March 7, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; CMS-4192-P

Dear Administrator Brooks-LaSure:

FMI – the Food Industry Association ("FMI"), on its own behalf and for the thousands of supermarket pharmacies operated by our member companies, is grateful to the Centers for Medicare and Medicaid Services ("CMS") for the opportunity to share our comments regarding the January 12, 2022, Proposed Rule, especially with respect to the proposed change to the definition of "negotiated prices," as codified at § 423.100 of the Part D Rules. FMI applauds CMS' decision to clarify the Rule in a manner that will save money for Part D beneficiaries, and it is a laudable first step in reforming the abusive practice of pharmacy Direct and Indirect Remuneration ("DIR")[1], implemented by Part D Plans ("Plans") and their subcontracted pharmacy benefit managers ("PBMs"). FMI's members are particularly concerned about the manner in which pharmacy DIR threatens patient access, and the way Plans and PBMs are leveraging such fees to erode competition among pharmacies for their own self-interest. FMI therefore calls on CMS to engage in even more comprehensive regulation of these fees and of Plans and PBMs, to protect patient access and competition.

I. Executive Summary.

FMI represents a wide range of supermarket member companies which, in turn, operate approximately 12,000 pharmacies inside retail supermarkets. Over the past several years, these pharmacies have seen a steady increase in pharmacy DIR resulting, in many cases, in pharmacy closures and in the difficult decision by FMI member companies not to build stores with pharmacies going forward. FMI believes this poses a threat to Part D patient access as pharmacies

[1] We note that "Direct and Indirect Remuneration," or DIR, is a broad term comprising many different forms of remuneration received by Plans from various stakeholders. We refer to "pharmacy DIR" throughout this comment, by which we refer to mandatory price concessions to which a pharmacy must agree as a condition for participation in a Part D Plan/PBM network.

patients have depended upon for years close in supermarkets, and the closure of stores results in decreased competition in the pharmacy marketplace, allowing PBM-owned pharmacies to dominate the pharmacy market.

FMI applauds the Proposed Rule as a laudable first step in providing relief in the marketplace and believes CMS should implement the Proposed Rule because it is likely to achieve the goals of (1) meaningful price transparency and competition (to a limited extent), (2) consistent application of all pharmacy payment concessions by Part D sponsors, and (3) the prevention of cost-shifting to beneficiaries and taxpayers. However, the Proposed Rule is unlikely to address certain terms and conditions that are not reasonable or relevant to FMI members, especially the DIR Programs and metrics that fail to accurately measure performance, do not provide pharmacies with an opportunity to improve their scores, and unfairly rank pharmacies against each other despite impactful socio-economic and business model differences. Thus, the Proposed Rule has significant gaps and possible unintended consequences CMS should address.

The gaps in the Proposed Rule include the lack of regulation of unreasonable and irrelevant DIR metrics; the possibility of higher administrative and credentialing fees imposed by PBMs to supplement income lost from pharmacy DIR; and lack of action regarding continued vertical integration of PBMs, resulting in reduced competition among pharmacies. CMS should apply the "reasonable and relevant" standard set forth in the Any Willing Provider Law ("AWPL") to DIR Programs, to the extent Plans continue to implement them going forward. Additionally, CMS should clarify this standard and its intent for pharmacies to enforce this standard through arbitration or litigation with Plans and PBMs, despite the lack of a private right of action. CMS should also regulate vertically integrated Payor/pharmacy entities to improve competition among all pharmacies.

CMS has statutory power, despite the Part D non-interference clause ("NIC"), to address these shortcomings. CMS commentary on the NIC reveals that CMS must enforce statutory requirements even if those requirements implicate negotiations between a Plan/PBM and pharmacies. Even with restrictions imposed by the NIC, CMS has the power to, and should, provide guidance to parties that the AWPL requirement terms and conditions for participation in Part D be "reasonable and relevant" to supermarket pharmacies, and that the question of whether those terms are in fact reasonable and relevant can be determined by a neutral arbitrator or court of competent jurisdiction. Additionally, CMS may clarify that reimbursement, in addition to other terms and conditions, must be reasonable and relevant. CMS can also promulgate rules regarding the performance metrics that are reasonable and relevant, and that these performance metrics as applied must be reasonable and relevant to specific kinds of pharmacies. To promote healthcare equity, these performance metrics should take into consideration the socio-economic circumstances that affect pharmacy performance, as well as whether the pharmacy dispenses specialty drugs, and other similar considerations.

