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January 16, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 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 Proposed Rule
File Code: CMS-4182-P

Dear Ms. Verma:

On behalf of many independent pharmacies throughout the country, we appreciate the opportunity to submit comments concerning the proposed rule entitled "*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*" ("Proposed Rule").[1] Our comments address proposed clarifications to the regulations governing the Medicare Prescription Drug Benefit Program ("Medicare Part D"), and in particular, those provisions related to home delivery of prescription drugs and "Any Willing Pharmacy" ("AWP") requirements. We look forward to working with the agency on this important initiative.

We applaud efforts by the Centers for Medicare and Medicaid Services ("CMS") to enforce the congressionally mandated Medicare Part D AWP provisions and make clear that the standard terms and conditions for network participation must be reasonable, relevant and accessible. These provisions are paramount to ensuring that Medicare Part D beneficiaries have access to a wide network of quality pharmacies to fulfill their prescription needs.

[1] 82 Fed. Reg. 56336 (Nov. 28, 2017).

Unfortunately, we have witnessed many independent pharmacies being excluded from participating in Medicare Part D networks based on unreasonable and burdensome terms and conditions, arbitrary and pre-textual pharmacy classifications, and erroneous audit findings.

These mechanisms are used by Part D plan sponsors ("Plan Sponsors"), and the Pharmacy Benefit Managers ("PBMs") that administer networks on behalf of the Plan Sponsors, to constrict pharmacy networks and eliminate competition. Over the past several years, the PBM industry has consolidated and grown more powerful. The three largest PBMs accounted for three-quarters of the United States prescription drug market in 2015, up from 49% in 2011.[2] There is particular concern that PBMs are using anticompetitive practices in order to steer business to their own in-house, closed door pharmacies, generally labelled by the Plan Sponsors or PBMs as "mail-order pharmacies." These actions exclude worthy and willing independent pharmacies from participating in Medicare Part D networks, causing significant harm to, and eliminating, small businesses that service and create jobs within their communities.

Background

Congress established "any willing pharmacy" requirements for pharmacies participating in the Medicare Part D program.[3] Pursuant to this law, Plan Sponsors must offer standard terms and conditions that are "reasonable and relevant" and permit any pharmacy willing to meet those terms and conditions to participate in the plans' networks.

Regulations established by CMS require Plan Sponsors "[t]o agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy."[4] The CMS Medicare Prescription Drug Benefit Manual plainly states the following:

> "Any willing pharmacy" refers to the requirement that Part D sponsors permit the participation in their Part D plan networks of any pharmacy – including non-retail pharmacies such as mail-order pharmacies – that is willing to accept the sponsor's standard contracting terms and conditions. These standard contracting terms and conditions must be reasonable and relevant.[5]

The intended result of the "any willing pharmacy" provision is to ensure that any pharmacy wishing to participate in a network has an opportunity to do so. CMS highlighted this fact in the preamble to the Medicare Prescription Drug Benefit Final Rule issued on January 28, 2005:

> Given the current industry practice of broad pharmacy networks and given Medicare Part D's any willing pharmacy provision, which includes the requirement that plans offer reasonable and relevant standard terms and conditions for network participation to all similarly situated pharmacies, we

[2] http://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336.
[3] 42 U.S.C. § 1395w-104(b)(1)(A).
[4] 42 C.F.R. § 423.505(b)(1) and (18).
[5] Medicare Prescription Drug Benefit Manual, Ch. 5 § 50.8.1.

anticipate that all pharmacies that wish to participate in Medicare Part D will be able do so.[6]

Under these requirements, Plan Sponsors, or the PBMs that maintain networks on their behalf, must make their standard terms and conditions accessible and ensure they are both reasonable and relevant. Similarly, many states have enacted AWP provisions of their own.[7] These requirements have been routinely ignored and violated by the Plan Sponsors and PBMs.

Contrary to the letter and spirit of these requirements, Plan Sponsors and PBMs routinely create terms and conditions that are neither reasonable nor relevant. By doing so, the Plan Sponsors and PBMs exclude independent pharmacies and create barriers to participation, instead of creating a "floor" for similarly situated pharmacies. Such unreasonable barriers include the following:

- Arbitrarily excluding open door, retail pharmacies, with a valid state license(s), from participation in the "retail" network if they provide home delivery or mail services to their patients. This is done in violation of federal and state law.

- Requiring pharmacies to maintain stock of a large range of different drugs that are inconsistent with the size and needs of their patient populations.

- Improper audit and termination determinations by Plan Sponsors and PBMs who have an ownership stake in, or affiliation with, pharmacies that serve as competitors of the independent pharmacies they regulate. The lack of independence and due process has a chilling effect on pharmacy participation and beneficiary choice.

