

INCREASING COMPETITION AND CHOICE

An Evaluation of Proposed Medicare Regulations and Their Impact on Pharmaceutical Access and Care

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EXECUTIVE SUMMARY:

For much of the past decade, Congress, regulators, and industry lobbyists have played a game of cat and mouse when it comes to how the Medicare prescription drug program (“Part D”) is administered. With the Centers for Medicare & Medicaid Services (“CMS”) once again considering new rules around Medicare prescription drug coverage plans; this white paper addresses the following:

- By passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Congress fully intended to provide beneficiaries broad pharmacy access through an any willing pharmacy (“AWP”) provision that permits willing pharmacies to participate in networks. The goal was to ensure that beneficiaries had access to a broad range of pharmacies and enhanced choice, competition, and service.
- Restricted pharmacy networks limit access, increase costs to beneficiaries, and diminish the level of service. These services are even more critical as pharmacies perform an increasingly critical role in delivering healthcare and reducing costs as envisioned by the Affordable Care Act (“ACA”).
- The proposed Medicare regulations restore Congress’ original intent and will enhance the delivery of services to beneficiaries without increasing costs.
- The critics of the reforms have manufactured several studies that are misguided and cannot rebut the data that CMS relies on. Rather, the facts indicate that expansion of services through AWP is likely to reap greater benefits for Part D beneficiaries.

The CMS Proposed Rule for fiscal year 2015 expands competition, access, and quality of care for beneficiaries. This paper focuses on one provision that permits any willing provider to participate in a prescription drug plan’s network. In enacting Part D, Congress provided an AWP provision to assure beneficiaries broad access to pharmacy services. CMS permitted more

restricted networks in a 2006 clarification. After several years of scrutiny of these restricted networks, CMS concluded reform was necessary to preserve access and assure cost-savings. CMS provides in its proposed regulations that all pharmacies that can meet a plan's contractual terms and conditions are allowed to participate in the plan's network.

The proposed changes will have a profoundly positive effect on millions of beneficiaries. These reforms could not be timelier. Pharmacists will play an increasingly crucial role in the delivery of healthcare services under the ACA and through the expansion of pharmaceutical treatments including medication therapy management. Community and specialty pharmacists will be increasingly utilized for their knowledge and skills to improve drug adherence, provide counseling, prevent re-hospitalization, and manage chronic conditions. The Proposed Rule will enhance the delivery of these valuable services by pharmacies.

Medicare Part D relies heavily on the use of for profit Pharmacy Benefit Managers ("PBMs"). CMS has recognized problems with the lack of transparency and conflicts of interest in the PBM marketplace and how these problems may lead to increased costs. Restricted networks, especially those that limit Medicare beneficiaries to PBM-owned mail order, can increase costs and diminish service.

The arguments of the opponents of the proposed regulations lack merit. They suggest that regulatory reform will increase cost. However, after careful analysis, CMS concluded otherwise. Studies by CMS and others indicate that there are little to no cost-savings associated with preferred pharmacy networks. Moreover, the PBM sponsored studies are flawed. Furthermore, properly using AWP will increase access and choice and lead to better services for Medicare beneficiaries.

Introduction

On January 6, 2014, CMS proposed significant changes to Medicare Part D and Medicare Advantage ("MA") (referred to throughout this paper as the "Proposed Rule").¹ There are numerous proposed changes that, according to CMS, will increase consumer choice and competition among plans, improve payment accuracy and the auditing process, and require new criteria for drug classification.² CMS projects that savings from the Proposed Rule will total \$1.3 billion over the next five fiscal years.³ For the purposes of this paper, we will be primarily discussing changes to Medicare's preferred pharmacy networks.

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The Proposed Rule's interpretation of the AWP provision is based on a lengthy and thoughtful review by CMS about the impact of restricted networks. CMS hoped that the use of restricted networks would lower costs and improve service. However, after several years of carefully reviewing the claims data, CMS found that restricted networks did not consistently lower costs. Crucially, CMS also found that restricted networks can harm beneficiaries through reduced service, less information, limiting choice and convenience.