CMS has, in the past, exercised its powers in a similar manner without running afoul of the NIC. CMS has published guidance in the form of the Part D Manual that clarifies the AWPL and the "reasonable and relevant" standard. CMS has also made clear its power to remove safe harbors

from the antikickback statute and has forbidden certain payment arrangements that result in significant waste, among other actions. CMS clearly has the power to, and should, regulate pharmacy DIR fees and reimbursement to improve the competitive disparities that have arisen in Part D.

We set forth the above in greater detail, as follows.

II. Background.

FMI is a trade association representing the food industry, including roughly 1,000 supermarket member companies that collectively operate almost 33,000 food retail outlets and employ approximately 6 million workers. Those companies also operate approximately 12,000 pharmacies inside retail grocery stores throughout the United States. The reach and impact of our industry is extensive, ultimately touching the lives of more than 100 million U.S. households on a weekly basis and representing an $800 billion industry. Throughout the ongoing COVID-19 health emergency, FMI members have been and remain a critical component of ensuring the availability of food, pharmacy and healthcare services in communities across this nation.

Supermarket pharmacies have played an outsized role in the COVID-19 vaccination effort while also serving as a bridge between our communities and other providers, offering patients immediate care that is close and convenient to home. Additionally, many FMI members have reported additional and extended operating hours to accommodate patient needs throughout the pandemic. This makes vaccine access more convenient, especially for seniors who are more prone to severe COVID-19 and also makes access safer and reduces the risk of exposure. Additionally, supermarket pharmacies offer in-store shopping while Part D patients wait for their prescriptions — a convenience that multiple studies have shown to be a decisive factor for adults ages 65 and older in choosing a pharmacy.[2] Accordingly, supermarket pharmacies have regularly garnered the highest overall satisfaction rating for brick-and-mortar pharmacies.[3] Unfortunately, however, the prevalence of pharmacy DIR poses an existential threat to supermarket pharmacies.

The impact of pharmacy DIR has been devastating to supermarket pharmacies and the patients who depend on them. These experiences include commentary from a growing pharmacy solution that services more than 300 sites in almost two dozen states with an estimated retail volume of more than $1 billion:

[2] Shiyanbola O.O., Mott D.A., Croes K.D., The structural and process aspects of pharmacy quality: older adults' perceptions., Int J Clin Pharm. 2016; 38: 96-106; Dominelli A., Weck Marciniak M., Jarvis J., Service preferences differences between community pharmacy and supermarket pharmacy patrons. Health Mark Q. 2005; 23: 57-79.
[3] Redman, Supermarkets rate high in pharmacy customer satisfaction, Supermarket News, Aug. 5, 2020, https://www.supermarketnews.com/health-wellness/supermarkets-rate-high-pharmacy-customer-satisfaction.

> *DIR Fees have had an increasingly negative impact on pharmacy operations, growing from 1.75% of revenue in 2018 to 2.65% of revenue in 2021 in our corporate stores. Extrapolating this across our participants, we estimate that our group paid $27.7 million in fees in 2021 alone. DIR fees are taking resources from our operators that should be invested in their pharmacies and teams for the benefit of the patients and communities we serve. In many cases profitability and cash-flow are being compressed to the point where several operators are contemplating exiting the profession. The difficulty that this poses to our patients is that many of our sites are in under-served rural communities that will struggle to find another pharmacy to replace it.*

Another member reports:

> *We have seen increased numbers of independent pharmacies seeking to sell to us, especially over the past 6 months. This is occurring in an environment where one would expect a lift in pharmacy revenues through COVID immunizations, etc.*

The information above is of particular concern to FMI members, as pharmacy closures result in fewer choices for Part D beneficiaries. Moreover, as members point out, these pharmacy closures result in less competition among pharmacies, which may result in increased costs for consumers. A related problem is the decision not to expand to underserved areas. Members point to rising DIR as the greatest contributing factor to closures and decisions not to expand. For example, another FMI member points out that the average net profit its pharmacy realizes after DIR in one particular Plan is -$0.21, a loss on every prescription filled in that network. Another regional supermarket chain reports, since the introduction of DIR, it went from a profit of more than $60 thousand per pharmacy per year to a deficit of $60 thousand per pharmacy per year, forcing closures in the past four years of seven pharmacies. Another large chain paid $136 million in DIR in the last three years. If this trend continues, chains like this are likely to exit the pharmacy business altogether, again reducing competition. Indeed, a large chain reported $30 million in DIR in 2021, resulting in a decision not to open new stores containing pharmacies, and suffering 17 pharmacy closures in its markets. These closures represent the dominant trend in the industry and threaten patient access to Part D drugs.

