March 7, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013
Attn: CMS-4192-P

Submitted electronically via regulations.gov

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:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the proposed rule titled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs [CMS-4192-P]" published in the *Federal Register* on January 12, 2022.[1] In this comment letter, we provide our feedback and suggestions in response to CMS's proposal to redefine negotiated price as the lowest possible payment that a Part D plan will make to a pharmacy, inclusive of all price concessions, effective January 1, 2023.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, AMCP's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP supports the Administrations' goals to reduce prescription drug spending for consumers and to encourage drug pricing transparency within the health care system. As the Administration continues to work to encourage system transformation that promotes affordable health care, AMCP recognizes that the need to address the rising cost of prescription medications remains critical and supports competitive marketplace solutions to lower costs for everyday Americans, including America's seniors receiving prescription drug coverage through the Medicare Part D program. AMCP continues its efforts to work with the Administration and Congress to find

[1] 87 Fed. Reg. 1842 (Jan. 12, 2022).

solutions and support proposals that achieve the goals of optimizing medication use at affordable costs.

To this end, AMCP is concerned that the Administration's proposal to redefine negotiated price is likely to result in unintended consequences for patients, payers, and taxpayers. By CMS's own admission, a policy which requires that most pharmacy claims be adjudicated using the lowest possible reimbursement to the pharmacy will raise premiums for a majority of Part D beneficiaries, and will lead to an increased burden to Part D sponsors, the Federal government and taxpayers. Furthermore, we generally caution CMS that focusing only on pharmacy price concessions may potentially serve as a diversion from the primary drivers of medication affordability – the rising list prices of pharmaceuticals. Lastly, AMCP believes this proposal interferes with Part D plan sponsors' ability to negotiate agreements with pharmacies in violation of the non-interference provision of the Part D statute.

AMCP offers additional comments and recommendations below.

CMS Should Consider the Full Implications on Cost to Beneficiaries, Part D Plan Sponsors and Taxpayers

In an effort to address beneficiary cost-sharing at the pharmacy counter, CMS proposes to require that all pharmacy price concessions for a covered Part D drug be included in the negotiated price at the point-of-sale. AMCP recognizes that a limited number of beneficiaries with high coinsurance for prescription medications may stand to experience some relief in out-of-pocket costs from this proposal. However, CMS has not adequately considered the full implications of this proposal on the majority of beneficiaries, Plan D sponsors, and taxpayers. As a result, and particularly in light of the fast approaching CY 2023 bid deadline, we encourage the Administration to withdraw and reconsider this major proposal.

Impact on Beneficiaries.

CMS's proposal will significantly increase premiums for the majority of Part D beneficiaries, especially patients with no prescriptions or those utilizing cost-saving generics. CMS admits as much in the proposed rule, finding that "[p]lan premiums would likely increase as a result of the proposed change to the definition of negotiated price" because it would "increase[e] the cost of coverage under the plan."[2] Importantly, CMS finds that beneficiaries who do not have significant pharmacy drug spending likely would see higher premiums without a corresponding offset in the form of lower cost-sharing for drugs.[3] These beneficiaries will see their *overall* costs increase as a result of this proposal.

CMS claims that it "expect[s] more than half of the non-low-income, non-employer group beneficiaries to see lower total costs."[4] However, this claim is also dubious. The analysis CMS uses to support this expectation is wrought with qualifiers and uncertainties. CMS states "a

[2] 87 Fed. Reg. at 1945.
[3] *Id*. ("[A] beneficiary who takes no medications will probably see a premium increase and no cost-sharing decreases….").
[4] *Id*.

beneficiary who takes several medications each month is *likely* to see cost-sharing decreases that are greater than the premium increase" but concedes that the actual amount of the cost-sharing decreases "will vary depending on an individual beneficiary's prescriptions, plan sponsor benefits, and contractual arrangements."[5] Notwithstanding the inherent complexity in reaching these conclusions, CMS provides little detail as to the variables it considered for its actual calculations. We ask that CMS revisit its conclusions and engage stakeholders in a deliberative process that would better inform the agency's calculations and decision making on this critical issue for patient affordability.

CMS's proposal is perplexing given the stability of, and even decrease in, premium rates over the last several years. In the proposed rule, CMS notes that "the average basic premium actually paid by beneficiaries has declined each year since 2017…."[6] Furthermore, "the average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 11.7 percent per year between 2010 and 2019…."[7] These developments have directly benefitted beneficiaries, as CMS itself admits that "beneficiaries focus more on premiums instead of cost sharing when choosing plans."[8] CMS attempts to discount this fact, noting that "[n]umerous research studies suggest that higher cost-sharing can impede beneficiary access to necessary medications…."[9] However, this point dismisses the express preferences of Part D beneficiaries, and overlooks the plethora of studies showing increased premiums arguably serve as an even larger impediment to drug access.[10]

Impact on Part D Plan Sponsors.