Not surprisingly major consumer groups have come out in support of the revised AWP regulations.⁴ These reforms will increase access for beneficiaries and will not lead to increased costs. The revised AWP regulations will also improve access for beneficiaries in rural and other underserved areas. Consumers value the relationship they have with their community pharmacist, who is often the

most accessible, convenient and trusted healthcare professional available to them, particularly in these underserved areas.

The PBM industry has suggested that the proposed regulations “micromanage” pharmacy and PBM relations, which will lead to increased costs and may “undermine the stability of the program.”⁵ Opponents of the regulations argue that allowing AWP to participate in a preferred network will “eliminate the economic incentive to join.”⁶ However, as we describe in more detail, CMS found that these effects are unlikely. Moreover, the Proposed Rule, especially the AWP provisions, is a response to complaints by consumers, the need to enhance service and transparency and the failure of preferred networks to consistently deliver lower costs. While some allege that these “limited networks” promoted quality and reduced costs, numerous studies demonstrate that the networks do not lower costs and are primarily used to drive consumers to large retail chains and mail order pharmacies.

The revised AWP regulations will also improve access for beneficiaries in rural and other underserved areas.

The purpose of this paper is to examine legislative purpose, actual “costs,” and impact of the proposed changes to Part D preferred networks. We first discuss the history of Medicare Part D and preferred pharmacy networks. We explain the Proposed Rule and note the specific changes to AWP and preferred networks. The paper explains why the changes are needed because of the new role of pharmacies in delivering healthcare in the era of the ACA. We also discuss transparency problems in the Part D market, including conflicts of interest that may lead to increase costs. We criticize the arguments of opponents of the proposed regulations and show the flaws of their studies that suggest the Proposed Rule will increase costs. Finally, we provide some concluding thoughts on the proposed

regulations and their potential impact on beneficiaries and payors.

A. History of Medicare Part D and Preferred Networks

The 1965 Medicare law was passed without a drug plan for seniors. Scholars believe that this exclusion was “more an oversight than an intentional omission.”⁷ Therefore, in 2003, Congress finally passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), which granted Medicare recipients the ability to pick a private insurance plan in order to cover prescription drugs.⁸ Currently, 37.4 million Medicare beneficiaries receive prescription medications through Part D.⁹ Congress wanted to ensure certain protections to beneficiaries, including allowing them to choose their provider. These protections are especially important to Medicare beneficiaries, the disabled and elderly who need the ongoing relationship with a community pharmacist, and place a great value on service and access. The MMA fulfilled these objectives by allowing the participation of any willing pharmacy, meaning that a “prescription drug plan shall permit the[ir] participation...” as long as the pharmacy “meets the terms and conditions under the plan.”¹⁰ Congress’ use of an AWP provision followed the lead of over twenty states that maintain a number of different any willing provider/pharmacy laws¹¹ and ensured both competition between pharmacies and access for all beneficiaries.

In 2006, CMS deviated from that Congressional intent and promulgated regulations that permitted more limited networks. Known as the Preferred Pharmacy Rule (“PPR”), CMS allowed prescription drug programs to charge different copayments based on which pharmacy the beneficiary selected.¹² Starting in 2011, PBMs and plans began forming preferred networks that eliminated many local and independent pharmacies, and instead relied on limited networks comprised of large chains or retail pharmacies.¹³ In their first year of the PPR’s operation, preferred networks drove 6.3 million Medicare Part D

enrollees from a local pharmacy to a “preferred” pharmacy.¹⁴ In 2014, 72 percent of all prescription drug plans (“PDP”) will utilize a preferred pharmacy network.¹⁵

Often overlooked is the fact that preferred networks frequently do not even solicit bids from most pharmacies. Preferred networks typically solicit bids from one or two mega-retailers, or often limit the network to the PBM’s mail order operation. Community pharmacies are not even given the opportunity to bid to participate in the preferred network.