- Requiring retail pharmacies that provide any mail delivery services to become part of a separate "mail order" network, with unreasonable and burdensome requirements designed to arbitrarily exclude them from participation.

- Requiring these pharmacies to be licensed in all 50 states in order to join the separate "mail order" network, regardless of whether the pharmacies do business in those states.

- Requiring these pharmacies to be accredited from a specific accreditation organization while precluding these same pharmacies from obtaining accreditation from other nationally recognized organizations. No PBM has provided a valid rationale for this behavior.

- Requiring levels of insurance that are unreasonable and not commensurate with the size of the pharmacy and requiring pharmacies to obtain equipment that is cost prohibitive and unnecessary.

[6] Medicare Prescription Drug Benefit Final Rule, 70 Fed. Reg. 4194, 4506 (Jan. 28, 2005).
[7] *See e.g.*, N.J. Rev. Stat. § 17:48E-35.7; Tenn. Code Ann. § 56-7-2359; N.C. Gen. Stat. § 58-51-37.

These issues must be resolved in order to protect pharmacies throughout the country while promoting beneficiary choice.

Pharmacy Classification Is Not a Valid Basis To Exclude Pharmacies From Network Participation

We agree with CMS regarding the manner in which pharmacies are treated based on ill-defined classifications that are inconsistent with current pharmacy practice. The following statements by the agency in the preamble to the Proposed Rule are accurate and summarize problems independent pharmacies and Medicare Part D beneficiaries face every day:

> *[I]t is inappropriate to classify pharmacies as "mail-order pharmacies" solely on the basis that they offer home delivery or delivery by mail.*[8]
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> *Section 1860D–4(b)(1)(A) of the Act requires Part D plan sponsors to permit the participation of "any pharmacy" that meets the standard terms and conditions. Accordingly, it is not appropriate for Part D plan sponsors to offer standard terms and conditions for network participation that are specific to only one particular type of pharmacy, and then decline to permit a willing pharmacy to participate on the grounds that it does not squarely fit into that pharmacy type.*[9]
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> ***
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> *Therefore, we are clarifying in this preamble that although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. In particular, we consider "similarly situated" pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.* [10]
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> ***
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> *Unclear references to the term "mail order" have generated confusion in the marketplace over what constitutes "mail-order" pharmacy or services. This confusion has contributed to complaints from pharmacies and beneficiaries*

[8] 82 Fed. Reg. 56336, 56407 (Nov. 28, 2017).
[9] *Id.* at 56408.
[10] *Id*. at 56408.

> *regarding how Part D plan sponsors classify pharmacies for network participation, the Plan Finder, and Part D enrollee cost-sharing expectations.*[11]
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> ***
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> *As discussed previously, our classifications of certain types of pharmacies were never intended to limit or exclude participation of pharmacies, such as pharmacies with multiple lines of business, that do not fit into one of these classifications. Additionally, we have recognized since our January 2005 final rule that pharmacies may have multiple lines of business, including retail pharmacies that may offer home delivery services (see 70 FR 4235 and 4255).*[12]

Consistent with the issues raised above, qualified, licensed retail pharmacies have repeatedly been subjected to arbitrary and ill-defined definitions of "mail order" used as a pretext to terminate them from Medicare Part D retail pharmacy networks. Plan Sponsors and PBMs, in a manner entirely inconsistent with federal and state pharmacy law, have used the lack of regulatory definition as an opportunity to take action against a retail pharmacy based solely on their provision of home delivery or mail services. Independent pharmacies have even complained that the PBMs have allowed them to join the PBMs' networks long enough to obtain information about the pharmacies' customers, and then terminated the pharmacies from the networks while offering to service their customers through the PBMs' own pharmacy. Because of the power differential between these pharmacies and the national PBMs that maintain many of these networks for Plan Sponsors, there is no ability for pharmacies to negotiate the terms applied to them.

We note that most Plan Sponsors or PBMs only make terms and conditions for a retail network available to pharmacies that express interest in participation and do not advertise the existence of any other "type" of network. When independent pharmacies inquire about joining the PBM's network, they are provided an application and terms for this retail network.

Proposed Definitions of "Retail Pharmacy" and "Mail-Order Pharmacy"

Based on CMS's accurate observations regarding the pharmacy classification issues, the agency must make clear that a pharmacy that is licensed or approved to do business within a state may not be excluded or prevented from participating in a Part D network based on classification or arbitrary definitions and distinctions created by Plan Sponsors and PBMs.