The manner in which DIR Programs are implemented is also opaque and inscrutable, often resulting in pharmacies being unable to predict or improve their own scores. With respect to FMI members operating specialty pharmacies, these pharmacies' adherence is unfairly measured in a manner that fails to account for the difficulties inherent in maintaining adherence, like drug vacations and holds for adverse reactions. These programs force pharmacies to expend significant

additional resources, not to improve patient adherence but merely to obtain data about how a PBM is tracking adherence. Moreover, PBMs use arbitrary metrics like formulary compliance and generic dispense rate, which penalize pharmacies for dispensing drugs as prescribed by a physician, and as approved by the Plan itself.

Furthermore, due to the unpredictability of pharmacy DIR, FMI members are often unable to account and accrue for any losses they may incur when PBMs recoup DIR fees months after the point of sale. Pharmacies that are solvent when they dispense a drug may find months later (and as demonstrated in members' statements above) that their pharmacy DIR netted an unforeseen loss for the pharmacy. This unpredictability limits our members' ability to open new pharmacies, especially in rural and underserved areas, as they cannot predict whether they can sustain expansion, as attested to by member chains who have ceased building new stores with pharmacies. Indeed, one large member chain recently built new sites in urban locations and had to forego including pharmacies in those new stores, as they could not build large enough stores to mitigate the losses from pharmacy. The same chain has had to reduce pharmacy hours and staffing, and has even had to reduce or eliminate patient cost-savings and rewards programs. As these experiences attest, negative profits driven by pharmacy DIR have the foreseeable results of ultimately closing supermarket pharmacies entirely, thus further limiting patient access. Absent substantial reform, this trend will likely continue.

III. The Proposed Rule.

In brief, as FMI understands the Proposed Rule, CMS has proposed to change the definition of "negotiated prices" at § 423.100. Under the current definition, "negotiated prices" means all price concessions from network pharmacies except those that cannot reasonably be determined at the point-of-sale. The new definition will require Part D Plans to report, as the "negotiated price," "the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug, taking into account all pharmacy price concessions." 87 FR 1912. The result will be more pricing transparency and lower out-of-pocket costs for Part D beneficiaries, while ensuring Part D Plans and their associated PBMs will not enjoy any profits from price concession. FMI views this as a significant first step in improving the Part D marketplace.

In the Proposed Rule, CMS stated its goal was to ensure (1) meaningful price transparency and competition, (2) consistent application of all pharmacy payment concessions by Part D sponsors, and (3) the prevention of cost-shifting to beneficiaries and taxpayers. 87 FR 1914. FMI agrees the Proposed Rule will likely advance these objectives to the public good and in favor of healthcare equity.

In terms of transparency, FMI agrees this Proposed Rule will likely provide CMS with a better understanding of the reimbursement pharmacies are receiving from Part D Plans. FMI hopes CMS will consider this newfound transparency as it evaluates the reasonableness and relevance of

pharmacy reimbursement under the Part D "Any Willing Pharmacy" law ("AWPL"), 42 U.S.C. §1395w-104(b)(1)(A). This is discussed more fully below.

Additionally, the Proposed Rule will likely, as CMS suggests, increase transparency in favor of beneficiaries, who will enjoy the benefits of pass-through pricing at the point of sale, rather than through premiums, which can unwittingly direct patients to Plans that will ultimately cost them more in co-insurance. 87 FR 1914. FMI agrees this change will especially help those beneficiaries who may be enticed by lower premiums but benefit more from lower co-insurance. We believe this change improves healthcare equity for Part D beneficiaries by providing patients with a more realistic picture of their relative financial responsibilities. Ultimately, this change should result in lowering costs for patients who bear a higher out-of-pocket burden due to more dire health conditions.

