

VIA Electronic Submission to <http://www.regulations.gov>

July 27, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2390-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability [CMS-2390-P; RIN 0938-AS25]

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) is pleased to provide our comments and suggestions on the proposed rule on Medicaid Managed Care as referenced above. NCPA represents the interests of pharmacist owners, managers and employees of nearly 23,000 independent community pharmacies across the United States. Together they represent a \$93 billion health-care marketplace, employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines.

Independent community pharmacists are proud to play a vital role in the Medicaid program as the backbone of its drug benefit. Local pharmacists provide expert medication counseling and other cost-saving services that help mitigate the estimated \$290 billion that is spent annually as a result of patients who do not adhere properly to their medication regimen. More than any other segment of the pharmacy industry, independent pharmacies are often located in the underserved and rural areas that are home to many Medicaid recipients. In fact, independent pharmacies represent 52% of all rural retail pharmacies and there are over 1,800 independent community pharmacies operating as the only retail pharmacy within their rural communities.¹ For the average independent community pharmacy, 93% of all revenues are derived from prescription sales, and 17% of all prescriptions revenues are from Medicaid.² In addition, 34% of our members serve a long term care (LTC) facility and 48% serve an Assisted Daily Living facility. In sum, approximately 40% of the LTC market is serviced by an independent community pharmacy.

Medical Loss Ratio

NCPA Urges CMS to Make Medical Loss Ratio Mandatory for Medicaid Managed Care to Safeguard Vulnerable Patient Population

NCPA is supportive of a Medical Loss Ratio (MLR) being applied to Medicaid managed care plans. MLR rules ensure that health plans spend a certain percentage of premiums on actual health care costs as opposed

¹ Based on NCPA Analysis of National Council for Prescription Drug Programs (NCPDP) data, Rural Urban Commuting Area (RUCA) Codes, and 2000 U.S. Census data.

² 2014 NCPA Digest Sponsored by Cardinal Health

to administrative costs and/or plan profits. Medicaid managed care plans are virtually the last type of health plan that has been allowed to operate in the absence of an MLR—Medicare Advantage, Medicare Part D and Exchange plans all operate under this type of necessary framework. In addition, a number of individual states already require Medicaid managed care plans to comply with a minimum MLR including Florida, Maryland, Virginia and Arizona. In the Proposed Rule, CMS allows but does not require states to impose MLRs on Medicaid managed care plans. In the event a state elects to impose a MLR on Medicaid managed care plans, CMS has proposed that states be required to adopt the same MLR definition and process as currently employed with Medicare Part D and Qualify Health Plans sold on Exchanges and that states impose a minimum MLR of 85%. NCPA urges CMS to make the MLR requirement mandatory which will ensure that Medicaid managed care plans spend a sufficient amount of premiums on actual medical care for their beneficiaries. This is an even more critical safeguard than with Medicare Part D and Qualified Health Plans given the vulnerable patient population that has health care coverage through Medicaid managed care organizations.

NCPA previously provided comments to CMS on when it was in the process of developing the requirement for Qualified Health Plans sold in the Exchanges as well as for Medicare Part D plans. Similar to our comments in these preceding instances, NCPA would like to share some of our thoughts and concerns on the calculation of an MLR, particularly with regard to the treatment of fees for Pharmacy Benefit Manager (PBM) services.

It is critical that PBM services not be considered medical/quality costs de facto as while some services that PBMs may provide health plans are medical/quality-related such as fees for medication therapy management services, there are many PBM services that simply do not meet the necessary definition. In addition, there should be no differentiation between the treatment of costs associated with management of pharmacy benefits regardless of whether the PBM is in-house, outsourced, or whether the Plan utilizes a PBM-owned mail order pharmacy. With regard to all PBM services, there needs to be a careful and thorough accounting of the specific services provided to ensure that these expenditures are appropriately allocated in the MLR.

CMS Should Clarify What Fees Paid to a PBM-Owned Mail Order Pharmacy are Deemed Medical Costs in the Calculation of MLR in the Final Rule for Medicaid Managed Care

NCPA is pleased to note that as with the commercial standards, this Proposed Rule would exclude from the Medicaid MLR numerator, Sponsor's payments to "third-party vendors for administrative fees, network development, claims processing and utilization management." This is critical to ensure that expenses do not receive different treatment depending on whether a service is performed by the plan sponsor or it delegated to a third party vendor.

