

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

March 7, 2014

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4159-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs [CMS-4159-P; RIN 0938-AR37]**

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) welcomes the opportunity to submit comments on the proposed rule for Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. NCPA also greatly appreciates the efforts of CMS to increase the transparency of the program and expand beneficiary access to the critical services provided under the Part D program.

NCPA represents the interests of pharmacist owners, managers and employees of more than 23,000 independent community pharmacies across the United States. Together they 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 Medicare Part D program, and have been on the front lines of providing medications, related counseling, and assistance with plans since the inception of the Part D program.

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 Medicare 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.<sup>1</sup>

NCPA is strongly supportive of many of the aspects of this proposed rule including moving away from a preferred pharmacy network structure and instead shifting to a preferred cost sharing model that will afford more seniors access to preferred cost sharing rates or lower prices as well as provide them with more choices in terms of where they prefer to access their pharmacy services. This shift in conjunction with the proposed inclusion of pharmacy price concessions in negotiated prices will also ensure that CMS and the federal government are not charged more money for these preferred cost sharing models—in sharp contrast to what

<sup>1</sup> 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.

is occurring today in many cases. NCPA is also strongly supportive of CMS' proposal to clarify what is meant by a "drug pricing standard." This change is critical to ensuring that pharmacies are appropriately reimbursed for providing prescription medication to Part D beneficiaries. NCPA also supports measures to "level the playing field" between mail order and retail pharmacies and to expand eligibility for Medication Therapy Management (MTM) services. NCPA believes that these aforementioned issues are critical ones that warrant immediate attention or remedy for the 2015 plan year to ensure beneficiary access to potential cost savings and improved health outcomes as well as to secure appropriate reimbursement to Part D providers.

### **Reducing the Burden of the Compliance Program Training Requirements (§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C))**

NCPA supports CMS' proposal to require that all contracting organizations accept a certificate of completion of the CMS training as satisfaction of the general compliance program training requirement. This proposal should greatly reduce the burden on pharmacists who may be asked to comply with varying requirements based on the vast number of organizations they contract with. We also agree with CMS' proposal that Part D sponsors should not be allowed to develop or implement sponsor specific training.

### **Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2))**

NCPA supports the proposal to allow CMS to require Part D sponsors to hire an independent auditor to perform full or partial program audits to determine compliance with CMS requirements and specification. NCPA appreciates the fact that CMS is proposing to release sub regulatory guidance to address things such as language and specifications to be included in the contract between the sponsoring organization and independent auditor. Regarding the requirement that a sponsoring organization hire an independent auditor to verify that any deficiencies have been corrected, NCPA asks that CMS make clear in sub regulatory guidance certain specifications to be included in this contract as well. For example, it is our understanding that PBMs oftentimes include very restrictive language in their contracts concerning issues such as what auditor their clients are allowed to use.

### **Timely Access to Mail Order Services (§ 423.120)**

NCPA strongly supports and shares CMS' commitment to ensuring reliable and consistent beneficiary access to medications, regardless of the type of dispensing pharmacy or mode of delivery. It is our privilege to serve these beneficiaries, and our obligation as providers in the Medicare Part D program is to the patient, not executives or shareholders. Our members are solely motivated to provide beneficiaries with high quality, cost-effective, and timely access to medications and counseling services.

CMS is correct that it is the industry standard in retail pharmacy that virtually all prescriptions are filled in real-time, on the day they are presented. While mail order may present a convenient option for beneficiaries, they should not be coerced into selecting this delivery method based on incentives such as zero dollar cost sharing, which as CMS notes, creates an increased demand for mail order and consequently causes disruptions to delivery timeframe and gaps in therapy when the volume becomes too large to handle at the fulfillment center. Therefore we concur with CMS' assessment that it is necessary and appropriate to establish fulfillment requirements in order to strengthen beneficiary protections and ensure consistent and reliable access to medications.