Consumers, pharmacies, and legislators objected to these restricted networks. Thirty Congressmen spoke out against CMS’ incorrect interpretation of the MMA, usage of PPR, and the application of AWP. Lawmakers noted that the purpose of the MMA was to promote access and choice for beneficiaries. Congressional members noted that the PPR had caused a “decrease in access to quality care” in contrast to the very purpose of the law.¹⁶ By closing off access to pharmacies, these limited networks have had an even more profound impact on rural areas or other underserved areas where the number of available pharmacies is limited.¹⁷

B. CMS’s Proposed Reforms for AWP

At the beginning of 2014, CMS acknowledged its mistake in failing to abide with Congressional intent and permitting restricted networks. After receiving complaints from Congress, consumer advocacy groups, and pharmacies, CMS issued a Proposed Rule that provides that PDPs should include “any pharmacy that can meet the terms and conditions... in the sponsor’s preferred network”¹⁸ – essentially the exact same language as the original AWP mandate in the 2003 Act establishing Medicare Part D. In support of the Proposed Rule, CMS noted their own studies as well as others that showed prices were not reduced when a PDP used a preferred pharmacy network.¹⁹ Moreover, CMS specifically noted that non-preferred community pharmacies were excluded regardless of their ability to provide cost-savings:

*Consistent savings are not seen uniformly. In some cases, pharmacies extending high discounts are the ones that have been excluded from limiting networks offering preferred cost sharing, while some pharmacies within the limited networks offer effectively no discounts compared to the rest of the network.*²⁰

Excluding lower cost, more efficient pharmacies is simply inconsistent with Congressional intent or sound policy.

As part of the proposed regulations, CMS changes the PPR requiring a PDP to create a pharmacy network through “preferred cost sharing.”²¹ CMS proposes that PDPs offer one contract with standard terms and conditions which “list all combinations of cost sharing and negotiated prices” that will allow AWP “the opportunity to compete for preferred cost sharing *if* the pharmacy can offer the requisite level of negotiated prices.”²² Furthermore, to ensure cost-savings, CMS has stated that a preferred cost-sharing tier in a network must provide “consistently lower negotiated prices than the same drugs when obtained in the rest of the pharmacy network.”²³ Pharmacies will now have a choice of which “tier” they can participate within for a given PDP.

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These regulatory changes are strongly supported by senior groups such as the Medicare Rights Center:

[P]lans distort market behavior by lowering beneficiary cost sharing where the full cost of the drug is the same or higher than it would be at a non-preferred pharmacy. Instead of harnessing the power of consumer choice to lower costs overall by aligning lower cost-sharing with

*lower total cost, the plans divide the interests of individual beneficiaries and the Medicare program in order to increase the profits of related-entity mail order pharmacies. This results in higher Medicare spending overall. Like CMS, we find these facts disturbing, and we agree that these practices reflect inappropriate cost shifting to CMS and taxpayers. As such, we strongly endorse CMS's proposal to revisit the current preferred pharmacy network structure in favor of a minimum savings standard under a preferred cost sharing system.*²⁴

In effect, CMS notes that these proposed regulations will not only provide actual cost-savings, but will also “level the playing field” for local, independent pharmacies allowing them to participate in any level of preferred cost sharing offered by the PDP.²⁵ CMS also anticipates that changing the interpretation of AWP will have the following positive effects:

- Increased access for beneficiaries to preferred level cost sharing with any willing pharmacy able to agree to the terms and conditions that include preferred cost sharing.
- Improved opportunity for competition among pharmacies contracting with the sponsor to charge no more than the ceiling price stated in the contract for preferred cost sharing, reducing costs charged to the program.
- Improved clarity for beneficiaries surrounding cost sharing levels available at retail and mail order pharmacies.²⁶

These restorations by CMS are aligned with Congress's initial intent when passing the MMA. No longer will a pharmacy be denied access to a preferred network at the PDP's whim. Instead, competition, quality, and price will dictate the level of cost sharing a pharmacy will receive. CMS has found that more efficient, lower-cost pharmacies have been excluded from preferred networks. Under the revised regulations, competition will determine the optimal level of access. Pharmacies will be able to choose any

offered level by the PDP. PDPs and some PBMs believe that competition and better pricing within Part D can only be achieved when plan sponsors are able to pick and choose their participants and dictate terms; in other words, allowing the PBMs to maintain monopsonistic control over access to the Part D program. However, the MMA was passed with the AWP provision with the intention of providing millions of beneficiaries' access to low-cost pharmaceuticals through competition.