With respect to competition, FMI agrees with CMS' assessment that this change improves competition *among Plans* by requiring a level playing field at the point of sale, thus preventing Plans from misleadingly characterizing their lower premiums as lower overall cost to the beneficiary. 87 FR 1914. Again, this enhances healthcare equity by providing beneficiaries with a more realistic reflection of their own out-of-pocket costs and by providing them with a more accurate slate of premiums from which to choose. However, as we discuss more fully below, we believe the anti-competitive effects of pharmacy DIR stretch beyond merely competition among Plans, and we believe CMS can do more to address the anti-competitive status quo inherent in the vertically integrated Plan/PBM/pharmacy entities that currently dominate the marketplace.

We also believe this Proposed Rule, in conjunction with the Final Rule set forth in 86 FR 5864, amending § 423.514(a) such that Part D sponsors will be required to disclose their pharmacy performance measures to CMS, is a positive step toward ensuring that pharmacies' performance, when calculated, is done so on an equitable basis. To the extent Plans continue to institute performance networks in light of the Proposed Rule, ensuring transparency in the manner performance is assessed in conjunction with transparency in pricing will be a positive step. However, FMI members stress that, to the extent Plans and PBMs continue to impose DIR Programs upon our pharmacies, CMS must implement regulations addressing the disparities created by these programs for pharmacies.

With respect to the consistent application of all pharmacy payment concessions by Part D sponsors, we agree with CMS that "[r]equiring the negotiated price to reflect the lowest possible pharmacy reimbursement as proposed would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements, and thus closer to the actual cost of the drug for the Part D sponsor." 87 FR 1916. We can confirm on behalf of FMI members CMS' observation that "pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim." Ibid. This is true for multiple reasons, but especially because (1) most Performance Networks are designed such that some pharmacy

price concession is mandatory; and (2) PBMs design Performance Networks to only produce the possibility of incentive payments to those pharmacies in the very top percentile of performance metrics. Compounding the difficulty of reaching a performance tier that results in payment back to the pharmacy is that no consideration is given to inherent performance handicaps, like lack of generic substitutes,[4] socio-economic disparities between pharmacy geographic locations,[5] or differences in dispensing practices between retail and specialty drugs. As CMS rightly observed, "performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties." Ibid. The Proposed Rule will at least create a more transparent system reflecting the realities of these inequitable performance programs.

The Proposed Rule will also clearly benefit taxpayers and beneficiaries by reducing their exposure to heightened liability through the four phases of the Part D Benefit. 87 FR 1914. This benefits beneficiaries as their out-of-pocket responsibility is reduced and improves overall healthcare equity, while adding a welcome reduction in the public cost burden.

All these positives are reasons to applaud the Proposed Rule, but above all, the Proposed Rule at last shifts the burden of performance networks to Plans, rather than Part D beneficiaries. As CMS observed, "DIR amounts that Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts, by an average of 0.6 percent and as much as 3 percent as a share of gross drug costs from 2010 to 2020," resulting in a massive windfall for Plans and PBMs, to the detriment of beneficiaries. 87 FR 1913. FMI members can attest to the fact that the "3 percent as a share of gross drug costs from 2010 to 2020" comes directly from their pharmacies in the form of DIR, often resulting in pharmacy closures. Forcing Plans to report the lowest possible reimbursement will at least shift this 3 percent away from Plans and PBMs to the pockets of patients. However, FMI hopes that, absent any profit to the Plan, Plans will decide to terminate their inequitable performance networks altogether.

While we believe the net benefits to Part D stakeholders are self-evident, we anticipate Plans and their PBMs will likely offer objections to the Proposed Rule. We respond to those anticipated objections as follows.

We anticipate Plans and PBMs will argue that they cannot implement the suggested changes beginning in 2023, as they may already have some contracts in place for that year. We believe this argument lacks merit for several reasons. First, we know that all or substantially all PBMs have contractual terms in place that account for any change in DIR, either requiring immediate

[4] Particularly relevant in programs utilizing Generic Dispense Rate ("GDR") as a performance metric.

[5] This is especially disturbing, as it exacerbates existing healthcare inequities by punishing pharmacies dispensing to the most vulnerable populations.

renegotiation of rates or setting a fixed reimbursement rate in such a situation. We believe CMS can require these Plans and PBMs to present these contract terms to CMS if requested. Notwithstanding this fact, now that CMS has concluded beneficiaries and the Part D Program are better protected under the Proposed Rule, we believe any additional delay in providing the proposed relief would improperly place Plan and PBM profits above patient well-being. Given the contract provisions discussed above, as well as the concern for beneficiaries, we believe CMS' current proposed timeline is completely appropriate.