CMS's proposal will also lead to an increased burden on Part D plan sponsors. For one, cost-sharing is a vital piece of the Part D program, as it allows plans to direct a portion of costs based on individual care utilization. However, CMS's proposal undermines the impact of cost-sharing requirements and creates incentives for beneficiaries to utilize brand name drugs with high total costs, which would increase overall costs for the program.

Furthermore, CMS's proposal overlooks how difficult it will be for Part D plan sponsors to implement these changes. CMS states that the proposal "would, if implemented, provide a clearer reporting standard for Part D sponsors relative to the requirements in place today, which require Part D sponsors to assess which types of pharmacy payment adjustments fall under the reasonably determined exception."[11] CMS further states that it "expect[s] this increased clarity would reduce sponsor burden in terms of the resources necessary to ensure compliance."[12] However, fundamentally altering the pharmacy price concession framework will undoubtedly lead to increased administrative burden on Part D plan sponsors. For example, the timing of this proposal poses significant issues for Part D plan sponsors. Plan D plan sponsors are in the midst

[5] *Id*. (emphasis added).
[6] *Id*. at 1913.
[7] 87 Fed. Reg. at 1913.
[8] *Id*. at 1911.
[9] *Id*. at 1913.
[10] See, e.g., Senate RPC, Medicare Part D Prescription Drug Coverage (2019), https://www.rpc.senate.gov/policypapers/medicare-part-d-prescription-drug-coverage.
[11] 87 Fed. Reg. at 1916.
[12] *Id*.

of developing CY 2023 bids without clear direction on the future viability of post point-of-sale pharmacy price concessions. Should the agency finalize this proposal before the close of the CY 2023 bid cycle, Part D plan sponsors will have less than a few months to implement the finalized changes (a likely impossibility in the absence of a CMS-operated reinsurance demonstration). This would impose a significant administrative burden on Part D plan sponsors. For example, Part D plan sponsors will necessarily need to re-negotiate existing contracts and negotiate new contracts with pharmacies to ensure compliance with these changes. CMS did not account for this increased burden in the proposed rule. As such, CMS certainly underestimated the actual costs of this proposal to Part D plan sponsors.

CMS's proposal also overlooks the value of post point-of-sale price concessions as a key tool to developing pharmacy networks and lowering costs. Post point-of-sale price concessions allow Part D plan sponsors to develop preferred pharmacy networks, which lower overall costs for the program, and provide beneficiaries with lower cost-sharing and the ability to receive pharmacy services at their preferred location. Post point-of-sale price concessions also allow Part D plan sponsors to "align incentives towards improving practice patterns at the pharmacy," which increases the overall quality of pharmacy services for Part D beneficiaries.[13] CMS's proposal does not adequately consider how effectively removing this tool would impact Part D plan sponsors, and the Part D program generally.

Impact on the Part D Program.

CMS's proposal would also lead to an increased burden on the Federal Government and taxpayers. Specifically, CMS's proposal would result in a significant increase in government funding of plan premiums and low-income premium payments. As mentioned above, in part because of growing utilization of pharmacy price concessions, "the average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan *declined*, by an average of 11.7 percent per year, between 2010 and 2019…."[14] CMS's proposal would reverse these advancements. Again, the agency notes that the proposal would likely have a "significant impact on Government costs, which would increase overall due to the significant growth in Medicare's direct funding of plan premiums and low-income premium payments."[15] The agency estimates that, if the proposed rule is adopted, the Government will incur an additional $40 billion in Part D costs over 10 years.[16] Even with the consistent increase in prescription drug list prices over the last several years, the Part D program has made significant progress in mitigating increased costs. CMS should not finalize a proposal that would in practice remove one of the pillars of the program's success.

[13] https://www.pcmanet.org/wp-content/uploads/2017/07/Value-of-PDP-DIR_20170706.pdf.
[14] 87 Fed. Reg. at 1913. (emphasis added).
[15] *Id*. at 1945.
[16] "Additionally, there are a variety of transfers to and from the Federal Government (the Medicare Trust Fund and the United States Treasury) which in aggregate will increase dollar spending by $3.8 to $3.9 billion annually." *Id*. at 1952.

CMS's Proposal Does Not Address the Underlying Cause of High Drug Prices

AMCP appreciates the importance of reducing prescription drug spending for consumers and encouraging drug-pricing transparency within the health care system. However, this proposal would accomplish neither of these goals. Instead, CMS's proposal seeks to address the rising price of drugs by implementing changes that may lower cost-sharing for a limited number of Part D beneficiaries. However, this proposal does nothing to address the primary cause of the high cost of drugs being provided at the pharmacy: manufacturers' ability to set high list prices, and to increase prices year-over-year, for drugs that are often misaligned with clinical value. This is partly why CMS's own estimates indicate that this proposal will lead to higher premiums for a vast majority of Part D beneficiaries, and higher overall costs to the Federal government and taxpayers. CMS's emphasis on pharmacy price concessions to bring down drug costs for Part D beneficiaries is misplaced.

Moreover, a narrow approach that only addresses patient cost-sharing can potentially to serve as a diversion from the real cause of the high cost of prescription drugs. Furthermore, it is counterproductive. As mentioned elsewhere in this letter, requiring that all pharmacy price concessions be included in the negotiated price reduces existing Part D plan tools to negotiate lower prices.