C. AWP Reform is Necessary to Improve Pharmacy Services in a Post-Affordable Care Act World

The changing role of pharmacists throughout the United States is often missed in the conversation of Part D reform. The view that pharmacy access is simply a matter of dispensing drugs is misguided and ignores the increasingly critical role of pharmacies in improving healthcare and reducing overall healthcare costs. Limited networks, which almost always rely on mega-retailers and mail order, often do not and cannot provide the same level of services as community and specialty pharmacists. Community pharmacists are the most accessible health care professional and provide a wide range of healthcare counseling. Because of the close relationship with a community pharmacist there is greater drug adherence and better healthcare outcomes. For the disabled who take specialty medications the role of the community pharmacist is vital, because they educate the patient on drug administration, monitor health care and provide counseling. None of these services can be adequately provided in a restricted network, especially one that limits consumers to mail order.

Moreover, the changing nature of the American healthcare system requires these pharmacists to take on greater responsibilities. Many of these obligations stem from implementation of the ACA. The ACA was created not only to increase enrollment in a variety of private and public health insurance pools, but also to fundamentally change the way beneficiaries and providers view healthcare. The

law serves to move providers away from the siloed, fee-for-service healthcare model into a patient-centered system that encourages collaboration and rewards providers for quality of care.²⁷

As part of the new approach to healthcare, practitioners will be asked to contribute in new, meaningful ways to provide quality of care for all beneficiaries. In particular, pharmacists will play an important role in ensuring both care for short-term health risks and management of long-term illnesses. For example, the increased usage of the accountable care organization (“ACO”) model, in which providers collaborate together throughout an episode of care, will often require the use of pharmacists to ensure the patient returns to full health.²⁸ In ACOs, pharmacists could be expected to ensure that patients follow specific medication regimens, avoid adverse events, prevent hospital readmissions, and help patients manage chronic conditions such as diabetes.²⁹ Pharmacists who can utilize these skills in an ACO model will ensure lower costs throughout the system while also safeguarding a higher quality of care.

Improving delivery of specialty drugs. Reforming AWP will improve the delivery of specialty drugs by improving adherence and providing a greater level of services. Specialty drugs are used to treat complex and chronic conditions including Hepatitis, various forms of cancer, transplants, and HIV/AIDS. Specialty pharmacists are effectively part of the healthcare delivery team, provide intensive counseling, and regularly monitor patients to ensure effective adherence.³⁰ By 2018, specialty drug costs are expected to surpass the total spent on all traditional drugs combined.³¹ There is an increasing need for specialty pharmacists to manage the ever-growing costs in the specialty drug realm. PDPs often place specialty drugs on a “non-preferred brand tier” which can cost payors and beneficiaries thousands of dollars a month in specialty drugs.³² With rising usage and higher costs, it is essential for plans to utilize the services of community-based specialty pharmacists who focus on disease management

techniques, waste reduction, and medication adherence which ensure that a beneficiary receives proper care while also lowering overall cost when compared to a standard retail pharmacy.³³

Improving drug adherence. Reforming AWP will improve overall drug adherence, by enabling community pharmacies to fully participate in networks. Regulators and members of the healthcare industry have long been aware of the issues associated with improper drug adherence. In 2009, the New England Health Institute (“NEHI”) estimated that a lack of medication adherence costs the country roughly \$290 billion per year due to excess hospitalizations and healthcare complications.³⁴ Along with higher costs, poor drug adherence leads to thousands of premature deaths.³⁵ To address this growing issue, the MMA specifies the usage of medication therapy management (“MTM”) services to encourage greater utilization of MTM. Defined by 11 national pharmacy organizations in 2004, MTM services are designed to optimize therapeutic outcomes while also reducing the risk of adverse events.³⁶ The MTM definition was finalized under Section 432.153(d) of the MMA, which required that Part D sponsors must establish the availability of MTM services to their beneficiaries.