We anticipate Plans and PBMs will also argue that the Proposed Rule will limit a Part D sponsor's ability to incentivize quality improvement from pharmacies and drive better clinical performance. This argument is misguided. In the Proposed Rule, CMS rightfully points out that defining the negotiated price as the lowest possible reimbursement a network pharmacy will receive inclusive of all pharmacy price concessions will not diminish quality of care because sponsors can incentivize pharmacies via future incentive payments that would increase reimbursement from the level of lowest possible reimbursement per claim. 87 FR 1916. In other words, CMS has made it clear that Plans will not be prevented from offering pharmacies incentive payments for improved performance. Indeed, this would be a marked improvement over the current system, in which pharmacies are forced to place a significant amount of reimbursement at risk with little potential for improvement.

We also anticipate Plan sponsors and their PBMs will argue that price concessions applied as DIR at the end of the coverage year result in a lower Plan premium, and that price concessions lower the estimated Plan liability, subsequently reducing the price of coverage to a Plan beneficiary. There are multiple false premises reflected in this potential objection. First, it assumes all pharmacy DIR is reflected in lower premiums. On the contrary, as CMS notes, DIR a sponsor receives that is above the projected amount factored into its Plan bid increases Plan revenue and contributes to Plan profits but not necessarily lower beneficiary premiums. 87 FR 1913. Second, it assumes the only price reduction of value is reflected in the premium, as opposed to co-insurance or out-of-pocket expenses. As CMS points out, higher DIR results in higher out-of-pocket costs for more than half of all Part D beneficiaries, even after accounting for the premium savings tied to higher DIR. Ibid. Thus, lower premiums due to pharmacy DIR are not a net positive benefit for beneficiaries; in fact, they ultimately raise beneficiary costs.

We further anticipate the Plans will argue that because pricing adjustments are contingent upon performance measured over a period of time that extends beyond the point-of-sale, they cannot be known in full at the point-of-sale. This is of course solved by the Proposed Rule itself, which in essence standardizes the negotiated price, making it predictable and not subject to the "reasonably determinable" exception. Beyond this objection, Plans may argue it is unfair to require Plans to report the lowest possible reimbursement as the negotiated price because it may not (and likely will not) accurately reflect the actual reimbursement paid to pharmacies. In other words, Plans will likely argue that they should not be forced to take on the risk of negative DIR—

that is, DIR paid to pharmacies, rather than paid by pharmacies to Plans—that they may incur under the Proposed Rule. The problem with this objection is that it assumes pharmacies should continue to shoulder all the risk of performance programs, as is the current status quo, while Plans and PBMs bear zero risk and, in fact, profit by as much as 5 percent of the billions of dollars represented in their bids under the risk corridor structure. The fact that Plans themselves may not have the incentive to offer incentives to pharmacies for performance does not change the fact that Plans may choose to offer incentives to pharmacies. They will have merely lost the right to profit from pharmacies' risk in doing so.

Thus, FMI welcomes this first step in improving pharmacy DIR under the Medicare Part D Program. Unfortunately, FMI has identified certain unintended consequences and possible gaps in the Proposed Rule. In the next section, we detail those unintended consequences and gaps.

IV. Unintended Consequences or Gaps In the Proposed Rule.

The Proposed Rule, while offering much needed reform to the Part D Program with respect to pharmacy DIR, lacks a view of pharmacy DIR through the lens of the AWPL, as codified at 42 U.S.C. § 1395w-104(b)(1)(A), and further expounded upon in CMS Rules at § 423.505(b)(18). The AWPL requires Plans "[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…." This critical Rule was further clarified in the Medicare Part D Prescription Drug Benefit Manual ("Part D Manual") at, inter alia, Section 50.5.3. In that section, CMS plainly stated, "Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18)." Thus, the Proposed Rule has overlooked this crucial standard in reviewing pharmacy DIR, as the Proposed Rule does not address the reasonableness and relevance of DIR metrics and other aspects of the program to pharmacies. FMI encourages CMS to revisit its review of pharmacy DIR considering this "reasonable and relevant" standard.