## **Proposed standards present a reasonable timeframe**

NCPA believes the 3- or 5-day standard compliance time frame for mail order fulfillment is reasonable and consistent with industry standards. We would also encourage CMS to establish mechanisms to ensure that these standards are being met, so that there is a way to capture when the prescription order is received and when it is sent out. We understand that there may be extenuating or unforeseen circumstances such as inclement weather, natural disasters, or prior authorizations requiring additional time needed to process the prescription, and CMS may receive feedback from the parties responsible for fulfilling these prescriptions in a timely manner that the proposed standards are unrealistic. However, as community pharmacists servicing patients at the retail level and in the normal course of business, we would disagree that the proposed standards are unachievable. Our members have business operations and workflow processes in place that can accommodate the filling of prescriptions on the same day, and can notify the patient or prescriber almost immediately should an issue arise such as illegible orders, clinical concerns, or resolving third party rejections. Beneficiaries receiving their medications through mail order deserve the same level of services, and the importance and need for such fulfillment standards cannot be stressed enough.

## **Appropriateness of 30-day fills at mail order**

As always, the primary concern of our members is ensuring that patients receive the right medications when they need them, regardless of pharmacy type. We share and strongly support CMS's perspective that the filling of initial or routine 30-day supplies at mail order may not be in the best interest of the patient for a variety of reasons. As CMS notes, there is a fairly tight turnaround timeframe to process a script for a 30-day supply via mail order, from end to end. Undue stress may be placed on beneficiaries who are trying to make sure the script is mailed in or that a refill is requested early enough to ensure sufficient time for process and delivery, and this may result in refill-too-soon edits from the last date the script was processed. From a clinical standpoint, there are certain medications (e.g. transplant drugs, mental health, or other agents with a narrow therapeutic index) for which timely access and adherence is critical once patients have been stabilized on a regimen. Should something go awry in the processing of these claims, patients could be placed in the precarious position of experiencing a delay or going without their lifesaving medications.

Therefore, we agree with CMS that filling initial prescriptions or routine 30-day supplies at mail order is not good practice. This practice should not be incentivized in any way and we strongly support CMS' proposal that the cost sharing at mail order cannot be less than the standard cost sharing at retail for prescriptions for 34 days or less, regardless of whether a preferred cost sharing level is available.

## **Additional beneficiary protections**

While we believe that beneficiaries should be able to choose the method of delivery for their prescriptions that best meet their needs, there should be additional protections in place to ensure that care is not compromised. The growing chorus of beneficiary complaints CMS has received regarding problems with mail order should serve as a strong indicator that beneficiaries deserve greater clarity and expectations regarding their mail order benefit and options available should problems arise.<sup>2</sup>

NCPA supports CMS' proposal to establish additional requirements for beneficiary materials and communications relating to mail order services, and would encourage that this language not only appear in marketing materials from plans but also the Medicare & You Handbook provided by CMS. The Agency should train its customer service representatives that beneficiary complaints about mail order problems are

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<sup>2</sup> Centers for Medicare and Medicaid Services, Sample of Beneficiary Complaints Relating to Mail Order.

<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/SampleofBeneficiaryComplaintsMailOrder.pdf>. Accessed January 2014.

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valid and should be logged in the Complaint Tracking Module. CMS may consider future metrics related to these types of complaints. NCPA further believes that providing beneficiaries options for accessing medications when a delivery is lost or delayed is in the best interest of the patient, and would recommend the allowance and coverage of a lost fill at a retail pharmacy location to provide continuity of care.

### **Medication Therapy Management Program (MTM) under Part D (§ 423.153(d))**

NCPA has long supported the efforts of CMS to promote the MTM benefit to beneficiaries, and we appreciate the agency's recognition of community pharmacists' in the provision of such services. Over the years we have championed for incremental changes to bring greater visibility to the MTM program, such as in the Medicare & You handbook, and providing eligibility information on Medicare Plan Finder. NCPA also commends CMS for program changes such as automatic enrollment of targeted beneficiaries in the MTM program, unless they opt out, and providing greater consistency in how MTM is delivered, through the standardization of structured MTM documents. Like CMS, we remain concerned with the low enrollment figures for the MTM program, and believe the proposed changes represent a monumental shift in the right direction.