The Reforms will enhance the delivery of MTM. MTM services have been effective at raising quality of care for those patients who suffer from chronic conditions. According to the Center for Medicare & Medicaid Innovation (“CMMI”), not only do MTM programs effectively target high risk patients with complex drug therapies, but also MTM provides patients with conditions including diabetes, congestive heart failure, and chronic obstructive pulmonary disease better health outcomes than those patients with identical conditions that did not receive MTM services.³⁷ Although some mail order pharmacies offer MTM, it is delivered far more effectively in a retail or community pharmacy setting. A 2012 Health Affairs study found that patients receiving integrated intervention for their treatment of diabetes were 2.1 percent more adherent

than patients that did not receive MTM.³⁸ The benefits were “greater in patient[s] who received counseling in the retail setting... [which] suggest that the in-person interaction between retail pharmacists and patient was a contributing factor to improved behavior.”³⁹

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Along with better quality of care, MTM has also led to a decrease in healthcare costs. In 2012, the Congressional Budget Office (“CBO”) noted that programs and services, such as MTM, that properly manage prescription drug benefits could produce medical savings to the entire Medicare program.⁴⁰ Recent studies on MTM have proven the CBO’s assertions correct. In the CMMI report, MTM services, specifically those that utilized comprehensive medical review, reduced Medicare Part D beneficiaries suffering from diabetes and congestive heart failure overall hospitalization costs by \$400 to \$525.⁴¹ CMMI also noted the strong potential for future savings to the Medicare plan through MTM. According to CMMI, an effective Part D plan was able to use MTM to save Medicare Part D \$45 per diabetes patient.⁴²

Given the importance of MTM, the Proposed Rule expands the use of MTM services. Originally, CMS had an initial goal of 25 percent of Part D beneficiaries being eligible for MTM; however, CMS has noted that they continue to see restrictive criteria from plan sponsors such as narrowing the list of chronic conditions.⁴³ In turn, this has led to unsatisfactory MTM enrollment. To expand these effective services and increase cost-savings, CMS has lowered the

criteria for participation in MTM: targeting (1) patients having two chronic diseases, (2) take only two prescription medications, (3) and have a total drug expenditure of \$620.⁴⁴ By lowering the criteria, CMS estimated that important, cost-effective MTM services will be available to 55 percent of Part D beneficiaries.⁴⁵ Given the expanding growth of the program and the cost-savings and improved quality of care, it will be of great importance to provide proper access to any willing pharmacies that offer MTM services.

The future of healthcare will increasingly rely on the services of knowledgeable and well-trained pharmacists. With the changes to the system through the ACA and the implementation of payment models such as ACOs, these healthcare providers will have greater responsibility in patient care and controlling costs for payors. Furthermore, pharmacists will have a greater role under an expanded MTM program. In the long run, PDPs and PBMs that limit access to their services through preferred networks to mail order and/or mega-retailers will only raise costs to payors and the Medicare system. Therefore, it is essential that Part D beneficiaries continue to have access to their local and specialty pharmacists.

D. The Need for Reform: Conflicts of Interest and the Lack of Transparency

Opponents of increasing access and competition through AWP argue that limiting the number of pharmacies within a given network will guarantee cost-savings for the payors, beneficiaries, and ultimately the Part D program. However, proponents of limited networks, particularly PBMs, have other vested interests in limiting the size, scope, and transparency of their networks. As CMS observes:

*We note that most PBMs own their mail order pharmacies, and we believe their business strategy is to move as much volume as possible to these related-party pharmacies to maximize profits from their ability to buy low and sell as high as the market will bear.*⁴⁶

PBMs are the middlemen of the prescription drug delivery system. As third party administrators, PBMs process drug claims for both health plans and pharmacies, which can allow these payors to limit the administrative burden of processing claims and give pharmacy staff instant access to a beneficiary's plan information.

PBMs have experienced a period of growth that has changed the industry dramatically. PBMs currently serve 221.2 million individuals and 64 percent of individuals receive services from the two PBM giants, Express Scripts and CVS Caremark.⁴⁷ With total PBM revenues at over \$250 billion,⁴⁸ and profits skyrocketing from \$900 million to \$10 billion over the last decade, Medicare administrators, payors, and beneficiaries have raised concerns.⁴⁹

Addressing Conflicts of Interest. PBMs were originally designed to be pure middlemen without any other interest but developing networks. The major PBMs have developed their own pharmacy operations by owning mail order operations⁵⁰ or retail stores⁵¹ thus creating a significant conflict of interest. Often, PBMs may favor drugs in which they receive a greater margin because they are dispensed by mail order, even though the plan sponsor or consumer may pay more. PBMs often seek to drive consumers to more highly profitable mail order distribution and away from independent pharmacies that offer the level of quality, advice and personal service consumers prefer. And consumers often suffer as a result.⁵² Some PBMs have also expanded to include their own Part D PDP.⁵³ Driving Part D beneficiaries to mail order operations and restricted networks deprives them of choice, increases chances of adverse medical reactions, and deprives them of valuable community pharmacy services. These conflicts of interest have been the primary reason community pharmacies have been shut out of preferred networks. As CMS observed:

We received more than 200 comments in response to our discussion on this topic... most of these comments were from pharmacies concerned about barriers to entry for participation in preferred networks, and many of these

*argued that such limited networks violate the statutory intent of the network access provision.*⁵⁴

Given these conflicts, it becomes increasingly evident why particular PBMs would restrict access and favor their own pharmacies. PBMs are beholden to their shareholders as private companies and must ensure high profits and good returns on investment. With ever-increasing consolidation within the PBM industry⁵⁵ and the use of expanded PBM services, some PBMs are clearly compromised by their participation as both an intermediary and competitor to pharmacies. It is for this reason that CMS proposes to balance the conflicted interests of PBMs. By reducing barriers and ensuring AWP can participate, PBMs will have to openly compete for beneficiaries instead of forcing patients into their company-owned pharmacy.

Addressing the lack of transparency. PBMs have also faced heightened scrutiny for a lack of transparency in the plan's "negotiated prices."⁵⁶ Negotiated prices are "the payment amounts pharmacies receive from plans for covered Part D drugs dispensed to plan enrollees."⁵⁷ The CMS payment to plans are based on these negotiated prices.⁵⁸ Negotiated prices are determined by a number of factors and can be reduced by the inclusion of "price concessions."⁵⁹ CMS intended the price concessions would not come from pharmacies, but would come instead in the form of rebates offered by drug manufacturers.⁶⁰ However, due to ambiguous language, PBMs use price concessions such as "network access fees" and "administrative fees" to increase profits.⁶¹ Pharmacies receive nothing of value for paying these fees other than "the ability to participate in the Part D network."⁶² Since these fees *are not* reflected in the negotiated price, negotiated prices can increase and shift costs "to the beneficiary, the government and taxpayer."⁶³

Lack of pricing transparency to increase revenues at the expense of industry participants is not a new tactic of the PBMs. Even a federal court has noted how problematic lack of transparency by PBMs is:

This lack of transparency also has a tendency to undermine a benefits provider's ability to determine which is the best among competing proposals from PBMs. For example, if a benefits provider had proposals from three different PBMs for pharmacy benefits management services, each guaranteeing a particular dollar amount of rebate per prescription, the PBM proposal offering the highest rebate for each prescription filled could actually be the worst proposal as far as net savings are concerned, because that PBM might have a deal with the manufacturer that gives it an incentive to sell, or restrict its formulary, to the most expensive drugs. In other words, although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs.⁶⁴

To address this problem, CMS proposes making PBM fees more transparent by revising the definition of price concessions. Now, "all pharmacy price concessions must be reflected in the negotiated price."⁶⁵ Noting these fees are used to offset PBM operating costs, CMS now requires that if these fees are deducted from a pharmacy's payment, the costs are now price concessions and will be treated as such under Part D cost reporting.⁶⁶ Therefore, PBMs will be forced to apply these price concessions to the negotiated price. By enacting this regulation, CMS is ensuring cost transparency for pharmacies and beneficiaries:

This would preclude the differential reporting that is taking place today, and put all plans on a level playing field in reporting drug costs and price concessions from network pharmacies. Consistent and transparent pricing would also promote increased price competition among network pharmacies and will align beneficiary and taxpayer interests in minimizing costs.⁶⁷

Along with price concessions, PBMs also use non-transparent Maximum Allowable Costs ("MAC") to increase profits. MAC prices are the upper limits that a PBM or prescription drug plan will pay a pharmacy for generic

drugs or brand named drugs that have a generic version available.⁶⁸ Under the current MAC pricing system no two MAC lists are the same and pharmacies have neither access nor insight into actual costs until after dispensing the drug to the beneficiary. Given the secretive nature of MAC pricing, numerous state legislatures have passed laws regulating MAC usage and transparency.⁶⁹

As CMS notes, transparency in MAC pricing is essential because when pharmacies are unable to determine their reimbursement it presents risks within payment accuracy offered by plan sponsors and for consumers who search on the Medicare Prescription Drug Finder Plan.

