March 7, 2014

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
Docket ID: CMS-2014-0007
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4159-P Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule

To Whom It May Concern:

Community Catalyst strongly supports many regulatory changes in the proposed rule, especially those that would:

- Increase regulatory scrutiny of pricing and cost-sharing practices, to ensure that seniors receive lowest costs, and the program achieves best possible savings
- Interpret non-interference clause narrowly, especially in light of subsequent statutory reforms concerning PBM practices
- Ensure that Part D plans pass on savings on generic drugs to their beneficiaries, through evidence-based drug pricing standards (§ 423.505(b)(21))
- Expanding audit and inspection authority (§ 422.503(d)(2), 423.504(d)(2))
- Provide adequate notice of plan and formulary placement and cost-sharing changes to CMS and to consumers(§ 423.128(g))
- Refocus Part D plans on expanding cost-sharing advantages, rather than limiting provider networks.

Increase regulatory scrutiny to guarantee consumer and system savings

As drugs become available as generics, their prices drop by 60-90% or more in their first year. This creates the promise of easier access and affordability of these drugs by the millions of seniors that use Medicare Part D. It also creates an opportunity for the program to reap substantial savings. CMS saw the average premium for Part D plans drop for the first time in 2012, and the average generic copay plummet to a $2 median in 2013. These promising developments are related largely to the advent of increased access to generics drugs due to the patent cliff.

Unfortunately, these savings are not guaranteed. We have seen gaming of the drug pricing terms by PBMs to inflate the prices of newly available generics, driving up costs for both consumers and their plans. As more generics continue to become available it is vital that CMS implement the regulatory scrutiny to ensure that the program and its beneficiaries reap the full benefit of these savings from drugs going off the patent cliff. We urge CMS to move forward with these important proposals that provide critical protections to beneficiaries and help maintain the integrity of the Part D program.

Interpreting MMA's non-interference clause narrowly, in light of PBM transparency reforms under the ACA

In part, we support the CMS interpretation of the so-called non-interference clause. Specifically, we support the agency's determination that this statutory language does not prohibit their involvement in, and regulatory scrutiny of, the contracting and negotiation practices between Part D sponsors and pharmacies. We also support CMS's interpretation that the MMA's statutory language in no way "limits our authority to require full disclosure or uniform treatment and reporting of drug costs and prices."

However, both of these provisions of the MMA should also be read and interpreted in light of the subsequent enactments by Congress, including section 6005 of the Affordable Care Act. This 'PBM transparency' provision charges HSS with a duty to gather information about a range of PBM practices, including generic utilization, the amounts of rebates, the amount of such rebates passed on to plan sponsors, and the amount of such rebates, discounts, "that the PBM negotiates that are attributable to patient utilization under the plan . . . ." The law also allows CMS to make limited disclosures of this information, as needed, to carry out "Part D . . . ." so long as the name of the PBM is not disclosed.

In light of these obligations under the ACA, efforts by CMS to ensure that Part D Sponsors and their related PBM's are contracting fairly with pharmacies should include increased regulatory scrutiny of the role that PBMs play in contracting and pricing practices. In cases where the transparency of these practices granted to HHS and CMS under the law reveals improper or unfair practices that impact beneficiary cost-sharing, further regulatory action is warranted. Similarly, if such transparency into PBM practices reveals that the market competition intended under the MMA is being subverted by PBM practices, further regulatory action by CMS would be warranted as well.

Adopting evidence-based standards for drugs, especially Maximum Allowable Cost for generics (§ 423.505(b)(21))

For two decades, drug pricing fraud by manufacturers, wholesalers, price publishers and Pharmacy Benefit Managers (PBMs) and pharmacies has been a source of considerable waste in our health system. Unfortunately the systemic non-transparency of actual transactional drug prices has allowed manufacturers, PBMs and other parties to game the drug pricing system for profit. As a result, Congress enacted some price transparency provisions under Section 6005 of the Affordable Care Act. Some states -- Arkansas, Kentucky, North Dakota, Oregon, and Texas -- have followed suit, enacting state laws requiring the transparency of MAC prices for generics. Other states (e.g. Alabama, Oregon, Idaho) have enacted Average Actual Acquisition Cost (AAC) rules that require Medicaid programs be charged prices that reflect actual, evidence-based costs.