### **Achieving CMS' "Triple Aim" through MTM programs**

Expanding the MTM eligibility criteria and increasing beneficiary access to these critical services will help achieve the triple aim of better care for patients, improved health in our communities, and reduced costs throughout the healthcare system. As CMS noted, there is growing evidence that MTM services not only improve the quality of care beneficiaries receive, but can also generate medical savings. NCPA believes that prevention is the best medicine, and whether it's catching a medication error before it leads to a hospitalization or effective chronic disease management, MTM services present opportunities to improve patient care while providing greater efficiencies within the healthcare system.

NCPA appreciates the analysis CMS has conducted thus far in examining the impact of Part D MTM programs, and recent evidence from both CMS data and the Congressional Budget Office (CBO) confirms the positive impacts associated with comprehensive medication reviews, not only in relation to improved adherence and health outcomes, but also in medical savings.<sup>3,4</sup> In addition to studies conducted by CMS and CBO, additional studies have shown that adherence and MTM services can lead to a reduction in overall healthcare expenditures.

MTM can lead to savings through different methods: a comprehensive medication review is an opportunity for a pharmacist to review a patient's entire medication regimen, and identify potential cost-effective alternatives or eliminate duplicate therapies. MTM is also intended to improve medication adherence, which may increase drug spend through greater utilization, however studies have found that higher rates of medication adherence result in significantly fewer hospitalizations and lower health care costs, and that these savings are actually greater in patients over age 65.<sup>5</sup>

MTM services have proven to be a cost-effective care delivery model that provides enhanced quality to those that qualify. Broadening the eligibility criteria means that more beneficiaries will be able to take advantage

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<sup>3</sup>CMS Center for Medicare & Medicaid Innovation, Medication Therapy Management in Chronically Ill Populations: Final Report, August 2013

<sup>4</sup> Congressional Budget Office, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services, November 2012.

<sup>5</sup> M. Christopher Roebuck, Joshua N. Liberman, Marin Gemmill-Toyama and Troyen A Brennan. Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending. *Health Affairs*, 30, no.1 (2011):91-99

of a covered service to thoroughly review all of their medications, and that will likely keep them well and out of the hospital.

#### **Part D infrastructure is not built to support MTM expansion**

NCPA is disappointed to see that despite previous attempts from CMS to strengthen the MTM program, with the latest coming from 2010 Call Letter and subsequent regulation that modified the criteria to reduce variability in eligibility, that Plan Sponsors still choose to employ restrictive program requirements, negating the Agency's efforts to create a more robust benefit. While this is concerning, we cannot say that we're surprised, due to the structure of the Part D benefit, and the way the MTM program is factored into a plan sponsor's bid.

As CMS notes, when trying to calculate the overall costs of providing comprehensive medication reviews, "we cannot definitively score this proposal because the portion of the administrative costs attributable to MTM is not a specific line item that can be easily extracted from the bid." Plan sponsors will employ cost containment strategies to keep administrative costs down for more favorable bids. Therefore, the current structure of considering MTM programs as an administrative cost is actually counterintuitive to promoting better adherence and improved patient outcomes. For these plans, the drug spend is completely segregated from the health spend. As a result, any increases in drug spend, including those resulting from improved medication adherence and expanding MTM programs, adds to the plan's overall costs and consequently increases their bid.

NCPA strongly believes that more seniors should qualify for MTM services, as they have been shown to produce long-term benefits. As the healthcare payment paradigm shifts from a volume- to value-based system, we would strongly encourage CMS to reconsider the structure of MTM benefit to one that is rewarded for quality improvement.