CMS's Proposal Contravenes Recent Efforts to Promote Value-Based Arrangements in the Part D Program.

AMCP is also concerned that CMS's proposal would devalue existing pay-for-performance arrangements, and would contravene growing efforts to promote value-based arrangements in the Part D program. CMS only last year began collecting pharmacy performance measures used to determine whether a financial reward or penalty will be incurred after the point-of-sale.[17] In last year's final rule, the agency stated that collecting these measures would "enable CMS at a minimum to better understand how the measures are applied."[18] Notwithstanding, just a year later CMS is now moving forward with a policy that will practically thwart the entire concept of pay-for-performance measurements by restricting the ability of a Part D plan to utilize negative pharmacy DIR.

We note that the elimination or restriction of performance-based pharmacy arrangements is entirely out-of-line with current CMS payment policy. Pharmacy performance payments are in their essence value-based payments, and serve a vital role in advancing key quality measures that provide a net benefit to the Part D program.[19] With this proposal, CMS is threatening a key value-based tool. Rather than take the time to assess the data being collected, the agency is moving forward with a policy that hamstrings plans and will diminish the use of pharmacy performance measurement, and thus the use of value-based arrangements in the Part D program, all to the detriment of Part D beneficiaries.

[17] 86 Fed. Reg. 5864, 5955.
[18] *Id*.
[19] See Attachment A: Pharmacy Pay-for-Performance Principles for Consideration.

CMS's Proposal Violates the Non-Interference Clause of The Medicare Statute.

The Medicare Statute expressly prohibits CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and Part D plan sponsors."[20] In the proposed rule, CMS states that its proposal does not violate this non-interference clause because "it does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point-of-sale."[21] According to CMS, "[t]he requirement that pharmacy price concessions be passed through to the point-of-sale price only directly impacts the price that is used to determine beneficiary cost-sharing and the information that is populated and reported on the PDE record, but it does not dictate the amount that is ultimately paid to the pharmacy or the timing of payments and adjustments."[22] This assessment misunderstands the Part D plan sponsor and pharmacy negotiating process.

As mentioned above, pharmacy price concessions after the point-of-sale provide Part D plan sponsors negotiating leverage to incorporate certain quality metrics into their agreements with pharmacies, which lower overall costs to the program. Requiring that all pharmacy price concession be included in the negotiated price would significantly restrict, if not completely remove, the ability of Part D plans to negotiate pharmacy price concessions. Part D plan sponsors would largely lose the ability to negotiate downside incentives with pharmacies tied to performance or quality targets. Thus, to the extent CMS's proposal would require certain kinds of pharmacy rice concessions be passed through at the point-of-sale, it would clearly constitute interference in Part D plan sponsor negotiations.

Furthermore, CMS notes that its proposal would "not require the renegotiation of any contractual arrangements between a sponsor and its contracted entities."[23] However, as mentioned above, this claim has no basis in reality. Irrespective of when the proposal is finalized, Part D plan sponsors will inevitably need to re-negotiate existing contracts and negotiate new contracts with pharmacies to ensure compliance with these changes.

Conclusion

While AMCP remains a strong proponent of developing solutions to reduce patients' out-of-pocket costs, we are concerned that this proposal is not the right approach. Instead, we urge CMS to consider reforms in other regulations and laws that address the rising cost of prescription drugs without placing an increased burden on Part D beneficiaries, Part D plan sponsors, and the Part D program itself.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact Jennifer Mathieu at 703.286.2654 or jmathieu@amcp.org.

[20] 42 U.S.C. § 1395w-111(i)(1).
[21] 87 Fed. Reg. at 1915.
[22] *Id*.
[23] *Id*. at 1918.

Sincerely,

Susan A. Cantrell RPh, CAE
Chief Executive Officer

Attachment A

Pharmacy Pay-for-Performance Principles

Performance-Based Reimbursement and Direct and Indirect Remuneration (DIR) Fees

Executive Summary

Health care services provided by pharmacists are a vital part of comprehensive patient care. AMCP supports the use of payment arrangements for pharmacists that include performance-based metrics related to these health care services, on which some of the pharmacist's reimbursement is based. At the direction of its Board of Directors, the AMCP Public Policy and Professional Practice committees developed the following principles for pay-for-performance to promote the use of these arrangements that lead to improved patient outcomes:

1. Measures used in pharmacy pay-for-performance contracts must be fair, attainable, meaningful, and applicable to the pharmacy type being evaluated and the patient populations being served.

2. The Medicare Part D program should adopt a core set of standardized pharmacy performance measures based on consensus and input from pharmacy providers, pharmacy benefit managers, health plans, and other pharmacy stakeholders, while allowing plan sponsors the flexibility to utilize additional measures that are reported to CMS.

3. Pharmacy performance measures must recognize and respond to issues of health equity and socioeconomic disparities by benchmarking performance based on size, geography, and patient demographics.