However, the Center for Consumer Information and Insurance Oversight (CCIIO) has supplemented the commercial MLR regulation with a series of technical bulletins providing sub-regulatory guidance on commercial MLR issues in form of a frequently asked questions (FAQ) document. While NCPA does not believe CCIIO intended to create an exception to the aforementioned treatment of fees to third-party vendors for administrative services, the answer to Question # 12 of this document may be perceived to do just that in the event a PBM owns a mail order pharmacy. The answer to Question #12 states that when payments are made to a third-party vendor that provides clinical services to enrollees through its own employees, then "the entire portion of the amount the issuer pays to the third party vendor that is attributable to the third party vendor's direct provision of clinical services should be considered incurred claims, even if such amount includes reimbursement for third party vendor administrative costs directly related to the vendor's direct provision of clinical services." While it seems CCIIO is merely highlighting that vendor overhead and administrative costs are considered in any reimbursement formula and that reimbursement for pharmacy services should not be allocated between medical and administrative costs in the MLR calculation, some

have interpreted this sub-regulatory guidance more broadly such that any fees for administrative services in the management of pharmacy benefits or otherwise provided by a PBM-owned mail order pharmacy are deemed medical costs for purposes of the MLR calculation. NCPA urges CMS to take the time in the final rule to clarify the confusion surrounding the provision of administrative services by PBM-owned mail order pharmacies or other entities owned or affiliated with PBMs to ensure consistency in calculation of MLRs related to Medicaid managed care organizations but also Medicare Part D and Qualified Health Plans.

The ambiguity as to the treatment of fees to PBM-owned mail order pharmacies in the MLR apportionment process is one that was explicitly warned against as early as 2010. A December 17, 2010 issue of *Drug Benefit News* cites an investment analysis by Credit Suisse that suggests that there exists “a considerable gray areas around the MLR requirements.” This same investment analysis also asserts that “the additional scenario in which an insurer may be able to allocate its pharmacy business to medical costs is mail order.”

PBMs profit greatly by driving their pharmacy benefit clients and enrollees to their wholly-owned mail order pharmacies. As such, more transparency and accountability is needed related to administrative and clinical services when provided by PBM-owned mail order pharmacies to their affiliated PBM and Medicaid managed care plans rather than less. It has been conclusively shown that when given a choice, 83% of patients prefer to fill their prescription at a community pharmacy. There have also been significant concerns reported associated with the use of mail order pharmacy that have caused patients to be unable to take medications including delays in receiving medications, temperature sensitive drugs being left outside or on delivery trucks, drugs lost in transit, medication switching and even the wrong drugs being shipped. In addition, the Medicaid patient demographic indicates that many of these patients suffer from more than one chronic medical condition and benefit greatly from face-to-face interaction with a community pharmacist.

Given the fact that CMS currently has a keen focus on the quality of health care provided, plans should not be granted additional financial incentive to drive vulnerable Medicaid beneficiaries into a mandatory PBM-owned mail order pharmacy program vis-a-vis favorable treatment of administrative fees paid to such PBM-owned mail order pharmacies in the MLR calculation. A plan should not be allowed to effectively “game” the MLR apportionment process simply by utilizing a PBM-owned mail order pharmacy for clinical and administrative services.

ACA PBM Transparency Requirements for Medicare Part D and the Exchanges Should Also be required for Medicaid Managed Care Plans to Ensure Accurate MLR Calculations

In practical terms, many times plan sponsors do not know that their PBM is reimbursing the pharmacy at one price while charging a much higher price to the issuer for the same transaction. While the PBM may claim that this discrepancy stems from additional administrative costs, the price differential represents profit for the PBM from the “spread.” In order for there to be a meaningful delineation between medical and administrative costs by the Issuer in compliance with the MLR rule, it is crucial that PBMs be required to disclose to the issuer, the amount dispensed to the pharmacy for each transaction versus the amount that was charged to the plan for the same transaction.