CMS has proposed to resolve some of the confusion highlighted above by promulgating a new definition of the term "mail-order pharmacy" and revising the current definition of "retail pharmacy." The definitions proposed are:

[11] *Id.* at 56408.
[12] *Id.* at 56409.

- "Mail-order pharmacy" means a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.[13]

- "Retail pharmacy" means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.[14]

We agree with CMS that the definition of "mail-order pharmacy" should not turn solely on whether a pharmacy provides services by mail, as valuable home delivery or mail delivery services are provided in many retail pharmacy settings. However, we are concerned that the proposed definition's reliance on whether the pharmacy provides prescriptions at "mail-order cost sharing" does not fully resolve the existing confusion and ambiguity in the marketplace. There is no definition of "mail-order cost-sharing" in the relevant regulations, leaving Plan Sponsors and PBMs room to interpret its meaning and create their own definitions. Further, cost-sharing is typically determined by the Plan Sponsor or PBM that controls the terms and conditions for network participation. We believe this could continue to create situations where the Plan Sponsors and PBMs arbitrarily treat pharmacies differently for exclusionary purposes.

To remedy this confusion, we propose that CMS define pharmacies as "mail-order" based on whether they are closed door establishments. We suggest that the definition be revised to state:

> "Mail-order pharmacy" means a licensed pharmacy that is a closed door establishment that is never open to the public or its patients, which only dispenses and delivers covered Part D drugs via common carrier.

We have a similar concern with the proposed changes to the definition of "retail pharmacy." Because there is no definition of "retail cost sharing," we believe the exclusionary practices currently used by PBMs and Plan Sponsors could be adapted to continue to prevent willing retail pharmacies from joining retail pharmacy networks. As a result, CMS should make clear that any licensed pharmacy open to dispense supplies of covered Part D drugs to the walk-in general public, including a pharmacy that delivers covered Part D drugs to the patient via any common carrier, should be classified as a retail pharmacy. We suggest the following definition:

> "Retail pharmacy" means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public, regardless of whether that pharmacy provides home delivery services or delivery by any common carrier, from which Part D enrollees could purchase a covered Part D drug.[15]

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[13] *Id.* at 56508.
[14] *Id.* at 56509.
[15] *Id.* at 56509 (Nov. 28, 2017).

Notwithstanding these definitions, we also propose that CMS make clear, through additional regulatory provisions, that if a pharmacy is licensed and approved to do business in a state, neither a Plan Sponsor nor a PBM may exclude that pharmacy from participation on a classification basis. It is essential that any state licensed pharmacy be able to access equal terms of participation and that the PBMs and Plan Sponsors be precluded from creating arbitrary, exclusionary distinctions through their terms and conditions. A state licensed pharmacy should never be excluded from participation based on an arbitrary Plan Sponsor or PBM classification that bears no relationship to the pharmacy's ability to provide services. The terms and conditions to enter a Medicare Part D network must be reasonable, relevant, accessible and transparent.

Burdensome and Duplicative Accreditation Requirements That Create a Barrier to Network Participation Should Be Prohibited

Another way in which Plan Sponsors and PBMs have created barriers to entry into Medicare Part D networks is by applying expensive, burdensome and duplicative accreditation requirements.

Plan Sponsors or PBMs have dictated to pharmacies that a specific accreditation organization will serve as the exclusive vendor and must be used in order to participate in their Medicare Part D network. We have been informed that in many cases such vendor is extremely costly and the process of accreditation can take well over a year (often two years). The PBM is thus establishing an unreasonable standard designed solely to exclude independent pharmacies from entering or participating in the network. We agree with CMS that "[w]here there are barriers to a pharmacy's ability to participate in the network at all, it raises the question of whether the standard (that is, entry level) terms and conditions are reasonable and relevant."[16]

CMS has not mandated that Plan Sponsors or PBMs require use of a specific accreditation organization to participate in a Medicare Part D network. Yet, these PBMs are shutting out pharmacies based on this requirement, even in cases where a pharmacy is already accredited by a reputable recognized accreditation organization, even one that has been previously approved by CMS to accredit providers (*e.g.*, The Compliance Team). The PBMs refuse to provide any rationale for this behavior and refuse to demonstrate any transparency governing the accreditation process.

In contrast to other sectors like a hospital where a single accreditation covers all modalities and services the hospital provides, the pharmacy accreditation space has been fragmented. Oftentimes, pharmacies are required to obtain multiple, duplicative types of pharmacy-based accreditations in order to participate in a network (Specialty Drugs, Compounding, Mail-Order, etc.). These differing requirements can present barriers to entry and preclude otherwise qualified pharmacies from joining or remaining in networks, limiting beneficiary access.