4. A fair and meaningful performance-based contract will be transparent, with clear and concise provisions that are available and accessible to all participants in advance of any performance measurement period.

5. Prior to the development of a standard measure set, the specifications of the measures included in a contract must be unambiguously defined.

6. The organizational level at which metrics will be calculated and compared under a performance-based agreement must be precisely defined in the contract.

7. Participants in pharmacy performance-based contracts must agree upon a plan for collecting, integrating, and analyzing the data needed to meet contract requirements, including identifying who will be responsible for the analysis and who will pay for these tasks.

8. Adjusting pharmacy reimbursement systems to compensate pharmacies for the needed investments in data reporting infrastructure required to meet performance-based contract requirements should be considered.

9. Performance-based price concessions are an important and necessary component of pay-for-performance programs.

10. Fees calculated based on pharmacy performance on agreed upon measures should be based on known, fixed metrics.

11. Price concessions should never be structured as a "claw back," where payment for a prescription product may be owed from the pharmacy to the payer. This should not be confused with the appropriate use of financial withholds or recoupments in performance-based arrangements.

12. Performance-based reconciliation reporting should be completed no later than 90 days post-plan year to allow parties to meet contractual obligations.

13. Preferred pharmacy networks are a vital tool for lowering patient costs and improving quality and outcomes.

Principles approved by AMCP Board of Directors Oct. 18, 2021

Background

Pharmacists are well-suited for participation in interventions designed to increase value and promote quality in health care. Examples of how pharmacists are improving care delivery include providing Medication Therapy Management (MTM) comprehensive medication reviews for patients, dispensing and administrating vaccines to eligible Medicare Part B and D beneficiaries, structuring medication management and reporting for patients, reducing the use of high-risk medications in the senior population, actively engaging in medication adherence programs, promoting the use of cost-effective therapies for beneficiaries, and actively engaging in beneficiary satisfaction programs. As the opioid crisis continues to take its toll on countless Americans, pharmacists are also at the front lines in providing education, counseling, and strategic interventions to combat this epidemic.

Increasingly, performance-based reimbursement for pharmacies is showing value to the U.S. healthcare system. Pharmacies and the pharmacists whom they employ can help to improve the efficient delivery of high-quality care, including supporting efforts to decrease the use of low value services, through participation in performance-based programs.

The use of performance-based contracts and payments between payers and pharmacies has helped to control patient premiums, as evidenced by analyses of the Medicare Part D program from multiple independent government agency reports.[1,2] Plan sponsors pass through collected price concessions to help keep coverage affordable for patients.

In addition, performance-based contracts are used by payers to build high-quality pharmacy networks and drive better outcomes for patients. The development of quality pharmacy networks rewards high performing pharmacies that deliver improved care to patients while protecting patient access. Research has shown, for example, that the vast majority of Medicare Part D beneficiaries are enrolled in plans that use preferred pharmacy networks and, of these, eighty-five percent are satisfied with their plan.[3,4]

Because a pharmacy must be measured and meet performance targets to maximize reimbursement for these efforts, health plans utilize both *positive* and *negative* payments (known as pharmacy Direct and Indirect Remuneration fees, or pharmacy DIR) in order to recognize and pay for this performance. Because a pharmacy's quality performance is

[1] Centers for Medicare and Medicaid Services. Medicare Part D – Direct and indirect remuneration. January 19, 2017. Accessed November 17, 2021. https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir

[2] Centers for Medicare and Medicaid Services. Medicare Part D – Use of pharmacy benefit managers and efforts to manage drug expenditures and utilization. July 2019. Accessed November 17, 2021. https://www.gao.gov/assets/gao-19-498.pdf

[3] Drug Channels. New Part D enrollment data for 2020 preferred pharmacy networks: CVS holds steady, Walmart rebounds, and Walgreens tanks. February 4, 2020. Accessed November 17, 2021. https://www.drugchannels.net/2020/02/new-part-d-enrollment-data-for-2020.html.

[4] Hart Research Associates. A survey of seniors about their Medicare Part D preferred pharmacy network plan. May 2013. https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-05-20-13-hart-research-preferred-networks-pp.pdf.

uncertain until it is measured at the end of a contract performance period, pharmacy DIR linked to a pharmacy's contractual performance typically cannot be determined or even accurately estimated at the point of service.

This effort to improve and promote performance-based pharmacy reimbursement is separate and distinct from the broader conversation around "DIR fees" that could include manufacturer rebates to plans and PBMs, which represent a much larger percentage of overall DIR fees.

As performance-based reimbursement and the use of pharmacy DIR fees have increased, they have drawn scrutiny from some pharmacies and pharmacists. While studies have shown that pharmacy DIR decreases costs for both the consumer and the health care system,[5] detractors state that it can create situations in which pharmacies are losing money on processed claims. While performance-based reimbursement structures vary, they often include: (1) financial incentives, such as additional payment for the achievement of certain quality measures and benchmarks; (2) withholds, where the payer retains a portion of the payment and for which the pharmacy can receive all or a portion of those withheld monies depending on the extent to which the pharmacy meets agreed upon quality metrics or other contractual obligations; and/or (3) recoupments, where contract agreements based upon quality metrics are settled after a measurement period. Actions such as "claw backs," which require pharmacies to give back some portion of reimbursement sometimes months after the point of sale, are often cited by those opposed to pharmacy DIR fees, but should not be confused with the appropriate use of financial withholds or recoupments tied to contractual agreements in performance-based arrangements as previously described.