In recognition of the inherent lack of transparency in the PBM industry, Congress included transparency provisions in the ACA that are now required of PBMs that manage prescription drug coverage under an Exchange or Part D health plan. Under Title VI, Section 6005 of the ACA, PBMs that serve health plans in the Exchange or Part D are required to confidentially disclose to the Secretary and the Plans, information regarding:

- The percent of all prescriptions provided through retail pharmacies compared to mail order and the generic dispensing rate and substitution rates of each;

- The aggregate amount and types of rebates, discounts and price concessions that the PBM negotiated on behalf of the plan and the aggregate amount of these passed on to the plan sponsor;
- The average aggregate difference between the amount the plan pays the PBM and the amount that the PBM pays the retail and mail order pharmacy.

These mandatory PBM transparency requirements were included in the federal health care reform legislation in recognition of the fact that such disclosures will grant the Secretary and the health plans better oversight with regard to the various revenue streams of the PBMs and therefore better enable them to correctly delineate medical vs. administrative costs with regard to PBM services and the calculation of MLR.

Other Payment and Accountability Improvements: Subcontractual Relationships and Delegation

Inspection and Audit Rights

The NPRM proposes to expand the existing inspection standards and audit rights for the state and federal government to allow the state, CMS, and the Office of Inspector General to conduct inspections and/or audits at any time. NCPA strongly supports this provision. A May 2014 GAO report identified a gap in state and federal efforts to ensure Medicaid managed care program integrity. The GAO found that CMS has largely delegated managed care program integrity oversight activities to the states, but given them little specific guidance. The study also found that CMS does not require states to audit their payments to MCOs, and that states were not closely examining the activities of MCOs.

MCOs Must Take Responsibility for Auditing Contracted Pharmacy Benefit Managers

Many health plans and insurers subcontract their pharmacy benefit management to a stand-alone pharmacy benefit manager (PBM). PBMs have come under fire for certain practices including opaque rebate schemes and pricing spreads, formulary designs and narrow pharmacy networks. Given the large amounts of public funds involved and the potential for fraud and abuse, CMS audits Medicare Part D plan sponsors to ensure their compliance. NCPA encourages CMS to require MCOs to take responsibility for auditing the PBMs they contract with.

Today, commercial and Medicare Part D plan sponsors are typically not allowed reasonable access to audit their PBMs to determine if the PBM is properly performing under contract terms. Plan sponsors must hire an auditor deemed acceptable by the PBM, the auditor must conduct the audit that is under the terms stipulated by the PBM, which in turn causes the audit to be prohibitively expensive – the cost can range from \$15,000 to more than \$200,000 depending on the size and scope of the audit – pricing them out of reach for many. Because of this, plan sponsors have no idea if the financial terms are being met. PBMs often allege that there is “transparency” and “disclosure” because plans can audit the PBM, but this is simply not the case. PBMs routinely decline to disclose what they are being paid by adding costs on to prescription drug claims. If they do disclose that spread pricing is occurring, the amount of spread is not disclosed.

CMS currently conducts audits of Medicare Part D plan sponsors to ensure compliance. Just this year, CMS released an updated version of the Part D plan audit protocols and announced the beginning of a new audit cycle, indicating that all plan sponsors will be considered for audit, even those audited during the previous (2010-2014) cycle. NCPA encourages this enhanced auditing and supports CMS efforts to strengthen the audit requirements for MCOs to better ensure program integrity and protect beneficiaries.

Beneficiary Protections: Continued Services to Beneficiaries and Coordination and Continuity of Care

NCPA supports the strengthening of transition of care standards for all Medicaid beneficiaries transitioning from one delivery system to another within Medicaid, and this is especially important in the long term care (LTC) population. NCPA believes such care transition standards should be developed by a stakeholder panel convened by CMS and based on best-available clinical evidence to ensure a level of consistency. While care coordination has the potential to improve outcomes, provide operational efficiencies and lower overall health care costs, these services can quickly become complex when implementing in a population that typically receives care from multiple prescribers and requires more intensive medication monitoring. Managed long-term services and supports (MLTSS) are not currently widely adopted in the states and therefore such organizations do not have experience managing patients who require LTSS. Patients residing in LTC settings tend to be medically complex, thus requiring greater care. They are generally elderly, with multiple chronic conditions, and cognitive or functional limitations and safe and effective care coordination is especially critical. Therefore, CMS should consult with stakeholder organizations in developing a set of clearly defined roles and responsibilities among managed care entities and providers involved in the transition of beneficiaries at various points of care delivery.