Thus, in light of this standard, the Proposed Rule does little to enact much needed reforms to the practical reality of DIR Programs from the perspective of providers. For example, the Proposed Rule does not require that pharmacy DIR fee performance metrics be relevant to a grocery store chain's community pharmacy practice. As alluded to above, performance programs ignore not only socio-economic disparities[6] that result in punishing supermarket pharmacies located in the most vulnerable areas, but also ignore performance metrics that fail to account for structural disadvantages inherent in supermarket pharmacy dispensing, including cost containment metrics such as Generic Dispense Rate (GDR) that unfairly hold supermarket pharmacies to account for a

[6] See, e.g., Hensley et al., Poverty, Transportation Access, and Medication Nonadherence, Pediatrics, Vol 141, Issue 4, April 1, 2018 (https://publications.aap.org/pediatrics/article/141/4/e20173402/37725/Poverty-Transportation-Access-and-Medication) (finding prescriptions originating from the highest poverty quintile were significantly more likely to not be filled than those from the lowest poverty quintile).

physician's choice to prescribe a brand drug or that penalize supermarket pharmacies for dispensing brand drugs for which no generic equivalent exists. This holds true for metrics like formulary compliance as well, which penalize supermarket pharmacies simply for dispensing the product prescribed and over which the pharmacy has no control. Due to these and similar metrics, most pharmacies fall below typical DIR measurement tiers and pay higher DIR fees as a result. Supermarket pharmacies would raise these disputes directly with PBMs and Plans but face hurdles in doing so, which are also not addressed by the Proposed Rule.

The Proposed Rule does not ensure there is a mechanism for pharmacies and PDPs and/or PBMs to settle disputes regarding the reasonableness and relevance of the terms and conditions. Although CMS rules require that the "reasonable and relevant" standard be incorporated into all contracts among Plans, PBMs, and pharmacies, 42 C.F.R. § 423.505(i)(3)(iii), PBMs and Plans nevertheless attempt to sidestep adherence to the "reasonable and relevant" standard by stating that no private right of action exists under the AWPL or CMS Rules. This is despite the fact that at least one Circuit Court has recognized a breach of contract action enforcing statutory language incorporated into the contract. Trone Health Servs., Inc. v. Express Scripts Holding Co., 974 F.3d 845 (8th Cir. 2020). Plans and PBMs instead argue that whether a contract is "reasonable and relevant" is solely a function of whether pharmacies will agree to those terms, ignoring the fact that the vast majority of pharmacies have little choice but to agree to these terms, and are offered no opportunity to negotiate. This renders the "reasonable and relevant" standard meaningless—a result CMS surely did not contemplate in drafting the Rule.

Additionally, the Proposed Rule does not address alternative ways that PDPs will claw money back from pharmacies if pharmacy DIR becomes unprofitable. FMI fears its members will be subjected to enhanced credentialing fees, transactional fees, or other unforeseen fees that Plans and PBMs will impose in a manner not necessarily connected with the "negotiated price" of a drug.

Although the Proposed Rule includes language addressing Administrative Service Fees and Plan responsibilities to report these in their bids, 87 FR 19117-18, the Proposed Rule offers no new Rule as to such fees; it only reaffirms CMS' previous interpretation of them. Without clear guidance on these fees, Plans and PBMs are likely to continue raising these "administrative" costs against pharmacies and, so long as CMS continues to do nothing to enforce the requirement that these be reported as pharmacy DIR, Plans and PBMs will simply interpret them as not pharmacy DIR.

Finally, although the Proposed Rule addresses competition among Part D Plans, it does nothing to address anti-competitive activity in which vertically integrated Plans/PBMs/pharmacies continue to engage. These vertically integrated payor entities result in, for example, "no bid"

contracts between Plans and PBM affiliates.[7] These entities also distort incentives for PBM-owned pharmacies, permitting them to out-compete other pharmacies. That is, PBM-owned pharmacies may accept lower reimbursement directly, or through pharmacy DIR, because the additional profits will inure to the affiliated PBM or Plan, which then essentially subsidize their pharmacies. These predatory pricing arrangements eviscerate the pharmacy marketplace by forcing supermarket pharmacies to compete, not merely against PBM-owned pharmacies, but against the PBMs and Plans. This arrangement also permits PBM-owned pharmacies to increase their market share. Thus, CVS Specialty now holds approximately 27% of the specialty drug market, permitting it to purchase drugs below the acquisition costs of other pharmacies, and further eroding equity in the market. We believe CMS has substantial legal footing to address this issue, and the other foregoing unintended gaps and consequences of the Proposed Rule, as follows.

