Submitted electronically via: PartCDcomments@cms.hhs.gov

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Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: Request for Information: "2017 Transformation Ideas"

The National Community Pharmacists Association (NCPA) appreciates this opportunity to submit comments in response to the Request for Information (RFI) seeking input and recommendations on ways in which to improve and transform the Medicare Part D program.

NCPA represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together, they represent an $81.5 billion health care marketplace and employ more than 250,000 individuals on a full or part-time basis. Independent community pharmacies are often located in underserved inner-city and rural areas. In fact, independent pharmacies represent 52% of all rural retail pharmacies and there are over 1,800 independent community pharmacies operating as the only retail pharmacy within their rural communities.[1] Community pharmacists are front-line health care providers who regularly work with seniors to address their various concerns with prescription medications—including the proper usage of the medications themselves as well as helping them navigate the increasingly complicated Part D marketplace.

Recommendation #1: CMS should finalize the concept included in 2014 proposed guidance on *Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions* that sought to implement the new definition of "negotiated price" in Medicare Part D to include all pharmacy price concessions that can be reasonably estimated based on historical data/experience.

[1] *Based on NCPA analysis of National Council for Prescription Drug Programs (NCPDP) data, Rural Urban Commuting Area (RUCA) Codes, and 2000 U.S. Census data.*

Many times, the Part D sponsor or its pharmacy benefits manager (PBM) receives additional compensation after the point of sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug. CMS issued a Fact Sheet entitled *Medicare Part D-Direct and Indirect Remuneration (DIR)* in January 2017 that clearly outlines the myriad of problems that this growing trend is producing. The CMS Fact Sheet found that "Part D sponsors and PBMs are engaging to a greater extent in arrangements that feature compensation after the point of sale and as a result there is a growing disparity between gross Part D drug costs, based on costs of drugs at the point of sale, and net Part D drug costs." The Fact Sheet also stipulates that this trend has the effect of increasing patient cost-sharing at the point-of-sale. In addition, because the Medicare program pays the cost-sharing on behalf of dual eligibles, this trend is increasing Medicare's costs for these beneficiaries. Higher beneficiary cost sharing drives patients through all of the Part D benefit phases faster and leads to higher costs in the catastrophic phase—in which Medicare liability is 80%. Finally, the CMS Fact Sheet found that the trend favoring post point of sale price concessions is increasingly shifting risk away from Plan sponsors and PBMs and onto the federal government and taxpayers.

In addition to the problems and challenges to Part D beneficiaries and the federal government due to the rising DIR trend, pharmacies are also negatively impacted. Pharmacies are at a distinct disadvantage when price concessions are taken or collected from pharmacies after the point-of-sale. Even though DIR fees are usually determined on a claim by claim basis, in practice they are assessed or charged to the pharmacy as a lump-sum with no claim-specific detail. In addition, DIR fees are assessed post-adjudication, or retroactively, which creates operational and cash flow challenges for pharmacies.

This situation is further complicated by the fact that pharmacies are reimbursed for virtually all generic drugs (approximately 88% of all drugs dispensed) via "Maximum Allowable Cost" (MAC) lists—that are created, maintained and changed at the sole discretion of PBMs. The pharmacist does not "find out" what they will be reimbursed for any generic drug until such time as the claim is adjudicated or submitted to the PBM for payment just prior to that drug being dispensed to a patient. From a practical standpoint, a pharmacy believes they are being

reimbursed a certain amount based on the remittance they receive at the time the claim is adjudicated. However, once DIR fees are assessed months later, the ultimate reimbursement on that claim or any claim may be significantly lower. Typically, most PBMs do not provide any claim-level detail to pharmacies that would provide them with a clear picture as to how much money was extracted from each individual claim. In addition, without this level of detail, it is virtually impossible for the pharmacy to determine exactly what their reimbursement was for each claim or conversely how much money they lost. All of these factors make it extremely challenging for pharmacies both from a cash flow and business planning perspective.

It is also important to point out that pharmacies are also at a distinct disadvantage in terms of negotiating power with PBMs—particularly independent community pharmacies. The PBM marketplace is extremely concentrated and nearly three-quarters of all prescription claims are processed by just three companies. Large pharmacy chains can certainly use their market power to attempt to push back on PBMs on pricing and payment practices; however, independent community pharmacies—even those who are represented by Pharmacy Services Administrative Organizations (PSAOs)—typically have very little negotiating power and often must agree to the offered terms or lose potential prescription business. Also, as detailed above, PBMs have virtually unilateral control over the pricing for 88% of all drugs dispensed and therefore have the ability to manipulate the interplay between the contractual pricing terms, the MAC list amounts and the DIR calculations affected by these prices.