NCPA also supports best practices that plans offer new enrollees transitional care for an ongoing course of treatment for 30 days following the effective date of coverage. Plans will have different provider networks, and consumers may not always be aware of their provider's inclusion in the network, or able to switch providers if they are undergoing a course of treatment with a provider that is not in the new issuer's network. In such a case, it may take time for the new enrollee to select a new in-network provider and to meet with the new providers to ensure that there is no disruption in treatment.

Modernize Regulatory Requirements

NCPA Recommends CMS Establish TRICARE Retail Pharmacy Access Standards As a Minimum Threshold for Medicaid Managed Care

NCPA appreciates CMS' proposal to modernize network adequacy standards for Medicaid managed care plans. Approximately three fourths of Medicaid beneficiaries today receive services through some type of managed care arrangement, and that figure is expected to grow. The Congressional Budget Office predicts that an additional 18 million Americans will enroll in Medicaid by 2018 due in large part to Medicaid expansion under the Affordable Care Act. According to the health care consulting firm Avalere, among states expanding Medicaid eligibility, the percentage of enrollees in managed care exceeds the national average – rising from 73 percent in 2013 to 79 percent in 2016 (10.2 million). Of the 28 states and the District of Columbia committed to expansion, 16 states and D.C. plan to enroll over 90 percent of the newly eligible into Medicaid managed care organizations (MCOs).

As state experience has demonstrated, these new managed care enrollees' need for medical services is likely to be high, as will their need for access to the full range of health care providers. Existing Medicaid regulations do not define with a great deal of specificity how plans are to ensure that their networks are adequate. Rather, federal regulations leave MCOs and states a good deal of discretion to define network adequacy. A December 2014 report by the HHS Office of Inspector General concluded that, despite federal requirements requiring Medicaid MCOs to maintain a provider network sufficient in number, type and geographic distribution sufficient to provide adequate access to Medicaid services, "significant vulnerabilities" exist that "raise serious questions about the abilities of plans, States, and CMS to ensure that access-to-care standards are met."

The NPRM proposes that states must establish time and distance standards for the following network provider types: primary care; OB/GYN; behavioral health; specialist; hospital; pharmacy; and additional provider types. NCPA appreciates CMS' proposal to modernize the regulatory network adequacy standards for Medicaid MCOs, and supports policies that ensure timely, meaningful access for patients to providers, hospitals and pharmacies. Providers should be available in sufficient proximity to patients with network adequacy standards that ensure meaningful coverage for all necessary care.

NCPA supports CMS' recommendation that states establish time and distance standards for Medicaid MCOs, especially as they relate to pharmacy services. It is worth noting that of the 33 states with risk-based Medicaid managed care plans, 32 have established standards regarding provider distance or time that generally apply solely to primary care providers. As the OIG notes, "state standards vary widely and are often not specific to providers who are important to the Medicaid population. In addition, these standards often apply to all areas within a state and do not take into account differences between urban and rural areas. Without standards for specific provider types or areas, states may not be able to hold plans accountable for ensuring adequate access to care." According to the OIG analysis of state data, "standards for the maximum distance to a primary care provider range from 5 miles to 60 miles. The standards for maximum travel time to see a primary care provider range from a low of 30 minutes to a high of 60 minutes."

NCPA would encourage CMS to establish at least a minimum requirement regarding access to pharmacy services in order to protect consumers from the kind of disparate standards that exist in the states today. Towards that end, we would suggest that CMS utilize the TRICARE access standards, as these standards are applied in the Medicare Part D program to ensure adequate access to pharmacy care for Medicare Part D beneficiaries. Specifically, we recommend the access standards as contained in the TRICARE Pharmacy Program, Fourth Generation (TPharm4) contract, beginning May 1, 2015.

Under the Department of Defense TRICARE program, the pharmacy benefit management services contractor is required to secure the participation of a sufficient number of pharmacies (not including mail service) in their pharmacy networks to ensure convenient beneficiary access. These standards require a certain percentage of beneficiaries to live within a specified number of miles of a retail pharmacy based on whether they reside in an urban, suburban or rural area.