#### **Effective strategies to improve access to MTM services and ensure high degree of quality**

Many Medicare beneficiaries become eligible for enrollment in an MTM program, but may not receive these services because of the lack of effective outreach and communications, or confusion. We concur with CMS' assessment that for certain populations who may be more vulnerable, such as beneficiaries residing in a long-term care (LTC) facility, plan sponsors could be doing more to reach the patient or an authorized representative to coordinate the comprehensive medication review (CMR).

We fully support the intentions of the Agency to provide MTM services to a broader population of beneficiaries and to implement the CMR requirement in the LTC setting. However we would caution that the feedback we've received from pharmacists in the first year of the program implementation would indicate that there is room for improvement in terms of coordination and outreach to improve access to MTM services for Part D enrollees. In a recent NCPA member survey on MTM services, the large majority of pharmacists who provide long-term care services noted that they have not seen CMRs being completed in the facilities they service, nor have they observed coordination amongst MTM providers and other health professionals in the facility regarding CMR recommendations and monthly drug regimen reviews (DRR). **[See Attachment 1 for NCPA MTM Survey]**

We caution that there is still a lack of clarity between LTC facilities and the plans as to how these reviews will be carried out. Additionally, an inherent potential conflict exists between the CMR and the required DRR by the consultant pharmacist if the CMR is conducted by the plan sponsor and not a consultant pharmacist familiar with the resident's medication history. We believe there can be more coordination between MTM sponsors and providers to ensure safe and appropriate medication use, especially in this

vulnerable population. NCPA recommends the Agency continue outreach and dialogue with LTC stakeholders on how to best provide CMRs in these settings that is in compliance with requirements set forth by CMS.

NCPA believes that it is important to expand the number of metrics related to MTM services and supports CMS' move toward including more clinical and less process-based measures in rating Part D plans. MTM can serve many beneficial purposes, including decreasing wasteful and unnecessary drug spending, reducing patient use of potentially harmful combinations of drugs, and improving patient adherence and proper usage of beneficial drugs, which ultimately decreases long-term health care costs. We also encourage CMS to continue to use validated performance-based measures for pharmacy providers, such as use of the Pharmacy Quality Alliance (PQA) measures. Without effective measurement tools, it is difficult to track the benefits and progress of such programs.

It is critical for CMS to track how plans are actively engaging patients in MTM services, or else the efforts to expand eligibility criteria will not be successful. In doing so, NCPA strongly encourages CMS to obtain data on the method by which the medication review was delivered (telephonic or face-to-face), as well as monitor outreach methods used by plan sponsors. The feedback we've received from pharmacists is that outreach by some plans to offer a CMR to beneficiaries comes from an unknown person or worse, an automated robo-call from a call center and comes across as a sales pitch. Weary seniors may think it's a scam and decline the service offering, and by default that serves as their opt-out of the MTM program.

We would contend that MTM delivered face-to-face or in an interactive telehealth method with a trusted pharmacist will yield enhanced patient understanding of their medications, improved adherence, and lower costs. A study comparing MTM interventions found drug costs decreased for those who received service from community pharmacists, decreased somewhat for patients who received service from a call center pharmacist, and were unchanged for those who received MTM via educational mailings.<sup>6</sup>

We strongly recommend that CMS apply the findings from the Center for Medicare and Medicaid Innovation called *Medication Therapy Management in Chronically Ill Population: Final Report* to improve upon the MTM program overall. The study found that the best-performing Part D organizations were able to improve medication adherence and quality of prescribing while keeping health care costs (including drugs) from rising. In addition, the practices from high-performing MTM programs described in the CMMI report exemplify how NCPA believes MTM should be executed:

- establishing proactive and persistent CMR recruitment efforts;
- targeting and aggressively recruiting patients to complete a CMR based on information on medical events such as recent a hospital discharge in addition to scanning for the usual MTM eligibility criteria; and
- coordinating care by utilizing trusted community relationships including networks of community pharmacists to recruit MTM eligible candidates, and utilizing existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients

In summary, NCPA strongly supports CMS' efforts to improve and expand beneficiary access to MTM through the new proposed criteria, which are more in line with the medication utilization of typical senior patients. NCPA maintains that effective MTM can generate savings for Medicare from avoidable hospitalizations and avoidable expensive acute care. Patients also will benefit from MTM upon discharge

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<sup>6</sup> Winston S, Lin Y. Impact on drug cost and use of Medicare Part D of medication therapy management services delivered in 2007. *J Am Pharm Assoc.* 2009;49(6):813–820.

from the hospital and any time a beneficiary undergoes a transition of care. Both situations would allow beneficiaries to benefit from MTM services where there is the added potential to reduce costly hospital readmissions due to medication misuse or non-adherence.

NCPA especially shares CMS' concern that Part D plans are restricting MTM eligibility criteria to limit the number of beneficiaries who qualify for MTM. NCPA strongly encourages CMS to concentrate on MTM underutilization and to take corrective action against plans that fail to employ effective outreach strategies to contact beneficiaries regarding their MTM benefit. We urge CMS to continue to explore strategies that enhance the MTM service offering for enrollees to take full advantage of the program benefits, and we recommend the continued monitoring and review of how the CMR to LTC residents is being offered and conducted. We also encourage CMS to consider an innovative payment structure for MTM services that incentivizes quality improvement.

### **Efficient Dispensing in Long-Term Care Facilities and Other Changes (§ 423.154)**

#### **Prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques**

NCPA supports the CMS proposal to prohibit payment arrangements that penalize efficient LTC dispensing techniques. NCPA first brought the issue of such payment arrangements to CMS' attention in a letter dated December 18, 2012. At that time, and still today, several of the largest Part D plan sponsors prorate dispensing fees, including for all generics and non-solid oral doses dispensed to nursing home facilities. As pharmacy's costs do not decrease when dispensing a smaller day supply, there is no incentive with these models to dispense a shorter day supply, rather, the opposite may apply.

NCPA greatly appreciates CMS recognizing, in the preamble to the rule, that "there is no justifiable rationale for proration, since the cost of dispensing is not directly related to the quantity dispensed," as well as recognizing that prorated dispensing fees are contrary to Congress' intent in enacting section 3310 of the Affordable Care Act.

#### **Misinterpretation of language as requiring the proration of dispensing fees**

NCPA is supportive of CMS eliminating section 423.154(e) which may have led to plans sponsors misinterpreting this paragraph and prorating dispensing fees and might cause additional confusion related to the daily cost-sharing rate requirement now applying whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply.

#### **Additional waiver for LTC pharmacies using restock and reuse dispensing methodologies under certain conditions**

NCPA appreciates CMS' provision to allow pharmacies options to reduce waste, however restock and reuse dispensing methodologies may not be a workable solution for most pharmacies. We have questions regarding whether restock and reuse conditions would need to be met for all drugs as well as concerns with varying state requirements surrounding these practices.

## **Interpreting the Non-Interference Provision (§ 423.10)**

### **Current CMS authority to shift from a preferred pharmacy network model to a preferred cost sharing model to ensure expanded beneficiary access and federal govt. savings**

NCPA strongly agrees that CMS, under its current authority and without any “re-interpretation” of the Non-Interference Provision is within its rights to make the proposed changes that would allow all pharmacies to have the opportunity to participate as a preferred pharmacy or offer preferred cost sharing, as long as they are willing to agree to a plan’s terms and conditions (including reimbursement).

NCPA believes that not only is the Agency authorized to make these changes, they are obligated to do so in order to ensure that these types of arrangements do not result in increased costs to the federal government in violation of Soc. Sec. Act, sec. 1860D-4, subd. 4 (b)(B) and to ensure that Part D beneficiaries have adequate access to these potential cost savings arrangements.

The Part D program currently contains an “any willing pharmacy” provision along with a related provision that seems to allow subsets of pharmacies to offer reduced cost sharing so long as these arrangements do not result in an increase in payments made by the Secretary under section 1860D-15.