Importance of point-of sale price/"Negotiated Price"

It is important to realize that the price recorded on Prescription Drug Event (PDE) records is extremely significant. The price reported on the PDE by the Part D sponsor to CMS quantifies the amount paid to the pharmacy that dispensed the drug at the point of sale. It is this point-of- sale price, otherwise known as "negotiated price" that is used to calculate beneficiary cost-sharing, and to adjudicate the Part D benefit as "it is the primary basis for determining plan, beneficiary and government liability." Any fees or payment that are made after the point-of-sale are not reflected in the negotiated price but rather are reported to CMS separately. It is also important to point out that drug prices used in the Medicare Drug Plan Finder upon which many consumers make critical choices about which Part D plan to choose are based on point-

of-sale prices. With the vast proliferation of DIR and post point-of-sale price concessions, this drug price information available to consumers is grossly inaccurate.

In recognition of the challenges and distortions produced by the rising DIR trend, in 2014 CMS moved to finalize a new definition of "negotiated price" for plan year 2016 to include all pharmacy price concessions which can be "reasonably determined" at the point of sale. CMS went on to issue accompanying guidance that proposed "reasonably determined" to include reasonably estimated but ultimately did not finalize this guidance.

Overwhelming majority of DIR fees can be reasonably approximated based on historical/prior experience

NCPA strongly supports this proposed guidance based on the fact that estimation based on historical data is a concept that has been widely used by other government agencies—including the IRS for estimated tax liabilities.

Moving forward, NCPA recommends that CMS finalize the concept that was espoused in the original proposed guidance but recommends the following specific language that provides a greater level of specificity and would in fact require that plan sponsors utilize historical data to estimate pharmacy price concessions at the point of sale. This language will provide a more accurate picture of the true cost of a drug "out the door" of a pharmacy to beneficiaries, CMS and the public.

> **'(I) IN GENERAL.—Negotiated prices for covered part D drugs, including all price negotiated concessions, shall be provided at the point-of-sale of the covered part D drug. If the negotiated price, including all negotiated price concessions, is not possible to calculate at the point-of-sale, an approximate negotiated price (as established by the Secretary) shall be used under the prescription drug plan or MA–PD plan. ''(II) APPROXIMATE NEGOTIATED PRICE.—In determining an approximate negotiated price for a covered part D drug under subclause (I), the Secretary shall ensure that— ''(aa) such price reflects the estimated negotiated price that is based on the previous year's negotiated price concessions negotiated under the plan for all or similar covered part D drugs or is based on such other factors as the Secretary may determine appropriate; and ''(bb) the use of such price does not prevent the use of value- based contracts between drug manufacturers, PDP sponsors, MA organizations, and pharmacies.''.**

Recommendation #2: CMS should issue guidance to Part D Plans/PBMs regarding Maximum Allowable Cost (MAC) drug pricing that would require MAC lists to be provided to pharmacies in an interactive spreadsheet format and require Plans/PBMs to establish a valid MAC appeals process.

As of January 1, 2016, drug pricing based on MAC is subject to the regulations governing the disclosure and updating of prescription drug pricing standards. Sponsors must establish regular updates (at least every seven days) "to accurately reflect the market price of acquiring the drug" and indicate the source used by the Part D sponsor for making such updates. When updating prices, Part D sponsors also must disclose the drug prices in advance of their use for reimbursement, and MAC prices must be disclosed to network pharmacies in a manner and format that is useable by the pharmacies, so that pharmacies can validate the prices.

NCPA was very supportive of the finalization of this regulatory provision because prior to this date, Part D sponsors/PBMs claimed that because maximum allowable cost (MAC) pricing is not based on a published pricing benchmark but rather is based on a variety of sources chosen by the PBM, it was not a true drug pricing standard. This was a source of great concern to pharmacists as MAC pricing or "lists" are used by PBMs to set pharmacy reimbursement for virtually all generic drugs—which comprise the majority of medications dispensed.

There is currently no standardization in the pharmaceutical industry as to the inclusion of drugs on MAC lists or for the methodology as to how the PBM will determine the maximum price or how it is changed or updated. In this way, Plan sponsors and PBMs have free rein in developing these methodologies and in turn, the ultimate price. Also, in most cases, pharmacies do not have an effective avenue to appeal these prices, even if they themselves cannot find the product available to them on the market for the PBM-stated MAC price. Also, many times, the PBM or Plan sponsor does not update MAC prices often enough to keep up with marketplace changes and price swings. In these instances, pharmacies may lose money on these drugs or be forced to sell them below cost.

Lack of standardization or consistency in how MAC drug pricing information is made available to pharmacies.