In addition, under current Medicare Part D standards, pharmacy networks must be at least as inclusive as those required under the TRICARE program. The TRICARE program as well as the Part D program recognize the fact that adequate access to retail pharmacy services are essential and must be evaluated based on the beneficiaries location in either an urban, suburban or rural area. Ideally, states should allow all pharmacies that wish to participate be included in the network and consider the TRICARE retail pharmacy access requirements as a minimum threshold for network adequacy.

Lastly, the NPRM notes that CMS may permit an exception process to any of the provider network adequacy standards. In order to protect patients, NCPA encourages CMS to require states to review plans' exception policies to ensure that essential access to providers is not adversely impacted by the exceptions process. Additionally, monitoring of MCO networks must be transparent, publicly available, and easy for consumers to understand.

Criteria for Developing Network Adequacy Standards for MLTSS Programs

Similar to Medicare, NCPA recommends that CMS work with stakeholders to develop guidance to assist managed care organizations in determining policies for the provision of long term services and supports (LTSS) within Medicaid Managed Care. In Part D, CMS has developed guidance to address pharmacy performance and service criteria, convenient access standards, and other beneficiary protections that plan

sponsors should consider as they develop their prescription drug benefit offerings for institutionalized LTC Medicare beneficiaries. We believe that a similar set of guidelines would serve as the framework for states and managed care organizations.

CMS has developed the minimum performance and service criteria for pharmacies providing LTC service, based on widely used best practices and with input from various CMS divisions and external stakeholders. Part D plans are required to offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting) and any other standard terms and conditions established by the plan for its network pharmacies. These performance and service criteria are typically incorporated into an addendum to a Plan's standard network contract for those pharmacies that would like to be designated LTC network pharmacies, and include services such as special packaging, IV medications, compounding, emergency boxes, pharmacist on-call, and delivery services. Additionally, Part D plans must demonstrate that they have a network of participating LTC pharmacies that provide convenient access to LTC pharmacies for LTC residents who are Part D enrollees, and we would recommend the same principles be applied in developing network adequacy standards in MLTSS programs.

NCPA believes that the goals of any MLTSS arrangement should be improved access and quality for beneficiaries. Currently MCOs have very limited experience dealing with long term services and supports, and as states move toward MLTSS, CMS should make clear that individuals must be given the right to make informed decisions about enrollment. States also should have clear standards for network adequacy so beneficiaries have sufficient choice of providers in addition to service setting. We would also encourage CMS to ensure that MLTSS arrangements provide access to the most appropriate care. Individuals typically have strong relationships with their providers, and their long term health care needs likely will change over time; especially among older adults. Programs should offer adequate protections, such as access to out-of-network doctors and caregivers. Provisions for "any willing provider," will allow such critical relationships to continue as part of continuity of care.

Due to the added services provided by LTC pharmacies, NCPA would also like to highlight the need for clearly defined payment rates and provider reimbursement that is commensurate and aligned with program standards and ensuring access goals. LTC providers typically incur higher dispensing costs, yet have cited considerable Medicaid rate cuts, and those who are providers in MLTSS note lower payments compared to traditional state Medicaid. The current challenges with plan payments where MLTSS programs are providing lower or delayed reimbursements could negatively impact provider network stability and beneficiary access, and is an issue CMS should be aware of when addressing network adequacy.

State Monitoring Standards

With the expansion of Medicaid managed care and particularly the "carving in" of pharmacy services into existing Medicaid managed care programs, it will be critical for states to provide strong direction and oversight to the managed care organizations. NCPA is pleased to note the express inclusion in the proposed rule of "provider network management" as one of the specific aspects that must be included in any state monitoring program. For the purposes of pharmacy provider network management, it is critical that states ensure that (1) MCOs allow the participation of "any willing pharmacy"; and (2) states set the Fee for Service (FFS) Medicaid pharmacy provider reimbursement rate as a minimum reimbursement "floor" in order to ensure the participation of a sufficient number of pharmacy care providers to serve the large influx of Medicaid beneficiaries. Also, NCPA urges CMS to include other beneficiary protections outlined below as part of state monitoring programs.

