**Centers for Medicare and Medicaid Services**

**Department of Health and Human Services**

**Attention: CMS-4182-P**

**RIN 0938-AT08**

**Via Electronic Submission**

**Medicare Program; Contract Year 2019 Policy and Technical Changes to the**

**Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare**

**Prescription Drug Benefit Programs, and the PACE Program**

Dear Administrator Verma:

Thank you for the opportunity to comment on the proposed regulations regarding the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee–For-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program. The Independent Pharmacy Cooperative (IPC) represents the interests of pharmacist owners, managers, and employees of more than 2600 independent community pharmacies across the country. We commend CMS for addressing important issues in the proposed regulations that have concerned community pharmacies and our patients for many years. IPC wishes to voice support for the following provisions:

***Preferred Networks and Preferred Cost Sharing*:**

Part D plan sponsors and Pharmacy Benefit Managers (PBMs) extract DIR (Direct and Indirect Remuneration) fees from community pharmacies. Nearly all pharmacy DIR fees are clawed back retroactively months later rather than deducted from claims on a real-time basis. This reimbursement uncertainty makes it extremely difficult for community pharmacists to operate their small businesses.

In addition, a 2017 CMS study found “high cost DIR arrangements ease the financial burden borne by Part D plans essentially by shifting costs to the catastrophic phase of the benefit, where plan liability is limited.” It is evident that the arrangement likely results in higher costs to Medicare beneficiaries and tax payers. It is time to modernize Medicare Part D and do away with non-transparent, financially conflicted arrangements.

While it is crucial that these DIR fees are assessed at the point of sale, it is also important for CMS to ensure that contract pricing for drug reimbursement is adequate to support patient network access. In finalizing this rule, CMS should require all PDP 2019 contract plan submission to identify final net payment to pharmacies by each formulary drug to ensure that pharmacies are not incurring lesser net payments and endangering crucial health care access for patients. In order to ensure an adequate degree of transparency, CMS should require PDP’s in their 2019 CY Plans to communicate to the pharmacy the gross amount of a negotiated network prescription price, the amount, if any, of fees, discounts and other concessions, including DIR’s that are being deducted from the contract price, and the net reimbursement to the pharmacy for each Part D claim.

As for CMS’s request for ideas on capturing Manufacturer rebates at the point of sale, IPC believes that CMS already has an effective means to ensure proper accounting and payment of manufacturer rebates for formulary covered Part D prescription drugs. Since the OBRA Act of 1990, CMS has mandated all drug manufacturers provide the Medicaid program with the same drug rebates per covered drug as they provide to other payers (Section 1927 (a) (1) of the Social Security Act). This requirement was extended to the Medicaid Managed Care (MMC) programs in 2010 (Section 1903 (m) (2) (A) (xiii) of the Social Security Act) where managed care organizations are required to reconcile with pharmaceutical manufacturers to pay these OBRA 1990 mandated rebates at the same amount as under the Medicaid program. These MMC collected rebates are to be verified and passed through to each state Medicaid programs to be shared with federal government. The most efficient way for CMS to recover these rebates from the PDP would to extend the OBRA 1990 Medicaid rebate recovery mandate to the Medicare Part D program.

***Patient Lock-In:***

Section 1860D-4(c)(5)(D) of the CARA 2016 Act provides that, if a sponsor intends to impose, or imposes, a limit on a beneficiary’s access to coverage of frequently abused drugs to selected pharmacies or prescriber(s), and the potential at-risk beneficiary or at-risk beneficiary submits preferences for a pharmacies or prescriber(s), the sponsor must select the pharmacies and prescriber(s) for the beneficiary based on such preferences, unless an exception applies…

IPC agrees that since the statute explicitly allows the beneficiary to submit preferences then the preference should prevail over a sponsor’s evaluation of geographic location, the beneficiary’s predominant usage of a prescriber or pharmacy impact on cost-sharing and reasonable travel time.