Since this new rule has gone into effect, there has been a distinct lack of consistency among Plan sponsors and PBMs as to how this information is conveyed to pharmacies. The modes of access to MAC lists by pharmacies primarily consist of delivery via mail, email or providing limited access to a web portal. Also, some PBMs make this information available to each individual participating pharmacy while others only make the information available to the GPO. As most pharmacies contract with multiple PBMs, this is an unwieldy process. In addition, most pharmacies report that that in order to make effective use of the information they need to receive it in an interactive spreadsheet format, in which they can query multiple drug values at one time. Otherwise, even if the PBM provides a web portal, the pharmacist must manually enter in one drug at a time which is an extremely time consuming process. The net effect of this lack of standardization and the refusal of most PBMs to provide this data in a spreadsheet format is that the drug pricing information is not being provided "in a manner and format that is useable by the pharmacy" in violation of goal of the regulation.

In addition, many pharmacies continue to find that the MAC pricing values under which they are being reimbursed do not in fact reflect the "market price of acquiring the drug," and in fact find themselves "underwater" on many products. In order to ensure that pharmacies are being paid appropriately to cover their costs, CMS should advise Plan sponsors and PBMs that at a minimum they must demonstrate that they have a valid Part D MAC appeals process that would enable the pharmacy to demonstrate to the Plan/PBM that they are unable to obtain the drug for the price they are being reimbursed and require the Plan/PBM to address the issue within a certain amount of time.

Recommendation # 3: CMS should establish access standards for preferred cost sharing pharmacies or require plans to disclose in plan offerings and on Plan Finder the actual number of preferred pharmacies in each region.

NCPA has long expressed concerns regarding beneficiary access to preferred cost sharing pharmacies. To date, CMS has not established access standards for access to these pharmacies at which beneficiaries may access potentially lower copays. Instead, CMS has taken a number of other limited measures to attempt to improve access. CMS has highlighted its current authority to "respond to plan offerings they determine to be discriminatory in proposed availability and access to cost sharing" and has taken steps to identify "outliers" and does require these "outlier" plans to include a general disclaimer statement about potential limited access to cost sharing. While NCPA is certainly supportive of the steps taken thus far to improve beneficiary access to preferred cost sharing pharmacies; these measures do not go far enough to address the problem. NCPA is concerned that the draft disclaimer language, while technically accurate, does not provide enough detail in order to clearly convey to the consumer the potential ramifications of choosing such a plan and the impact it may have on their ability to conveniently access their prescription drug benefit.

In addition, NCPA would recommend that CMS implement access standards for preferred cost sharing pharmacies or require plans to disclose in all plan offerings and on the Medicare Part D Plan Finder tool, the actual number of preferred pharmacies in each individual region. In the near term, NCPA would recommend that those plans that are currently identified as "outliers" not be permitted to advertise that they offer "preferred cost sharing" in light of the fact that the lack of meaningful access renders any potential benefit or savings meaningless.

Recommendation #4: NCPA suggestions regarding implementation of Sec. 704 of the Comprehensive Addiction and Recovery Act (CARA).

Section 704 of the Comprehensive Addiction and Recovery Act (CARA) establishes a PDP sponsored drug management program for at-risk beneficiaries (aka "lock-in" program) in Medicare Part D. As CMS moves forward promulgating regulations to implement this new program, NCPA would like to reiterate some of our concerns that we have voiced with regard to

the impact it will have on medications and pharmacy services offered by small business community pharmacies.

Frequently abused drug definition:

Per the statute, a frequently abused drug is a drug that is a controlled substance that the HHS Secretary determines to be frequently abused or diverted. Besides opioids, NCPA strongly recommends that no other scheduled drugs be considered for the program at its inception. NCPA has been supportive of improved drug utilization controls to prevent overutilization of medications in Part D. NCPA appreciates the success of these efforts and that CMS has historically required plans take a step-wise approach to prevent overutilization. In this same manner we would ask the agency take a step-wise approach when developing the Part D lock-in program, especially in regards to drugs impacted. We understand and support the work that CMS has undertaken to quantify the concurrent use of opioids and benzodiazepines among Medicare Part D enrollees. We encourage the agency to support efforts by plans/PBMs to utilize current tools to address vs. adding benzodiazepines to the list of frequently abused drug for lock-in purposes. We also continue to encourage CMS to collaborate with the Pharmacy Quality Alliance related to measures that include criteria to monitor opioid and benzodiazepine overutilization. It is important to note that these are health plan level measures. We also think that it is wise to limit the application of PDP sponsor drug management programs to opioids for the time being to give such sponsors time to fine-tune such programs and identify operational difficulties before expanding the scope of the program to encompass additional drugs.