The use of pharmacy DIR and associated fees has drawn notice from law and policy makers, with the issue being included in the National Association of Insurance Commissioner's draft State PBM Licensure and Regulation Model Act, which would prohibit claw backs and potentially other forms of pharmacy DIR fees. Most recently, the Centers for Medicare & Medicaid Services (CMS) announced that it will begin collecting from Part D plans the pharmacy performance measures they use to evaluate pharmacy performance beginning January 1, 2022.[6] It is anticipated that this issue will continue to attract attention and action from federal and state lawmakers, particularly as the use of performance-based reimbursement continues to increase.

[5] Milliman. Value of direct and indirect remuneration (DIR): Impact on Medicare Part D prescription drug plan (PDP) program stakeholders. July 2017. Accessed November 17, 2021. https://www.pcmanet.org/wp-content/uploads/2017/07/Value-of-PDP-DIR_20170706.pdf

[6] Medicare and Medicaid programs: Contract year 2022 policy and technical changes to the Medicare Advantage program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Federal Register 86: 11 (January 19, 2021) p. 5864, 5957.

AMCP Pharmacy Pay-for-Performance Principles

Measurement

1. **Measures used in pharmacy pay-for-performance contracts must be fair, attainable, meaningful, and applicable to the pharmacy type being evaluated and the patient populations being served.**

2. **The Medicare Part D program should adopt a core set of standardized pharmacy performance measures based on consensus and input from pharmacy providers, pharmacy benefit managers, health plans, and other pharmacy stakeholders, while allowing plan sponsors the flexibility to utilize additional measures that are reported to CMS.**

3. **Pharmacy performance measures must recognize and respond to issues of health equity and socioeconomic disparities by benchmarking performance based on size, geography, and patient demographics.**

There are several types of measures that may be appropriate for inclusion in a standardized set of pharmacy performance measures – whether or not such measures are mandatory or recommended by a third-party, consensus-based organization. Common categories of measures, many of which are represented in existing CMS programs, that may be applicable to pharmacies include:

- Outcomes-based measures that track the health status of a patient resulting from care (for example, medication adherence, reduction in blood pressure, and improvement in hemoglobin A1c [HbA1c]);
- Structure-based measures that are relevant to an organization's capacity to provide healthcare (for example, the ratio of pharmacists to patients, and the use of electronic medical records);
- Process-based measures that evaluate the execution of specified steps (for example, time to fill, error rates, call center answering speed, and MTM completion rate for a comprehensive medication review);
- Patient-reported outcomes such as quality of life, symptom burden, health-related behavior, and patient experiences at the pharmacy, including satisfaction surveys;
- Cost/resource use measuring the frequency of units of defined services or resources (for example, cost per prescription, cost by category/class, generic substitution rate, and generic dispensing rate);

- Efficiency measures that evaluate the cost of care associated with a specific health outcome;[7,8] and
- Composite measures.

The use of pharmacy performance measures in managed care has been shown to positively impact patient care. For example, analysis has shown that the implementation of performance measures related to medication adherence have improved adherence to drugs for treating chronic conditions, such as statins, diabetes medications, and renin-angiotensin system (RAS) antagonists, resulting in significant avoided costs for the health system. In addition, the use of these measures was shown to narrow disparities in medication adherence for Black, Hispanic, and low-income beneficiaries.[9]

CMS has encouraged the industry to develop a set of pharmacy performance measures through a consensus-based process, which Medicare Part D sponsors could adopt to ensure standardization, transparency, and fairness.[10] To this end, beginning January 1, 2022, CMS will begin collecting pharmacy measures from Part D sponsors. CMS has received stakeholder comments in support of the development of a standardized set of performance measures, provided the performance measures are:

- **Fair**. The principle of "fairness" should apply to all pharmacy performance measures. This means incorporating fairness into (1) the development and selection of pharmacy performance measures, (2) the incorporation of measures into pharmacy contracts, (3) the relationship between performance measurement and payment, and (4) the transparency of the evaluation process.
- **Attainable.** In the past, critics of pharmacy performance measurement have levied legitimate criticisms against measures that are not reasonably capable of being achieved in all circumstances. This could be because, as noted below, the measure is not applicable to the particular pharmacy type but could also be the result of poor benchmarking or the failure to take into account different geographic or socioeconomic differences among pharmacies being measured. Pharmacy performance measures, particularly those tied to payment outcomes, should be attainable by each pharmacy being measured.
- **Meaningful**. While most measures in use today are developed based on consensus-based guidelines and are driven by proven quality outcomes, others may lack adequate

