Q: As a matter of current policy, many safety net pharmacies do not pursue payment when an individual attests to his or her inability to afford copays. Under Part D, may safety-net pharmacies waive beneficiary cost-sharing? Does this cost-sharing count toward TrOOP?

A: The MMA added a new exception to the anti-kickback statute under which pharmacies are permitted to waive or reduce cost-sharing amounts imposed under Part D, provided they do so in an unadvertised, non-routine manner after determining in good faith that the beneficiary in question is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing without regard to these standards for Part D enrollees eligible for the low-income subsidy provided the pharmacy does not advertise that the waivers or reductions of cost-sharing amounts are available. In other words, for low-income subsidy recipients only, pharmacies do not need to ensure that the waiver or cost-sharing reduction is non-routine and provided only after ascertaining financial need. However, they cannot in any way advertise the provision of the waiver or cost-sharing reduction. We have previously advised that, provided pharmacies follow these rules, such waivers or reductions of Part D cost-sharing by pharmacies would count toward a beneficiary's TrOOP.

Safety-net pharmacies typically include Federal, State, and locally supported community health centers (CHCs) or clinics, many of which are deemed Federally Qualified Health Centers (FQHCs), public hospital systems, and local health departments. In some communities, they also include mission-driven teaching hospitals, community hospitals and ambulatory care clinics. Rural health clinics (RHCs), small rural hospitals, and critical access hospitals (CAHs), clinics that receive Ryan White HIV/AIDS grant funding, and nurse managed clinics also are key components of the safety net. An estimated 12,000 safety-net providers participate in the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program, which allows them to purchase their prescription drugs at significantly discounted prices. Participation in the 340B Drug Pricing Program can enable safety-net pharmacies to provide prescriptions to their patients at lower-than-market prices.

However, we clarify that, to the extent that the party paying for cost-sharing on behalf of a Part D enrollee is a group health plan, insurance, government-funded health program, or party to a third party payment arrangement with an obligation to pay for covered Part D drugs, that party's payment will not count toward TrOOP. Thus, payments made for beneficiary cost-sharing by any entity – including a safety-net pharmacy – that has an obligation to pay for covered Part D drugs on behalf of Part D enrollees, or which voluntarily elects to use public funds, in whole or in part, for that purpose, will not count toward that beneficiary's TrOOP expenditures.

We clarify that receipt of Medicaid or Medicare Disproportionate Share Hospital (DSH) payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a "government-funded health program." We view Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services, and not akin to government grants and funding that are used, in whole or in part, to provide to (or pay on behalf of) an individual the costs of Part D drugs. That notwithstanding, any program that is operated or funded, in whole or in part, by any government agency, and which uses those funds, in whole or in part, to provide to (or pay on behalf of an individual) the costs of Part D drugs is a government-funded health program even if it pays these costs using a mix of private and public funds. To the extent that an entity that receives DSH funds uses non-DSH government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs, it will meet our definition of a government-funded health program, and any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee's TrOOP balance.

Similarly, participation in the 340B Drug Pricing Program does not in and of itself render a safety-net pharmacy a government-funded health program. However, as with DSH facilities, any use of government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs will render a safety-net pharmacy a government-funded health program such that any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee's TrOOP balance.

If a Medicare Part D network safety-net pharmacy is a government-funded health program or other TrOOP-ineligible payer and waives or reduces any applicable Part D enrollee cost-sharing after payment of a claim by the Part D plan, that claim must be flagged such that any applicable beneficiary cost-sharing that is waived or reduced by the pharmacy is not added to a beneficiary's TrOOP balance. Currently, there does not exist any capability under the NCPDP 5.1 transaction set for safety-net pharmacies to indicate a pharmacy's waiver or reduction of any applicable beneficiary cost-sharing so that such subsidies are not applied to the beneficiary's TrOOP balance. We recommend that plans set up manual processes with safety-net pharmacies in their networks in order to accurately maintain beneficiary TrOOP balances. Safety-net pharmacies that are not part of a plan's contracted pharmacy network will not be required to follow the administrative process described in this paragraph.