In the Proposed Rule, CMS also took steps to ensure transparency and accuracy for MAC pricing within Medicare Part D. As CMS notes, transparency in MAC pricing is essential because when pharmacies are unable to determine their reimbursement it presents risks within payment accuracy offered by plan sponsors and for consumers who search on the Medicare Prescription Drug Finder Plan.⁷⁰ In its proposal, CMS now recognizes MAC pricing as a "prescription drug pricing standard," which CMS defines as a pricing mechanism used to reimburse network pharmacies.⁷¹ Under such a standard, plans must ensure that MAC prices "accurately reflect the market price of acquiring the drug," and MAC prices must be updated no "less frequently than once every 7 days."⁷² Through the proposed regulations, plans are also required to "disclose all individual drug prices to be updated to the applicable pharmacies *in advance of their use for reimbursement claims*, if the sources... is not publicly available."⁷³ If finalized, these changes along with the acknowledgment of conflicts of interests for PBMs will have a positive impact in

promoting transparency and competition for payors and pharmacies.

E. Supposed Cost-Savings from Preferred Networks do not rebut the Need for Reform

Proponents of utilizing preferred pharmacy networks often cite to evidence of increased cost-savings to both beneficiaries and payors. PDPs such as the Humana Wal-Mart-Preferred Rx Plan suggest that they draw large numbers of customers, offer low to no copays on the majority of drugs, and supposedly lower prices for all parties in the Part D system.⁷⁴ However, more careful analysis suggests that these claims may be less than they appear.

In 2013, CMS released two separate studies based on actual Part D claims data that demonstrated that some PDPs did not achieve cost-savings through the usage of either preferred pharmacy networks or mail order. In their analysis of Part D PDPs utilizing preferred networks, CMS found that “prices are sometimes higher in certain preferred networks” when compared to non-preferred pharmacies.⁷⁵ In total, CMS estimates that 11 percent of all beneficiaries pay more for using “supposedly cheaper services” through preferred networks, with that number likely to increase given the growth rate of Part D preferred networks.⁷⁶ CMS’s mail order study of Part D PDPs again found that “negotiated prices are sometimes higher in certain preferred networks—contrary to our expectations.”⁷⁷ In its analysis of 57 PDPs, CMS found that mail order could charge as much as 83 percent more than community pharmacies.⁷⁸ CMS concludes that mail order pharmacies prices are “higher than at retail pharmacies for selected PDPs.”⁷⁹

CMS is not the only entity to find that certain preferred network pharmacies charge higher prices than pharmacies outside those networks. The National Community Pharmacists Association (“NCPA”) conducted a similar study that utilized pricing from the Medicare Plan Finder. Picking the commonly chosen AARP Medicare Rx

Preferred drug plan, NCPA examined costs of four different generic drugs including a popular generic version of Lipitor. Costs from the Medicare Plan Finder were then compared across preferred, mail order, and non-preferred pharmacies offered by the AARP Plan in nine different cities. NCPA found that 89 percent of the time preferred pharmacies charged more to Medicare for the drug than non-preferred pharmacies, and 100 percent of the time mail order costs were higher than non-preferred pharmacies.⁸⁰ This data confirms CMS’s studies that show costs can be higher in preferred networks.

In response, proponents of limited networks and mail order pharmacy services, including the Pharmaceutical Care Management Association (“PCMA”), have issued a number of papers that seek to rebut these studies. However, many of these studies are deeply flawed. For example, a recent Milliman study commissioned by the PCMA suggests that use of preferred networks could reduce Medicare spending by \$7.9 to \$9.3 billion.⁸¹ However, unlike the CMS and NCPA studies that relied on current market realities and actual payor data, the Milliman study cites nothing more than the authors’ experience as a basis for the claimed savings. The study even explicitly states: “this analysis is based on assumptions from Milliman’s *consulting experience*.”⁸²

In another example, PCMA commissioned a study by Avalere Health released in December 2013.⁸³ Similar to the Milliman study, the Avalere study argues: “PDPs with preferred pharmacy networks have lower premiums than PDPs without preferred networks.”⁸⁴ However, as with the Milliman study, the basis for their estimates is poorly documented. Notably, the Avalere study fails to account for other factors (e.g., higher deductibles) that could make PDPs with preferred (i.e., restricted) networks less expensive.