[7] Centers for Medicare and Medicaid Services. Quality measures: How they are developed, used & maintained. Accessed November 17, 2021. https://www.cms.gov/files/document/quality-measures-how-they-are-developed-used-maintained.pdf

[8] Pharmacy Quality Solutions. 2020 industry trend report in pharmacy quality. Accessed November 17, 2021. https://www.pharmacyquality.com/wp-content/uploads/2020/11/PQStrendreportinPharmacyQuality2020.pdf

[9] Centers for Medicare and Medicaid Services. 2021 national impact assessment of the Centers for Medicare and Medicaid Service (CMS) quality measures report. June 2021. Accessed November 17, 2021. https://www.cms.gov/files/document/2021-national-impact-assessment-report.pdf

[10] Medicare and Medicaid programs: Contract year 2022 policy and technical changes to the Medicare Advantage program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Federal Register 86: 11 (January 19, 2021) p. 5864, 5955.

evidence-based support for inclusion. Pharmacy measures should be meaningful in that they are supported by evidence demonstrating the measure is tied to better care and/or lower costs for consumers.
- **Applicable to the pharmacy type being evaluated and the patient populations being served**. As discussed below, given the diversity of pharmacy types and an increasing focus on specialization, not all pharmacy measures will necessarily apply to all pharmacy types. Pharmacies should only need to meet those measures which are applicable to their pharmacy type.

The development of a standard set of measures established by consensus with input from pharmacy providers, pharmacy benefit managers, health plans, and other stakeholders is important to the expansion of pharmacy pay-for-performance arrangements. Pharmacies tend to support standardized performance measures in large part because of the challenges associated with meeting inconsistent, duplicative, and often opaque criteria imposed by various health plans, an issue of particular importance for large multi-state pharmacies. A base standardized set of performance measures could reduce administrative friction for pharmacies and encourage pharmacies to invest in programs that are designed to enhance the quality of the services they provide based on objective and transparent criteria.

Some stakeholders are concerned that if health plans are required to adopt standardized performance measures, plans will have fewer tools to evaluate and shape pharmacy performance, which may lead plans to adopt narrower pharmacy networks, thereby limiting the options available to patients. Stakeholders should explore the potential effect of standardized measures on pharmacy networks and consider possible strategies to mitigate against potential reduced patient access.

Once standardized pharmacy performance measures have been developed and implemented, the uptake of such measures could be incorporated, through notice-and-comment rulemaking, into CMS's Star Ratings program to encourage Part D sponsors to adopt specific performance measures that CMS determines are most indicative of good performance and high-quality service.

In Medicare Part D, plans should be permitted to apply performance measures beyond a standardized set of measures established through a consensus-based process. Part D sponsors should report these performance measures along with the specifications and criteria used to evaluate performance to CMS. CMS needs to understand the additional measures that are being used by Part D plans to evaluate whether such measures are appropriate indicators of pharmacy performance that are based on achievable and proven criteria and whether the pharmacies are being evaluated fairly and consistently by plans.

As a threshold matter, only performance measures that are relevant to the type of pharmacy, such as retail, specialty, mail order, or long-term care pharmacies, and the

patient populations they serve should apply. For example, measures developed for retail pharmacies that serve a broad population are often a poor fit to evaluate specialty pharmacies that dispense medication and provide patient care services for specific health conditions, such as end-stage renal disease (ESRD), cystic fibrosis, or multiple sclerosis. To illustrate, a performance measurement tied to the adherence to hypertension medicines may be inappropriate to evaluate a specialty pharmacy that treats ESRD, since such medications are often placed on hold before and after dialysis treatment due to changes in the patient's blood pressure that occur during and after dialysis. If medically integrated specialty pharmacies are to be evaluated on medication adherence and patient outcomes, the performance measures should be relevant to the pharmacy's specialty type.

The development of consensus-based pharmacy performance measures implemented by third-party, independent, and consensus-based standard development organizations, such as the Pharmacy Quality Alliance (PQA), is vital. PQA has been working on developing consensus around separate standard sets of measures that would be appropriate for pharmacy performance models for community pharmacies and for specialty pharmacies.[11] URAC, an independent accrediting entity with experience in accrediting managed care and provider organizations, also has developed key performance measures for its accredited specialty pharmacies. Performance measures under development by URAC include call center performance, dispensing accuracy, distribution accuracy, prescription turn-around time, drug-drug interactions, and consumer experience.[12]

For retail pharmacies, PQA is developing measures regarding the concurrent use of opioids with benzodiazepines; statin use in persons with diabetes; adherence measures for diabetes medications, renin angiotensin system antagonists, and statins; completion rate for comprehensive medication review (CMR); polypharmacy (e.g., use of multiple anticholinergics in older adults); and proportion of days covered for antiretroviral therapies. PQA also plans to develop measures to assess pharmacy-level measures aligned with services provided by pharmacies (e.g., immunization status assessments, medication therapy problem resolution, HbA1c and blood pressure documentation) as well as outcome-based measures (e.g., blood pressure or HbA1c improvement). Through this effort, PQA is assessing the ability of pharmacists to attest and report on Healthcare Effectiveness Data and Information Set (HEDIS) clinical measures to provide greater alignment among payers and pharmacies as well as health plan quality programs. For specialty pharmacies, PQA is developing measures regarding the completion of chronic

