

A Checklist for Evaluating Charitable Copayment Assistance Organizations

You've made the decision to make a donation to financially support a charitable copayment assistance program or organization (or "CPAP" as they are known), or you are examining the possibility of doing so. Some donors choose to engage independent, third-party auditing firms to conduct program or compliance audits for some of the items listed below, and such audits typically require that the auditor and donor enter into a confidentiality agreement with the CPAP. Under those audits, the auditor may be able to review, among other things, the CPAP's board minutes, fund-specific financials (non-patient specific), board and key staff conflict-of-interest statements and, most importantly, the CPAP's compliance with its Advisory Opinion issued by the U.S. Department of Health & Human Services, Office of Inspector General ("OIG"). In any instance, and in an effort to help you choose the best CPAP for your philanthropy, we highly recommend that you fully address the following as part of your due diligence:

- ✓ How long has the CPAP been in existence? Is it financially stable? What is the status of its 501(c)(3) Federal tax exemption, and what is its 501(c)(3) public support percentage?
- ✓ Does the CPAP have an OIG Advisory Opinion and is its OIG Advisory Opinion, along with all amendments and modifications, posted on its website? If it does not have an OIG Advisory Opinion caution should be exercised, because the OIG Advisory Opinion is the primary roadmap that the organization must follow to ensure compliance with certain fundamental healthcare legal and regulatory requirements. Does the organization post its OIG Advisory Opinion, together with all amendments and modifications, on its website for transparency purposes?
- ✓ Obtain and analyze copies of the CPAP's IRS Form 990 for the past 3-5 years. Has the organization re-stated its financials and, if so, why? IRS Form 990 provides, among other things, information on the amount the organization receives in tax-exempt revenue (via donations and otherwise), the amount it spends on administrative and fund-raising fees, and the amount it spends on patient grants. IRS Form 990 also provides certain information relative to whether the CPAP is operating in compliance with applicable IRS requirements for 501(c)(3) charitable organizations. Does the CPAP post its IRS Form 990s and financial statements on its website for transparency purposes?
- ✓ Does the CPAP undergo regular, independent audits, both financial and programmatic? Most, if not all, OIG Advisory Opinions require that the subject CPAP have an independent review organization conduct an annual audit of its operations to verify that its charitable assistance program is in compliance with its OIG Advisory Opinion and other legal and regulatory requirements. How are the issues raised in such audits addressed by the organization? Copies of the CPAP's independent audits, both financial and programmatic, should be obtained and analyzed to determine whether the organization is adhering to applicable requirements and restrictions, including but not limited to the requirements set forth in its OIG Advisory Opinion and those imposed on it as a 501(c)(3) charitable organization.

- ✓ Check the percentage of donor dollars the CPAP spends on staff and executive compensation, as well as administrative and fundraising fees. How does the organization define, or separate, these fees in relation to operational fees and patient grants?
- ✓ Does the CPAP engage in any for-profit activities? Certain information in that regard can also be obtained from the IRS Form 990. How are those activities kept separate and distinct from the CPAP's charitable activities and how much for-profit revenue does the CPAP have relative to its tax-exempt income?
- ✓ Do the CPAP's executives, senior management or board members, or do any for-profit organizations with which they are involved, have consulting, management, or other business or vendor relationships with the CPAP or any of its donors? If such is the case, those relationships should be closely scrutinized, and information on any such relationship might also be available on the IRS Form 990. Ask for the organization's conflict-of-interest policy, and any annual or other conflict-of-interest statements and disclosure documents.
- ✓ What is the process the CPAP uses to define its funds? Is that process compliant with the organization's OIG Advisory Opinion and other legal or regulatory requirements? How is that process documented?
- ✓ What type of reports does the CPAP provide to its donors? Are the reports fully compliant with the organization's OIG Advisory Opinion and other legal or regulatory requirements?
- ✓ What type of products does the CPAP's funds cover? What is the process the organization uses to determine its product lists? How is that process documented? Does the organization post its product lists on its website for transparency purposes?
- ✓ Does the CPAP have any fund that provides financial assistance for only one drug, or for only the drugs made or marketed by only one manufacturer or its affiliates? If so, is that fund meeting the legal and regulatory requirements imposed by the OIG on those types of funds?
- ✓ What are the eligibility criteria for patients that are the recipients of financial assistance from the CPAP's various funds? Are they consistent across all funds? Are these criteria easy to find on the organization's website for transparency purposes?
- ✓ What about other aspects of the CPAP as an organization from a legal and regulatory compliance perspective? Is it under investigation by the OIG or the U.S. Department of Justice ("DOJ")? Has it been fined or penalized by the OIG or the DOJ? Has it entered into any settlement agreement(s) or corporate integrity agreement(s) with the OIG or DOJ. Is it party to any material litigation, dispute or the like, or does it have any material third party claims against it? Any documentation or information relative to any of the foregoing should be closely reviewed and scrutinized.