Soc. Sec. Act, sec. 1860D-4, subd. 4 (b)(A)

(b) Access to Covered Part D Drugs

(1) Assuring pharmacy access—

(A) Participation of any willing pharmacy—A prescription drug plan shall permit the participation of any willing pharmacy that meets the terms and conditions under the plan.

(B) Discounts allowed for network pharmacies—For covered Part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A) reduced coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. *In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D-15 to a plan.*

CMS has found that under this existing framework and in the absence of any further direction or guidance, in many cases these arrangements are resulting in increased costs to the federal government in violation of the Social Security Act. In addition, under this model, independent community pharmacies have been precluded from participation in these networks that offer preferred cost sharing (despite being willing to assume the terms of the contract), which restricts patient access to these potential cost savings.

In its proposed changes to the “preferred pharmacy” provisions along with the other proposed changes in the rule that would require all price concessions from pharmacies to be reported in negotiated prices, CMS is exercising its affirmative duty to ensure that all pharmacy networks in the Part D program are open to participation by all willing providers and that preferred pharmacy structures that offer reduced copayments to patients do not simply shift costs to the federal government in violation of the Social Security Act.

### **Interpretation of the non-interference provision related to negotiations between PDP sponsors and pharmacies and the any willing pharmacy provision**

NCPA believes strongly that the changes proposed by CMS with regard to pharmacy networks are consistent with the current CMS interpretation of the Non-Interference Provision that seeks to promote market competition by “decreasing the transaction cost of acquiring information on products offered in the market,



increasing the transparency of prices, ensuring a large number of buyers and sellers, and minimizing barriers to entry to the extent possible while ensuring quality.”

Congressional history provides that the Part D program was designed to be primarily driven by the operation of private market competition. NCPA agrees with the CMS interpretation of the role of the federal government in the Part D program as being tasked with promoting an efficient and competitive market for Part D drugs. It is NCPA’s belief that efficient and competitive markets are characterized by fully informed buyers and sellers who have access to all relevant data and contracting opportunities.

We further agree with CMS’ assessment that the non-interference provision was intended to address behavior surrounding the selection of drug products covered under Part D formularies and negotiations related to the selection of drug products that would be covered under Part D formularies –essentially the non-interference provision is intended to apply to negotiations between manufacturers and Medicare Part D plan sponsors.

It seems very unlikely that Congress intended the non-interference provision to be so broadly interpreted so as to allow behaviors that would prevent the Part D marketplace from operating in a fair and efficient fashion. The Part D program is indeed primarily based on the operation of the private marketplace and as such, even private markets are subject to varying degrees of regulation or operating parameters.

While CMS would be precluded from interceding in individual contractual disputes between PDP sponsors and pharmacies, as the steward of the Part D program they are responsible for establishing operational guidelines in order to ensure that beneficiaries have adequate access to pharmacy services and that the federal government is not shouldering additional costs due to the arrangements being set up between these entities.

In addition, it appears unlikely that the drafters of the Medicare Act intended to require that Congress step in to make operational adjustments to the program each and every time a problem arises in this area. CMS has the authority and the affirmative responsibility to make sure that the program is operating in the best interests of the Part D beneficiaries and the federal government. NCPA also recognizes that some stakeholders may point to the following highlighted language—“may not interfere with the negotiations *between drug manufacturer and pharmacies and PDP sponsors*” as proof that CMS may not intervene or provide guidance as to the arrangements between pharmacies and PDP sponsors.

However, NCPA strongly agrees with CMS that because there are no circumstances in which joint negotiations would occur among all three parties at the same time---manufacturers and pharmacies and PDP sponsors—that therefore the language is meant to be read or interpreted as “between drug manufacturers and pharmacies **OR** between drug manufacturers and PDP sponsors.”