V. The Noninterference Clause Does Not Bar CMS From Regulating PBMs.

CMS has a significant congressional mandate to regulate the Part D Program, with few limitations. One of those limitations, as briefly discussed above, is the NIC, 42 U.S.C. § 1395w-111(i). The NIC states,

> In order to promote competition under this part and in carrying out this part, the Secretary: (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.

CMS has set forth its interpretation of the NIC, which includes: (1) Promotion of competition; (2) Prohibition on requiring particular formulary; and (3) Prohibition on a particular price structure as between PBMs and pharmacies. We set forth our analysis as follows.

Although CMS has recognized it is not "free to interfere" in sponsor-pharmacy negotiations and acknowledged it cannot institute a price structure for the reimbursement of covered Part D drugs, CMS has commented that there are numerous statutory provisions that require the agency to directly intervene in the contractual relationship between PDPs and network pharmacies. 79 FR 1971. These provisions clearly signal Congress' expectation that CMS would be involved in at least some negotiations between PBMs and pharmacies. For example, Congress intended for CMS to issue guidance and enforce statutory provisions related to: "Interpretation of what 'access to negotiated prices' means, any-willing-pharmacy standard terms and conditions, prohibition on any requirement to accept insurance risk, prompt payment, and payment standard update requirements." Ibid.

[7] E.g., Cigna, the Plan that owns Express Scripts, Inc. ("ESI") utilizes ESI as its PBM; similarly, SilverScript, Inc. and Aetna—both Plans owned by CVS Health, use Caremark as their PBM, and UnitedHealthcare, which owns the PBM OptumRx, Inc. (Optum), also contracts with Optum as its PBM.

In this regard, CMS should intervene in disputes over whether proposed or finalized contractual arrangements violate/d its rules. Ibid. Further, CMS articulated a belief that nothing in the non-interference clause limits its authority to "require documentation of and access to all such agreements, **or to require the inclusion of terms and conditions in agreements when necessary to implement requirements under the Act.**" Ibid. (emphasis added). Clearly, CMS has sufficient statutory authority to require Plans and PBMs to adhere to the "reasonable and relevant" standard that CMS has imposed on all contracts. This means Congress intended for CMS to enforce contractual provisions between sponsors and pharmacies; indeed, CMS is required to address, relative to drug-cost-related issues, Part D mandates. As CMS has stated, this includes, "[i]nterpretation of what 'access to negotiated prices' means, any-willing-pharmacy standard terms and conditions, prohibition on any requirement to accept insurance risk, prompt payment, and payment standard update requirements." 79 FR 1971.

Thus, CMS should intervene where Plans and PBMs continue to impose performance metrics that are reasonable or relevant, while prohibiting the use of any metrics that cannot be shown to reasonably and relevantly improve pharmacy quality. Prohibitions on unreasonable terms could include prohibitions on, inter alia, adherence metrics for oncology that do not properly account for cessation of therapy to protect patient health, and similar pauses in therapy and other prescriber-initiated events, as well as formulary compliance and other metrics over which oncology pharmacies have no control.

Additionally, CMS may be involved in contract discussions in order to explain CMS requirements and to ensure compliance with Part D rules and regulations. 79 FR 1971. This means CMS can advise Plans and PBMs on the one side of negotiations, and pharmacies on the other, that to the extent they cannot determine terms and conditions are reasonable and relevant among themselves, the proper forum for determining such disputes is arbitration or through legal action, pursuant to their respective dispute resolution procedures. This issue is particularly fraught for pharmacies due to PBMs' refusal to recognize pharmacies' right to bring such cases as breach of contract actions, due to the lack of a private right of action in the Medicare statute.[8] Guidance to this point would ensure that CMS does not involve itself in determining the reasonableness or relevance of terms but leaves these "fact-specific questions … between negotiating parties." Part D Manual at 50.5.3. These questions of fact are clearly suited to a finder of fact like a neutral arbitrator or a jury, and CMS would avoid such complaints regarding pharmacy DIR and other Part D related disputes by clarifying that these disputes are meant to be adjudicated in this manner between the parties.