[11] Pharmacy Quality Alliance. PQA's proposed standard measure set for pharmacy accountability in value-based models. Accessed November 17, 2021. https://www.pqaalliance.org/assets/docs/PQA_Proposed_Standard_Measure_Set_for_Pharmacy_Accountability.pdf

[12] URAC, 2020 specialty pharmacy performance measurement. January 2021. Accessed November 17, 2021. https://mk0uracwebqjdtrmplxc.kinstacdn.com/wp-content/uploads/2021/02/URAC_Specialty-Pharmacy_Aggregate-Summary-Report_2020_FINAL.pdf

hepatitis C treatment as well as adherence to multiple sclerosis therapies, antiretrovirals, and rheumatoid arthritis treatments. Service and outcome-based measures planned for specialty pharmacies include specialty pharmacy turnaround time and drug-drug interaction consultation.[11]

In addition to the type of performance measurement, the organizational level at which metrics are calculated may have a great influence on the assessment of pharmacies. Sponsors may apply performance measures at the individual pharmacy level, as well as to an entire pharmacy chain. The performance calculation should be designed in a way not to create perverse incentives for, or disadvantage, an individual pharmacy based on whether it belongs to a chain of pharmacies or if it is a standalone pharmacy. Some plans, for example, assess a contracted organization's performance based on the performance of each individually attributed pharmacy within the network relative to the overall total organization performance. Under such a structure, an individual pharmacy could become the benchmark against which the entire organization is evaluated and may incentivize the organization to prioritize only certain pharmacies within its chain. In the Part D program, CMS also should consider whether plans should be required to evaluate performance measures at a Medicare region level in order to account for variables that could be attributed to a particular geographical area.

Lastly, issues of health equity and socioeconomic disparities can play a role in pharmacy performance measurement. Given that any given pharmacy may be located in a geographic region or area with vastly different health indicators, head-to-head measurement of unlike population areas may disadvantage a pharmacy that serves, for example, a disproportionate share of individuals living below the federal poverty level. Benchmarking against such differences in order to produce a fair and equitable accounting of actual performance will be critical in creating a just pharmacy performance measurement system.

Transparency

4. **A fair and meaningful performance-based contract will be transparent, with clear and concise provisions that are available and accessible to all participants in advance of any performance measurement period.**

5. **Prior to the development of a standard measure set, the specifications of the measures included in a contract must be unambiguously defined.**

6. **The organizational level at which metrics will be calculated and compared under a performance-based agreement must be precisely defined in the contract.**

Participants should have full details about the measures being used in the contract to measure performance. Prior to the development of standardized measures, the specifications of the measures included in a contract for performance-based reimbursement should be precisely defined so all participants have reasonable knowledge of what patient populations or drugs are included. For example, for cost/resource use measures such as dispensing rates, terms such as "generic," "brand," and "specialty" drug should be unambiguously defined. For outcomes-based and patient-reported measures, the patient population included in the numerator and denominator for the measure calculation should be explicit.

The organizational level at which metrics will be calculated under a performance-based agreement should also be transparent. Contracts may apply performance measures at the individual pharmacy level and compare against all other pharmacies participating in that network or may score and compare pharmacies across an entire pharmacy chain. There are numerous implications for participating pharmacies based on the comparison group, such as the level of risk exposure or the ability to implement changes to impact performance. Transparency about the comparison level is important to improve pharmacy performance and ease administrative friction.

Data sharing

7. **Participants in pharmacy performance-based contracts must agree upon a plan for collecting, integrating, and analyzing the data needed to meet contract requirements, including identifying who will be responsible for the analysis and who will pay for these tasks.**

8. **Adjusting pharmacy reimbursement systems to compensate pharmacies for the needed investments in data reporting infrastructure required to meet performance-based contract requirements should be considered.**

Some performance measures rely on the use of clinical pharmacy data or pharmacy claims data to identify dispensed medications. Tools exist to provide pharmacies with ready access to online resources to view, track, and manage performance on agreed-upon measures, connect them to resources to help them improve, and help them estimate expected bonuses or concessions. For example, Pharmacy Quality Solutions, Inc. (PQS) has developed the Electronic Quality Improvement Platform for Plans & Pharmacies (EQuIPP®), which provides performance data to plans and pharmacies to help guide medication-related quality improvement efforts. EQuIPP® analyzes data from prescription claims and member eligibility details obtained from health plans and pharmacy benefit managers, so claims that are not submitted to a patient's insurance provider are not captured or analyzed. EQuIPP® provides reporting on medication use quality measures such as medication adherence, gaps in care, and patient safety. The platform indicates the

adherence rates for diabetes, blood pressure, and cholesterol medications and identifies outlier patients who require more assistance with medication adherence.