NCPA believes that after evaluating all of the aforementioned considerations, that the non-interference clause of MMA does not prohibit CMS from establishing certain parameters around arrangements that PDP sponsors may enter into with pharmacies in the interest of maintaining an efficient and competitive private marketplace that adequately serves the needs of Medicare beneficiaries and allows the federal government to operate in a cost-effective manner. Also, NCPA believes strongly that by virtue of Medicare Part D being a taxpayer supported program, the current exclusionary pharmacy networks that exist in Part D are not what Congress intended.

### **Interpretation of the non-interference provision – related to access to pricing information**

The second part of the non-interference clause states that CMS “may not institute a price structure for the reimbursement of covered Part D drugs.” We agree with CMS’ interpretation that this particular section

would not allow CMS to prescribe or require that a specific pharmaceutical pricing benchmark or standard (whether published or non-published) be used—such as Average Wholesale Price (AWP), or Wholesale Acquisition Cost (WAC) or to require price concessions based on a price offered under another federal program (such as Medicaid).

We agree that CMS does have the authority to provide a definition of a pricing standard and accordingly provide parameters around how these pricing standards are made available to market participants. This type of activity is again consistent with the authority and the responsibility of CMS to pursue those activities that promote an efficient and competitive marketplace to ensure that market participants have the necessary information in order to make informed decisions about their own contracting activities and participation in the Part D program.

The current lack of a definition of “drug pricing standard,” and a single CMS-stated example of a drug pricing standard as one based on “published drug pricing,” has proved very troublesome. In today’s marketplace, reimbursement to pharmacies for virtually all generic drugs is based on “maximum allowable cost” pricing that is not based on *published* drug pricing but rather on a variety of different factors.

The Medicare Improvement for Patients and Providers Act (MIPPA) of 2008 made a number of significant changes to the Part D program including requiring the regular updating of prescription drug pricing standards. Later regulatory action required that sponsors’ contracts with downstream entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies and that a Part D sponsor pharmacy contract indicate the source used by the Part D sponsor for making any such pricing updates.

To date, PBMs have claimed that although MAC pricing is used to reimburse pharmacies for virtually all generic drugs, because it is not based on “published drug pricing,” it is therefore not a drug pricing standard and not required to be updated regularly. In order to ensure that critical Part D providers are paid appropriately for providing services to beneficiaries, it is essential that CMS expand upon their examples of what constitutes a “drug pricing standard.” It is also worth noting that the language of the proposed rule in no way requires a particular drug pricing standard be used and in fact includes the language, “including but not limited to” to account for any new pharmacy pricing methodologies that may emerge in the future.

### **Pharmacy Price Concessions in Negotiated Prices (§ 423.100)**

NCPA strongly agrees with the CMS findings and proposed changes outlined in this section. CMS states that because some Part D sponsors have been incorrectly reporting price concessions not as actual price concessions (that would have an effect on the negotiated price and plan bids) but rather in the DIR reporting mechanism this has produced a distortion in the treatment of costs that has significant effects on beneficiary cost sharing, CMS payments to plans, federal reinsurance and manufacturer coverage gap discount payments.

Because of the fact that these price concessions have been in many cases “mischaracterized” by plan sponsors, it has created a situation in which it is virtually impossible for the federal government/CMS and Part D beneficiaries alike to conduct a true “apples to apples” comparison of the many different part D plan options. In this section and elsewhere in this proposed rule, CMS speaks to their initial assumption with regard to the existence of preferred networks that there would be a natural alignment of cost savings among all participants in a particular Part D plan. In other words, the Part D plan that had the lowest prices—or the lowest cost to the federal government/CMS—would also have the lowest cost or lowest level of beneficiary cost sharing.

We agree that certain pharmacy price concessions that are essentially a “pay to play” cost for pharmacies to be able to participate in a certain network should not be allowed to be characterized as DIR but rather should be considered pharmacy price concessions as they are deducted from payments made to pharmacies for the purchases of Part D drugs and factored into the determination of “negotiated price.”