Pharmacy Networks in Medicaid Managed Care Programs Should Be “Any Willing Pharmacy”

Particularly with the large influx of beneficiaries into the Medicaid program, states and MCOs will need to secure the participation of additional pharmacy providers in order to ensure that all patients have sufficient access to pharmacy care providers. Many Medicaid patients take multiple medications and frequently require an increased level of oversight and care on the part of the pharmacist to ensure that the patient is utilizing the medications properly and adhering to their treatment regimens. Pharmacists are frequently the most accessible healthcare providers in many communities and are critical for the provision of immunizations and other preventative care services in the community. Access to pharmacy care services and prescription medications can play a critical role in managing chronic conditions and staving off costly downstream medical interventions.

Restrictive pharmacy networks would have a negative effect on Medicaid beneficiaries’ access to pharmacy providers which could result in an increase in state expenditures on downstream medical costs (such as emergency room visits). Many states already have some type of “any willing provider” statute ensuring that a provider will have the opportunity to be offered a contract to participate in a third-party program. This is applicable as the provider willingly accepts all of the terms and conditions of the contract that the MCO makes available to any other like-provider in the state. States should only contract with MCOs that ensure that there will be no variations in the terms and conditions applicable to providers. In some cases, smaller pharmacy operations are at a contractual disadvantage in comparison to larger chain operations and PBM mail order facilities. This is due to the size of the pharmacy operations in gross sales, physical facility size and the volume (in dollars or prescription volume) that the pharmacy expects to provide for the MCO. This does not provide a level playing field, especially for independent pharmacies that compete with PBM giants or large pharmacy chains and would also create access issues—as many Medicaid beneficiaries reside in very rural or urban areas typically not served by these large corporate entities.

CMS Should Require States to Stipulate to MCOs that the Fee-for-Service (FFS) Medicaid Pharmacy Reimbursement Rate Should Serve as a Minimum Floor

For Medicaid services provided under fee-for-service (FFS), federal statutes [42 U.S.C. 1396a (a) (13) (A) (2000)] require that pharmacy reimbursement be “sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.” However, these federal statutes do not apply to pharmacy reimbursement under Medicaid Managed Care. In addition, when a state wishes to change its reimbursement rate to pharmacy under FFS, the state must first obtain federal approval --regardless of whether the change is an increase or a decrease. In the absence of these protective federal “guardrails, “ it is likely that managed care plans and their PBMs are likely to ratchet down reimbursement rates which could have a drastic effect on pharmacy providers as well as the vulnerable Medicaid beneficiaries that they serve. NCPA suggests that CMS require states in their contracts with MCOs, stipulate that the current state Medicaid pharmacy reimbursement rate shall serve as a reimbursement “floor.” Unless these protections exist, there will be a disparity in the access to pharmacy care services enjoyed by those beneficiaries covered under Medicaid FFS and Medicaid managed care.

CMS Should Require States to Stipulate in Contracts with MCOs, That Drug Pricing Standards (Including Maximum Allowable Cost) be Updated Every Seven Days

In recognition of the lack of transparency surround Maximum Allowable Cost (MAC) pricing in the overall marketplace and Medicare Part D and the negative effects on providers and in turn beneficiaries, the 2015 Final Medicare Part D Rule stipulates that effective 2016, all Part D plans and their PBMs must make certain disclosures to contracted pharmacies about Maximum Allowable Cost (MAC) pricing. Specifically, the final rule finalized a definition of “prescription drug pricing standard” and clarified that MAC is a drug pricing

standard and as such must be updated every seven days. In addition, the rule provides that Part D sponsors (and downstream entities) must agree in their contracts with CMS to disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims. This provision will be effective for Medicare Part D in 2016.

CMS finalized this disclosure requirement in light of the fact that currently there is no standardization in the pharmaceutical industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the PBM will determine the maximum price or how it is changed or updated. Currently, payers and PBMs have free rein on developing these methodologies and in turn, the ultimate price. Also, in most cases, pharmacies do not have an effective avenue to appeal these prices, even if they themselves cannot find the product available to them on the market for the PBM-stated MAC price. Also, many times, the payer/PBM does not update MAC prices often enough to keep up with marketplace changes and price swings. In these instances, pharmacies may lose money on these drugs or be forced to sell them below cost.