Depending on what is being evaluated, the performance assessment may require data that are not available in pharmacy claims data or may need to integrate data from other data sources, such as electronic health records, hospital claims data, pharmacy system data, lab data, patient-reported outcomes data, and other clinical sources. As more and different data sources are needed to support complex performance metrics, payers and pharmacies must agree upon a plan for collecting, integrating, and analyzing the data, including identifying who will be responsible for the analysis and who will pay for these tasks.

Additionally, performance-based measures increasingly depend on the ability to access and accurately assess electronic health records and clinical data obtained from a variety of sources, so challenges with electronic health record interoperability and data standardization will need to continue to be addressed. Common issues with data capture, such as missing patient identifiers or patient records with multiple specialty pharmacy identification codes and longitudinal records, exacerbate these interoperability challenges.

All of these elements add a layer of administrative complexity to performance-based contracts above what is found in volume-based measures. Without a standardized set of metrics and reporting mechanisms, pharmacies that are being evaluated on multiple performance metrics by different payers face cumbersome reporting responsibilities. Implementation of pharmacy performance measures may require pharmacies to make substantial investments in data reporting infrastructure and potentially modify or develop new services. Reimbursement systems may need to be adjusted to compensate pharmacies for these investments.

Incentives and Performance-based Price Concessions

9. **Performance-based price concessions are an important and necessary component of pay-for-performance programs.**

10. **Fees calculated based on pharmacy performance on agreed upon measures should be based on known, fixed metrics.**

11. **Price concessions should never be structured as a "claw back," where payment for a prescription product may be owed from the pharmacy to the payer. This should not be confused with the appropriate use of financial withholds or recoupments in performance-based arrangements.**

12. Performance-based payment reconciliation should be completed no later than 90 days post-plan year to allow parties to meet contractual obligations.

Performance-based pharmacy contracts are a vital tool in the drive to move our health care system to one of value instead of volume. Performance-based price concessions are an important and necessary component of pay-for-performance programs, helping to create high-quality pharmacy networks, improve patient outcomes, and lower premiums.

Health plan sponsors and pharmacy benefit managers (PBMs) enter into performance-based contracts with pharmacies in an effort to create high-quality networks and use financial arrangements – often referred to as pharmacy direct and indirect remuneration (DIR) fees – to either pay incentive bonuses to or collect price concessions from network pharmacies based on their performance. Incentive payments and price concessions are critical tools for improving value and quality while lowering costs.

Payment incentives and price concessions are often structured as either a flat fee or a fee based on a percentage of ingredient cost. While percentage-based fees can drive value, they can also have a disproportionate impact on higher-cost drugs and performance-based contracts should be clear on which type of fee applies to each type of drug. In addition, performance-based fees calculated based on pharmacy performance on agreed upon measures should be based on fixed metrics, such as a minimum number of patients who are enrollees of the plan sponsor participant.

AMCP opposes the use of "claw backs," whereby payment is owed from a pharmacy to a plan sponsor or PBM, often months after the sale of a drug and not based on pharmacy performance. Use of payment withholds, where the payer retains a portion of the payment and the pharmacy can receive all or a portion of those withheld monies depending on the extent to which the pharmacy meets agreed upon quality metrics or other contractual obligations, recoupments based upon actual pharmacy performance on contractual quality and performance measures reconciled after the performance period, and/or bonus payment incentives are appropriate performance-based structures.

In a performance-based contract, pharmacies are paid a contractual amount for the ingredient cost and dispensing fee at the point of service and performance-based reimbursement adjustments – both bonus payments and price concessions – are retrospectively reconciled based on the pharmacy's actual performance on agreed upon value-based measures and benchmarks. Payment reconciliation should occur no later than 90 days after the end of the plan year.

Preferred pharmacy networks

13. Preferred pharmacy networks are a vital tool for lowering patient costs and improving quality and outcomes.

Preferred pharmacy networks include pharmacies participating in a plan's network that contract at a lower reimbursement rate in exchange for increased volume, and at which plan enrollees pay lower costs at the point of sale due to reduced cost sharing. Other non-preferred pharmacies are allowed to continue participating in the network, allowing for robust patient access. Additional savings achieved through the use of preferred pharmacy networks are used by health plans to stabilize premiums. Preferred pharmacy networks have been shown to reduce overall costs for enrollees beyond just lower cost sharing at the point of sale as well as to reduce costs for the health system in general. [13]

In addition, preferred pharmacy networks are increasingly being leveraged to improve outcomes and for quality measurement. Preferred pharmacy networks with performance-based arrangements often include quality measures that trigger pharmacist participation in patient health care management and that may improve medication utilization and adherence by ensuring that patients receive medications at more affordable costs. Furthermore, preferred pharmacy networks may incorporate pharmacist patient care services and interventions into performance-based arrangements that help improve quality care while providing incentives to pharmacies that achieve better health outcomes.

[13] Kaczmarek S J, Sheldon A, Liner D M. The impact of preferred pharmacy networks on federal Medicare Part D costs, 2014-2023. Milliman. October 2013. Accessed November 29, 2021. https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-01-23-15-milliman-preferred-pharmacy-networks.pdf