

**Patient Assistance Program (PAP) Attestation
Programs for Medicare Part D Enrollees Operating Outside the Part D Benefit**

PAP Sponsor: _____

The PAP Sponsor agrees that the following named individual will be designated as point-of-contact for this Attestation

(Name of Contact)

(Title/Component)

(Street Address)

(Mail Stop)

(City/State/ZIP Code)

(Phone No. - Including Area Code)

(E-Mail Address)

This document acknowledges that the undersigned has read and understands the Centers for Medicare and Medicaid Services(CMS) operational requirements specific to PAPs operating outside the Part D benefit. This acknowledgement must be signed prior to entering into a PAP Data Sharing Agreement with CMS. The purpose of the PAP Data Sharing Agreement is to enable the exchange of enrollment files between the PAP and CMS in order to facilitate the exchange of information about the specific drug usage of Medicare Part D enrollees enrolled in a PAP which is operating outside the Part D benefit, with the appropriate Part D plans. Once a PAP acknowledges that it has read and understands these requirements, and agrees to keep CMS well informed of any changes in the PAP's basic program design for as long as its PAP Data Sharing Agreement with CMS is in effect, it must sign and date the attestation at the end of this document. For assistance with any questions about this Patient Assistance Program Attestation, please send your inquiry to Mark.Smith@cms.hhs.gov. Once signed, Patient Assistance Program Attestations may be sent to Mark.Smith@cms.hhs.gov.

CMS Requirements for PAPs Operating outside the Part D Benefit in order to Exchange Part D Eligibility Data:

1. The PAP provides assistance with prescription drug costs, outside the Part D Benefit, to Medicare beneficiaries enrolled in Part D plans.

2. By reporting to the Part D plan the drug(s) covered by the PAP, the PAP provides the Part D plan with the information the plan needs to exclude from an enrollee's "true out-of-pocket" balance (TrOOP) any assistance the PAP provides for drugs that otherwise would be covered under Part D. The PAP may report information about the drug(s) covered by the PAP to the Part D plan using any of a variety of mechanisms – including via telephone, mail, electronic mail, and FAX. The PAP may not report information about the drugs(s) covered by the PAP to the Part D plan only by providing a notification to the enrollee, though it may use this method in combination with the direct provision of this information to the Part D plan via the mechanisms described above.
3. The PAP will never submit a claim for prescription drug assistance provided under its program to an enrollee's Part D plan.
4. The PAP will ensure that, for any of its enrollees also enrolled in a Part D plan, the Part D plan is notified of the drug(s) for which it is providing assistance outside the Part D benefit. With this information, the Part D plan will ensure that it makes no payment for the subsidized drug(s), and that it counts no portion of the cost of the subsidized drug(s) toward that enrollee's TrOOP or gross covered drug spend balances.
5. CMS believes that any copayments assessed by PAPs operating outside the Part D benefit should be nominal, since only nominal beneficiary cost-sharing is consistent with the concept of operating outside Part D. Moreover, the assessment of anything but nominal cost-sharing by PAPs appears inconsistent with the mission of a charitable organization structured to provide assistance with prescription drug costs to low-income patients.

I have read the contents of this Patient Assistance Program Attestation and attest that I understand these requirements. I further certify that I am an authorized representative of the business organization that sponsors this patient assistance program.

In addition to understanding the above requirements, I have submitted an attached written narrative describing our program. This narrative includes eligibility criteria and describes how the PAP's assistance will be provided and how it will operate outside the Part D program. I agree to update this narrative on a timely basis for as long as I am under a PAP Data Sharing Agreement with CMS, if the program changes to the extent the description is no longer accurate.

I am aware that neither this attestation nor our PAP Data Sharing Agreement with CMS constitutes a finding that this patient assistance program complies with all Federal fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. The HHS Office of the Inspector General (OIG) enforces Federal fraud and abuse statutes, and all questions regarding the compliance of specific arrangements with these statutes should be referred to the OIG.

The undersigned individual hereby attests that he or she is authorized to legally bind the PAP Sponsor.

(Name and Title of Individual - Typed or Printed)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone No. - Including Area Code)

(E-Mail Address)

(Signature)

(Date)