The Avalere study also asserts that preferred networks have higher Medicare Star Ratings, which are used to rate clinical and customer service performance, than do non-

preferred networks.⁸⁵ However, there are many serious flaws in the Avalere's study. For example, Avalere fails to note that restricted networks and open networks are not an apples to apples comparison. Given the high deductibles in restricted networks, healthier people with minimal risks tend to gravitate towards their services. In contrast, sick people prefer the open network, which tends to have higher copays but lower deductibles. Healthy people tend to visit pharmacies less frequently, and thus have generally limited opinions on quality of service and care, while sick people tend to visit healthcare providers more frequently and are therefore more likely to have at least one unsatisfactory experience. The Avalere study does not control for these confounding factors.

Additionally, the Avalere study is inconsistent with other evidence. When looking at quality studies of individual pharmacies, independent pharmacies tend to have the highest customer satisfaction. Consumer reports regularly find that independent pharmacies rank highest in overall service, quality of care, technology, and individualized service.⁸⁶ And J.D. Power and Associates recently found that "brick and mortar" pharmacies have higher customer satisfaction and perceived cost competitiveness when compared to mail order pharmacies.⁸⁷ And year after year, customers find that community pharmacists are among the most trusted of the health care professionals.⁸⁸

Two weeks prior to the Proposed Rule's comment deadline, PCMA sponsored still another study by Milliman that argued that allowing AWP would reduce sales volume and drive up costs, and that redefining preferred pharmacies could cause a loss of leverage for plans leading to higher costs.⁸⁹ However, these are manufactured problems and CMS addressed both of these issues in the Proposed Rule. First, CMS notes that under the current scheme, if limited networks always offered lower costs then "we would see consistently significant savings."⁹⁰ Secondly, with regards to concerns about pharmacies requiring higher market share in order to offer deeper discounts, CMS states that they are skeptical that retail pharmacies "will abandon their

market share" in favor of non-preferred networks.⁹¹ CMS's critique of the defection argument has been bolstered by the recent announcement that dozens of supermarket chains support the AWP and preferred cost sharing provisions.⁹² CMS has further noted that there is already one sponsor that successfully utilizes AWP in its preferred network.⁹³ CMS has clearly addressed all issues and proven that the previous iteration of preferred networks did not always save money. These proposed changes by CMS will ensure that PDPs provide sufficient cost-savings and pharmacy access for beneficiaries.

Conclusion

CMS's Proposed Rule for revising the AWP regulations is a step in the right direction. Any willing pharmacy should be given the opportunity to participate in any Medicare PDP given the Congressional intent and history of Medicare Part D, and the value of community pharmacies, specialty pharmacies, and pharmacists to beneficiaries and payors within the context of a changing healthcare system. As CEO of the National Community Pharmacists Association Doug Hoey observes:

These exclusive arrangements in a taxpayer-funded program hurt small community pharmacies, and Medicare data shows that preferred pharmacy plans often result in higher costs. Medicare beneficiaries who prefer to visit a community pharmacy should have the opportunity to keep that pharmacist as part of their health care team, particularly since it will not increase the costs to the government to do so.⁹⁴

Consumer choice drives market competition and improvements in quality. Allowing beneficiaries open access and the ability to choose between numerous pharmacies which offer valuable services will improve health outcomes, costs, and beneficiary satisfaction. Removing or restricting community and specialty pharmacies from a network at the expense of patients is not in their best interest nor is it what Congress intended.

Allowing open participation in the Medicare Part D program will not drive up costs; the status quo will. If allowed, some conflicted and non-transparent PBMs will funnel all beneficiaries into their system of pharmacies and PDPs. As noted by CMS, this business strategy is strictly for-profit and has already shown that it does not lower cost, increase quality, or increase customer satisfaction.

While the proposed regulations will not drastically alter the current Medicare marketplace, they will allow for fair and open competition among pharmacies leading to higher quality and lower price. Given the data, Congressional intent, and studies, it is clear that CMS should be allowed to finalize the Rule, ensuring equal opportunity and access to preferred networks.

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