do the organization's funds cover?** The majority of Charitable PAPs focus on assisting with high-cost products that are FDA-approved for the disease state. Restricting product coverage based on where the medicine is obtained (e.g., pharmacy versus physician office), how the medicine is delivered (e.g., oral versus infusion), or the way it is reimbursed (e.g., bundled payment versus carve-out) may be problematic.
- **Does the organization manage funds with only one product covered?** This can happen when no other FDA-approved product exists for the disease area. Even when this is the case, there are other points to consider: there is a serious unmet patient need; it is a serious and or rare disease involving a small patient population; the cost of the product is substantial; and the fund is defined such that new products for the disease would be added without hesitation.

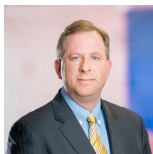
If more information is needed regarding Charitable PAP compliance procedures, please do not hesitate to contact the professionals at ML Strategies.



[View ML Strategies professionals.](#)

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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.