[16] *Id.* at 56410.

The exclusion of qualified accreditation organizations is used by the Plan Sponsors and/or PBMs as a pre-text to remove qualified pharmacies from the network. If accreditation is to be required, the accreditation standards must be public and transparent and neither Plan Sponsors nor PBMs may arbitrarily exclude pharmacies from utilizing nationally recognized accreditation organizations.

Additional Due Process Provisions

We support the efforts of CMS to codify in regulation the requirement that Medicare Part D sponsors make terms and conditions available to a requesting pharmacy within two business days of receipt of the request.[17]

As you know, CMS previously issued an August 13, 2015 memorandum to Medicare Part D Plan Sponsors making clear that "a Part D plan sponsor must make standard terms and conditions available for all Part D plans it offers" within two business days and that such terms and conditions must be "reasonable and relevant."[18] CMS made clear in this issuance that the agency "maintains the authority to review all materials related to a sponsor's compliance with the AWP requirement and may evaluate whether a sponsor's standard terms and conditions are reasonable and relevant."

CMS should routinely review a Plan Sponsor's terms and conditions and demand complete transparency to the public as to what constitutes "reasonable and relevant." We also propose the creation of an independent review process by which a pharmacy can challenge specific terms and conditions that it believes does not meet the AWP reasonable and relevant requirements.

Audit Process

Pharmacies have no meaningful input and/or opportunity to negotiate the terms of their contracts with PBMs or Plan Sponsors, and as such, the pharmacies have little or no recourse when a PBM or Plan Sponsor employs aggressive "audit" tactics. A pharmacy can challenge initial audit findings through an internal appeals process, but the appeal is reviewed solely by the PBM and the PBM alone, without any independent oversight, and the same PBM ultimately decides whether to accept any of the supporting documentation submitted by the pharmacy. The result is a process that is susceptible to abuse and manipulation, particularly since the PBM often has an ownership or financial interest in pharmacies that serve as competitors of the independent pharmacies they review and audit.

Another tactic used by the PBMs is to identify an audit as an "investigation," thus circumventing the laws of more than thirty (30) states that regulate how PBMs conduct pharmacy "audits." Indeed, many states have "pharmacy bill of rights"-type rules, which regulate pharmacy audits but contain exceptions for certain investigative activity. Plan Sponsors

[17] *Id.* at 56411 (Nov. 28, 2017).
[18] Ltr from Amy K. Larrick, Acting Director, to Medicare Part D Plan Sponsors, Compliance with Any Willing Pharmacy (AWP) Requirements (Aug. 13, 2015).

and PBMs conducting a review of a Pharmacy's claim or a Pharmacy's practice should comply with due process requirements governing state audits.

To prevent this type of behavior, an independent third party audit review process should be established to conduct audits and review pharmacy's practices. This will help ensure that all pharmacies network members have the ability to fully confront and refute any allegations of noncompliance.

Termination Without Due Process

Independent pharmacies are improperly terminated from Medicare Part D networks based on allegations that have no merit or minor issues that do not justify such draconian action. The manner in which these terminations take place provides little or no opportunity for a pharmacy to challenge the determination before it takes effect, and any appeals process typically is controlled internally by the entity that made the initial decision.

For example, pharmacies have received letters from PBMs informing them that a private internal review body has made a determination that the pharmacy has been terminated from the network. The pharmacies are not given information on the membership of these bodies or how they operate, and instead receive a final result with no understanding of what was considered or how that result was reached. In addition, pharmacy patients are often informed of the pharmacy's termination before or at the same time as the pharmacy, making it difficult for an independent pharmacy to maintain its business while challenging the determination. While independent pharmacies routinely receive termination notices, we question whether the PBMs have taken similar actions against the pharmacies with which they have an affiliation.

Faced with termination, these pharmacies typically must engage in arbitration/litigation or accept the result. This behavior is to the detriment of the numerous Medicare beneficiaries that are no longer able to use their chosen pharmacy and threaten the very survival of the pharmacies involved.

Similar to processes established for Plan Sponsors to appeal contract determinations made by CMS, the development of an independent administrative appeals process, including an independent Administrative Law Judge hearing, is necessary. No pharmacy termination should take place until a pharmacy receives proper due process and the ability to confront and challenge allegations made by a PBM in a neutral transparent forum.

Conclusion

We appreciate the opportunity to provide these comments and look forward to working with the agency on these issues.

Best regards,

Stephen M. Azia

cc: Jennifer Summa, Senior Policy Advisor
Katie Salsbury, Esq.