In light of the many vulnerabilities in our drug pricing system, we support the proposal to include "maximum allowable cost (MAC)" prices for multi-source generics in the category of prices that are subject to requirements that they (i) "accurately reflect the

market price of acquiring the drug" and (ii) be updated "not less frequently than once every 7 days" as codified under federal rule 42 CFR 423, 423.501, et. seq.

Expanding audit approaches and authority (§ 422.503(d)(2), 423.504(d)(2))

We support CMS efforts to bring in additional resources, through outside, independent auditors, to help ensure that drug pricing practices, PBM contracting, and PBM transparency practices are adequately reviewed and monitored, so as to help contain consumer and program costs. We caution that the large auditing firms often have extensive business dealings with PBM entities, and as such, face conflicts of interest in their efforts to audit a PBM on behalf of a health plan client. Safeguards to ensure that these auditors are independent and objective are essential.

Providing adequate notice of cost-sharing and other plan changes to CMS and to consumers(§ 423.128(g))

We also support the proposed changes to proposed § 423.128(g) that would require that Part D sponsors submit anticipated changes in a plan for upcoming plan years to CMS, and to provide the greatest possible notice to beneficiaries for any changes that are intended to be implemented after a plan year starts. We fully agree with CMS that "[t]o make informed decisions, enrollees need to understand how their benefits, including premiums and cost sharing, would change from one year to the next, should they reenroll in the same plan . . . And enrollees also need to be aware of changes that may take place during the course of the year as well."

Providing consumers with more information up-front about their anticipated costs is critical to allowing their informed selection of an appropriate plan. We also support the agency's recognition that the obligation of Sponsors to fully and clearly inform the beneficiaries about how formulary placement or other plan changes could impact consumer cost sharing is particularly important. We agree that, at a minimum, such a disclosure is needed to allow "beneficiaries currently taking a drug receive timely notice before such changes take place in order that they can decide whether to, for instance, change drugs or request an exception to cover the drug."

Refocusing Sponsors on increasing consumer opportunities for lower cost-sharing rather than limiting provider networks (§432.100, §423.120 §423.120(a)(8))

Finally, we acknowledge that allowing consumers covered under Medicare prescription drug plans to choose their pharmacies and pharmacists is critical to their quality of care. We commend CMS for the recent analysis of whether 'preferred pharmacy networks' were actually conferring reduced costs to the plans, their members, and the government. Your finding that some program Sponsors actually provided higher than average costs for some mail-order services is alarming, especially in light of the fact that these transactions involve the fewest actors, and should have the lowest possible prices.

In light of these concerns, we commend the agency for addressing the currently unregulated preferred networks. These limited networks are sold to beneficiaries as a

competitive option, promising lower costs and potential savings. But they can result in unnecessarily restricting access and services to seniors by eliminating community pharmacies from plans and forcing beneficiaries to use large retail or mail order services. We also applaud CMS's efforts to redirect the increasingly common emphasis on limited 'preferred pharmacy network' structures, in favor of requirements that emphasize lower cost sharing, and lower total costs..

Additional corrections and clarifications

Proportionate cost sharing for short-fill prescriptions (§ 423.153)
We also support the common-sense reforms to section 42 CFR 423.153 that would allow a proportionally lower copay or co-insurance amount for any drug dispensed for less than a full 30-day regimen. This rule will remove financial barriers to 'partial fills' which can help seniors coordinate all their prescriptions, saving unnecessary trips to the pharmacy. This reform will increase fairness by lowering consumer costs.

Excluding coupons from ambiguous definition of amount 'actually paid.'
We support CMS's efforts to ensure that there is no ambiguity concerning the use of copay coupons by Part D beneficiaries. The federal Anti-Kickback Statute and related OIG interpretations prohibit the use of copay coupons. We commend CMS for taking this action, and for acknowledging the role copay coupons issued by manufacturers can have to influence consumer and provider choices of more expensive drug products.