Another compelling case for requiring the regular updating of MAC prices is the current situation in the generic drug marketplace that has seen a wave of extreme price spikes in the costs of formerly inexpensive generic drugs. Because the PBMs have not been updating their MAC prices in a regular and consistent manner, many pharmacists have been forced to take significant losses when dispensing these medications to all patients. In order to ensure a fair and competitive marketplace and to ensure that pharmacy providers are reimbursed fairly for providing medications to beneficiaries receiving care under managed care, it is critical that this issue is addressed.

In recognition of the fact that the lack of transparency surrounding MAC pricing was proving to be detrimental to Medicare Part D providers and was impacting their ability to serve beneficiaries, CMS acted to require these necessary disclosures. In order to provide consistency in the marketplace and to ensure that pharmacy providers and beneficiaries in Medicaid managed care are not harmed by the lack of transparency in MAC pricing, NCPA strongly recommends that CMS require states to include similar provisions in their contracts with MCOs and their PBMs.

To Ensure Beneficiary Access to Specialty Medications, NCPA Recommends that CMS Stipulate that States and Contracted MCOs Follow CMS Medicare Part D Guidance on Access to Specialty Medications

In recognition of the fact that restricted access to specialty medications can be discriminatory in nature, CMS has provided regulatory guidance for Part D plans (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf). According to the Agency's own FAQ:

“Part D plans may not restrict access to certain Part D drugs to “specialty” pharmacies within their Part D network in such a manner that contravenes the convenient access protections of Section 1860D-4(b)(1)(C) of the Social Security Act and 42 CFR 423.120(a).”

Specifically, Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network of pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Therefore, Part D plans may not restrict access based solely on the placement of a Part D drug in a “specialty/high cost” tier because this tier placement alone is not indicative of any special requirements associated with such drug.”

The CMS guidance allows Part D plans to specify, on a drug by drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. These drug by drug requirements should only apply to special handling and dispensing that may be required by a “specialty” drug and not to reimbursement or other standard contracting terms and conditions. Requiring pharmacies to accept different reimbursement rates for certain “specialty” drugs is inconsistent with standard industry practice, could result in plans setting reimbursement rates below the market rates set in their standard contracts, and could be used to subvert beneficiary access to these medications.

NCPA strongly recommends that CMS stipulate that states and their contracted MCOs/PBMs utilize this Part D guidance on specialty medications in Medicaid managed care. Without this type of policy, Medicaid managed care beneficiaries could be at risk of restricted access to these vital medications in comparison to beneficiaries under other government affiliated programs.

CMS Should Stipulate to States and Contracted MCOs/PBMs that Consistent With Protections Provided to Consumers of Qualified Health Plans (QHPs); Medicaid Managed Care Beneficiaries Must Be Given the Option to Access Their Prescription Drug Benefit through Retail Pharmacies

NCPA is strongly supportive of the newly adopted requirement to the Essential Health Benefits prescription drug definition that requires that enrollees be provided with the option to access their prescription drug benefit through retail (brick and mortar or non-mail order pharmacies) and that plans may not have a mail order only prescription drug benefit. NCPA also agrees with CMS’ assertion that “making drugs available only by mail order would discourage enrollment by, and thus discriminate against, transient individuals and certain individuals who have conditions that they wish to keep confidential.”

CMS Should Advise States to Stipulate that MCOs/PBMs May Not “Tie” Pharmacy Participation in Any Medicaid Managed Care Contract To Participation in Any Other Commercial Contract

As a practical matter, it is inevitable that the managed care organizations and their contracted PBMs, will also be charged with the coordination of pharmacy benefits for a myriad of health plans, other than Medicaid managed care. Sometimes, managed care organizations/PBMs will contract with or allow the participation of some pharmacies with a condition that they also agree to participate in another network—many times at reduced reimbursement rates. NCPA feels very strongly that this type of “conditional” contracting should not be allowed—particularly when tied to a government-affiliated program.

Conclusion

NCPA appreciates the opportunity to provide community pharmacy and long term care pharmacy’s perspective regarding the modernization of Medicaid managed care regulations. Independent community pharmacy is ready and willing to work with the Agency to address rising costs in Medicaid programs in meaningful ways without compromising beneficiary access or quality of care. It is critical that provider reimbursement levels do not decrease to such a point as to discourage provider participation in Medicaid programs.

Sincerely,

Susan Pilch, J.D.
Vice President
Policy and Regulatory Affairs