Furthermore, the above guidance clarifies that CMS may examine "related-party" relationships, like those between Plans and Plan-affiliated pharmacies, because "there is no reason to believe that the Congress intended that we are prohibited from oversight of the sponsor's dealings with

[8] This is despite the Eighth Circuit's holding that laws otherwise lacking a private right of action may be enforced through a breach of contract action. Trone, 974 F.3d 845.

itself."[9] 79 FR 1971. Clearly, where a Plan and/or PBM is self-dealing, CMS may determine the extent of this self-dealing and the manner in which it affects competition within drug channels.

The above actions are well within the range of actions that CMS itself has determined it can take to further supplement the Proposed Rule. These actions also do not run afoul of the bounds of the NIC. Those bounds include (1) avoiding being the arbiter of private disputes; (2) not actively participating in negotiations between parties; and (3) not establishing either "absolute or relative indices of price for Part D drugs." Id. at 1971-72. Our proposal does nothing to implicate these prohibitions. The "reasonable and relevant" standard is a "fact-specific" determination that a jury or arbitrator is equipped to resolve on a case-by-case basis. Part D Manual at 50.5.3. This standard does not require a particular benchmark, and therefore is within the bounds of the NIC. In addition to CMS' own guidance set forth above, CMS has received direction from the Executive and Legislative branches relating to this Proposed Rule. The Biden Administration issued Executive Order 14036 on July 9, 2021, "Promoting Competition in the American Economy," which expressly encourages agencies like CMS to regulate, individually and collaboratively, to improve competition, and to investigate anti-competitive conduct. Both Democratic and Republican legislators have made attempts to alert CMS to these issues as well, through letters, committee reports, and proposed legislation. We believe this all provides CMS with a clear mandate to exercise the rulemaking and enforcement power to regulate Part D in the above manner. Indeed, CMS has taken similar action in the past.

CMS first interpreted the AWPL when it promulgated the Rule requiring "reasonable and relevant terms and conditions." CMS has offered substantial guidance through the Part D Manual, again requiring reasonable and relevant terms and conditions, including in drug reimbursement terms.[10] CMS has issued guidance to Plan Sponsors clarifying their responsibilities under the AWPL, and has even prohibited certain "payment arrangements" that result in penalizing pharmacies in a manner CMS finds would ultimately harm the goals of the Part D Program. 80 FR 7930. Thus, CMS clearly has the power to regulate PBMs more strictly as set forth above.

V. Additional steps CMS should take.

In conclusion, as set forth more fully above, FMI urges CMS toward the following actions, in addition to those contained in the Proposed Rule:

i. Issue guidance on that which constitutes a "reasonable and relevant" term in accordance with the AWPL and Medicare Prescription Drug Benefit Manual;
ii. Strengthen language previously set forth in the Part D Manual clarifying that an unreasonably low reimbursement rate that causes providers to lose money is not a reasonable or relevant term or condition and constitutes a violation of the AWPL;

[9] We note that, although CMS determined not to codify its interpretation of the noninterference clause as set forth above, it reiterated that the interpretation set forth in the January 2014 proposed rule "is the same interpretation we have been operating under in managing the Part D program since before the beginning of the Part D program." 79 FR 29844. In other words, the 2014 interpretation of the NIC should be read as CMS' current interpretation of the NIC, according to CMS' own statements.

[10] See Part D Manual at section 50.3.

iii. Provide guidance regarding relevant metrics for performance, which must include that:
    1. Pharmacy DIR fees cannot result in a net loss for the majority of pharmacies in a network,
    2. All similarly situated pharmacies are treated equally,
    3. Material differences in pharmacies are recognized and accounted for,
    4. Pharmacies are provided with a meaningful ability to impact their scores based on comprehensive book of business, as opposed to a small portion of claims, and
    5. Incentives align with good pharmacy care and patient safety;
iv. Issue guidance stating that the "reasonable and relevant" standard should be adjudicated in arbitration or litigation between Plans/PBMs and pharmacies; and
v. Review current PBM/Part D Plan DIR Programs to determine whether they contain "reasonable and relevant terms and conditions" for all participating pharmacies and, where they do not, issue appropriate sanctions.

FMI suggests the above actions are well within CMS' authority and will promote healthcare equity and marketplace competition within the Medicare Part D space, in accordance with stated Executive and Legislative goals.

Thank you for the opportunity to provide this input and your consideration. If you have any questions about these comments or would like additional information, please feel free to contact me or Peter Matz at pmatz@fmi.org or (202) 452-8444.

Sincerely,

Leslie G. Sarasin, Esq.
President and Chief Executive Officer