Exempted individuals:

In addition to the exempted individuals outlined in the statute (is one who receives hospice care, is a resident of a long-term care facility, ICF-MR, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy) NCPA strongly urges the agency to include residents residing in assisted living facilities (ALFs). Our members who provide pharmacy services to those residing in long-term facilities provide services to ALFs in a very similar, if not identical, fashion. This is due to the need ALFs have

because many patients are being admitted who would most likely qualify for a LTC facility if it were not for cost containment measures. To require a resident of an ALF to receive pharmacy services from a provider outside of normal ALF operations is not feasible and leads to disconnects in care. NCPA also agrees with other stakeholders that patients under a doctor's care for treatment of cancer or related conditions should be considered for a possible exemption under this section.

The information to be included in the first and second notices that are sent to lock-in patients and the standardization of such notices:

In addition to the requirements that the initial notice must include (make beneficiaries aware of potential at-risk status, provide resources addressing prescription drug abuse, appeal rights and a request for the beneficiary to submit preferences for prescribers and pharmacies), NCPA strongly recommends that the initial notice make abundantly clear the lock-in program only applies to opioid medications. While the law only requires the lock-in to prescriber and pharmacy apply to frequently abused drugs, NCPA is very concerned that the plans/PBMs will effectively cause all of the patient's scripts to be filled at the lock-in pharmacy.

Concerns regarding beneficiary choice/ access and potential Plan/PBM conflicts of interest:

NCPA is concerned that legitimate patient access and therefore adherence and compliance will be negatively impacted by the Part D lock-in program. In virtually all of the Medicaid lock-in programs, it is the beneficiary that has the clear ability to choose both the in-network prescriber and pharmacy. Since preference only is to be considered by plans/PBMs when delegating prescriber/pharmacy for purposes of the Part D lock-in program, there must be protections in place for continual access. Our members have relayed to us that a very common scenario with lock-in programs is when the lock-in pharmacy is closed and the patient has no alternative to obtain their medication. In these instances we have learned of unfortunate hospital admissions. NCPA therefore recommends that there be a back-up plan in place for a beneficiary to obtain medications when their lock-in pharmacy is closed.

In addition, the agency must address potential plan/PBM "conflicts of interest." As NCPA has articulated in the past, there are multiple PDP sponsors that have existing commercial relationships with large retail pharmacy chains. In no way should plans/PBMs be able to assign patients to those pharmacies in which they have a financial stake. The CARA Act provides that an "at-risk" patient may be "locked-in" to a pharmacy chain or group of pharmacies under common ownership and control. Also, if a PDP sponsor determines that a beneficiary's choice of pharmacy is determined to be a contributing factor in that beneficiary's "at-risk" status, the PDP sponsor may re-assign the beneficiary to another pharmacy. We feel strongly that if a PDP sponsor determines that a beneficiary's choice of pharmacy is contributing to his or her "at-risk" status and that pharmacy is part of a group of pharmacies under common ownership or control, the PDP sponsor may not simply assign that beneficiary to another location of that pharmacy chain.

We urge CMS remain vigilant in ensuring appropriate patient access. We strongly recommend that CMS require plans/PBMs report percentage of times when beneficiary preference is/is not taken into account and also to track which pharmacy the plan/PBM utilizes to override patient preference.

Recommendation #5: CMS must assess the reliability of existing PQA measures currently being used in the marketplace to determine performance at the pharmacy level

NCPA would like to take this opportunity to remind CMS that many large Part D plans already have contractual requirements in place using existing PQA measures that were developed for use at the health plan level, to measure quality at the pharmacy level. The implications for our members based on these requirements are great and we are urging both PQA and CMS to further assess the reliability of existing PQA measures at the pharmacy level. There are many outstanding questions in the methods that are currently or will be used in the future to determine reliability. There is a lot of concern in the independent pharmacy community at this time in regards to factors that are entirely out of the control of the pharmacist that have been (and will continue) to negatively impact pharmacy reimbursement. For example:

- Patients' who are chronically ill and on very complex medication regimens have more complex needs than patients stable on chronic medications, even though pharmacy claims could be viewed as identical

- Physicians who determine that a statin for example is not in the best interest for a diabetic patient or any physician decision that would run counter to a pharmacy level measure

- Patients' who move to another pharmacy but the original pharmacy is still being measured on a patient they no longer care for

- Low pharmacy denominators determining broad reimbursement rates

- Health plan member enrollment until death or disenrollment being used to assess pharmacies vs using the pharmacy's actual patient population

We appreciate your thorough review related to the use of health plan level measures being used at the pharmacy level to measure individual pharmacy performance, a growing trend that shows no sign of slowing.

Conclusion

In closing, NCPA greatly appreciates the opportunity to share our thoughts and recommendations on ways in which to increase innovation and transparency in the Medicare Part D program in order to better serve beneficiaries.

Sincerely,

Susan Pilch, J.D.

Vice President, Policy and Regulatory Affairs