In addition, each PDP contract should include the following:

* Clear language in the “lock-in” determination to the patient as to what ownership interest a plan has in a pharmacy provider that is eligible to be a “lock-in pharmacy”.
* Create a conflict of interest standard in regulation that prohibits a plan on a denial of a beneficiary preference for a “lock- in” pharmacy from selecting a pharmacy provider in which they have an ownership interest.
* Include in the regulations that any violations of these beneficiary protections shall be used in determining a MA-PD or PDP’s Star performance rating by CMS.
* Include in regulation that any pharmacy that has an “at risk” beneficiary with a “lock–in” determination for frequently abused drugs prescription(s), cannot have this prohibition on dispensing this prescription be a factor used by the plan in determining that pharmacy’s performance.

IPC supports the proposed rules exemption from the CARA 2016 Part D lock-in requirements for hospice, Long Term Care (LTC) facilities, single pharmacy served facilities (i.e. Assisted Living Facilities, group homes) and cancer patients. This proposal is consistent with the need to appropriately serve these vulnerable Part D patients (many of whom are dual eligible Medicare and Medicaid patients) without increasing the risk of these patients abusing or misusing Controlled Dangerous Substance (CDS) scheduled Part D prescription drugs.

There is a risk for CDS diversion that CMS needs to address in the final rule. Current Drug Enforcement Agency (DEA) policies allow for CDS prescriptions to have 90 day quantity limit, provided they are filled and dispensed for 30 days at a time. However, this dispensing restriction is not applied to 90 day supplies of CDS prescriptions dispensed through mail order. For CMS to allow Part D CDS schedule II prescriptions to be filled in full 90 day quantities and dispensed by mail-order pharmacies provides as much of a diversion and misuse risk that CARA 2016 seeks to prevent with retail pharmacy lock-ins.

***Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types***

While IPC understands these proposed Any Willing Pharmacy Standards only apply to the traditional Medicare Part D network plans, these A-W-P requirements should apply to Part D preferred networks in order for all Part D patients to have the benefits of the same pharmacy choice options as the proposed rule provides to beneficiaries in traditional Part D network plans.

IPC agrees with the proposed change in the definition of mail order. The current definition makes it financially onerous and resource exhaustive for a small pharmacy to meet all of the national requirements and places a convenience burden on beneficiaries.

***Limitation to the Part D Special Enrollment Period for Dual and Other LIS-Eligible Beneficiaries***

IPC opposes the proposed rule that would establish a separate SEP that can be used by any dual or other LIS-eligible beneficiary within a certain period of time after a change to an individual’s LIS or Medicaid status. While it may be reasonable to apply some enrollment restrictions on “at risk” patients to discourage circumventing the CARA lock-in requirement, it isn’t for all LIS individuals. The LIS patient population is highly transient and frequently has complex and changing drug regimens. The current regulation is designed to address the LIS patient’s unique characteristics and has served the Medicare program and LIS patients well. IPC supports the current Enrollment Period definitions for the LIS population.

***Pharmacy Credentialing Restrictions***

IPC applauds CMS for adding provisions to this proposed rule that no PDP contracts can require a Part D participating network pharmacy to have credentials that are beyond the licensing requirements from federal and state governments. IPC has seen contracts that require expensive and unnecessary credentialing mandates for pharmacies to participate in PDP pharmacy networks without providing any additional performance or safety benefits for patients. It is important for CMS to recognize in the final rule that this credentialing restriction does not prevent PDP’s from implementing Star rating requirements or performance standards consistent with PDP network pharmacy contracts.

***PDP Pharmacy Network Contracting Standard Terms and Conditions Requirements***

IPC applauds CMS for including in the proposed regulations that PDP pharmacy network contracts have standard terms and conditions available to each network participating pharmacy that requests such documents by no later than September 15th of each benefit year. We also fully endorse the proposed requirement that these documents be provided to a requesting network participating pharmacy within two days of receipt of the request. This proposal rectifies consistent problems IPC members have faced over the years in receiving from PDP’s these basic documents governing their participation in a particular PDP pharmacy network.

***Conclusion:***

The proposed rule takes substantial and very welcomed steps toward addressing Medicare Part D PDP practices that have been plaguing beneficiaries and pharmacies. IPC commends CMS for recognizing the need for significant changes to the Part D program and we urge that the final regulation retain these changes to protect the interests of beneficiaries, further promote pharmacy competition, provide true patient choice and utilize taxpayer money in the most cost effective manner.

Respectfully,

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Sr. Vice President of Government Relations

Independent Pharmacy Cooperative