We agree with the proposed interpretation that states that negotiated prices are the amounts that a network pharmacy receives in total for covered Part D drugs and that these prices must reflect all price concessions from network pharmacies. Also, any other negotiated price concessions, such as discounts, direct or indirect subsidies, rebates and DIR referenced in the statute would be those price concessions offered by sources other than network pharmacies (or their contracting organizations). In practice, these “other negotiated price concessions” refers to those offered by prescription drug manufacturers.

We also agree with the CMS proposal that certain incentive payments to pharmacies such as generic dispensing rates should not be included in negotiated prices for a number of reasons. If these payments are included, the negotiated price would be higher at those pharmacies that are striving to provide an additional layer of efficiency and enhanced patient care services that could ultimately save money in overall health care spending. These types of incentive payments are really more appropriately characterized as contingent price increases that are not able to be accurately predicted before the point of sale or reflected in the data included under Plan Finder. We agree that these types of incentive payments should be excluded from the negotiated price and instead reported back in reconciliation DIR.

However, this issue does present a concern that NCPA has regarding certain types of incentive payments that may be offered to pharmacies. Obviously, incentives offered for increased generic dispensing are ones that could potentially be met by all pharmacies. NCPA has concerns that plans/PBMs may attempt to “offer” various incentive payments for activities or pharmacy characteristics that only a very small subset of pharmacies can comply with or only related entity pharmacies could reasonably comply with.

For example, a plan may offer a pharmacy incentive payment based on a pharmacy being open for 24 hours or operating an urgent care center on the premises. Both of these activities or services would be virtually impossible for small, independent pharmacies to comply with and obviously are tailored to large pharmacy chains or publicly traded companies. Also, although these example activities provide convenience, they do not have any direct impact on either proper medication use or cost savings on Part D drugs.

To ensure that this is not an area that will produce distortions in the market, NCPA recommends that CMS specify that in order to be excluded from the negotiated price, pharmacy incentive payments must be associated with activities that all pharmacies could reasonably comply with. Conversely, pharmacy incentive payments that are tailored to meet the operating structure or parameters of a certain type of pharmacy (chain)/related-entity pharmacy and not related to proper medication use or cost savings must be included in negotiated price.

### **Preferred Cost Sharing (§ 423.100 and § 423.120)**

Moving forward, CMS proposes to allow different levels of cost but seeks to provide further clarity that any “preferred” or lower cost sharing should be aligned with lower costs across the board—for Part D plan and other government subsidy costs. CMS in this proposed rule therefore will allow preferred cost sharing as long as “such preferred cost sharing is offered in accordance with 423.120(a)(8) and for Part D drugs with consistently lower negotiated prices than the same drugs obtained in the rest of the pharmacy network.” CMS clarifies that sponsors must offer beneficiaries and the Part D program lower negotiated prices on all drugs in return for the lower cost sharing and that essentially whatever pricing standard is used to reimburse

drugs purchased from network pharmacies in general, that a lower pricing standard must be offered at the preferred level of cost sharing.

NCPA believes strongly that any new cost sharing provisions or parameters should require plan sponsors to provide providers and patients the greatest degree of transparency as possible regarding the various cost sharing options so that these participants in the Part D program have the necessary information in order to compare plan offerings and make informed decisions about the effects of their choices.

NCPA would also like to provide comment on the following proposed regulatory language in this section:

(iii) Must offer payment terms for every level of cost sharing offered under the sponsor’s plans consistent with CMS limitations on the number and type of cost sharing levels (preferred, standard, extended day), and for every type of *similarly situated retail pharmacy*.

It is unclear what is meant by “similarly situated retail pharmacy.” In examining past CMS guidance and materials, this term has always been used to distinguish or delineate between pharmacies based on geographic location for the purposes of ensuring access. It may be helpful for CMS to provide further confirmation regarding their intended meaning of this term. Unless the intended meaning of this term is provided, it is possible that plan sponsors may attempt to use the term “similarly situated” as a term to delineate between retail pharmacies based on a wide variety of variables including publicly traded vs. independent or ability to meet certain operational considerations such as extended hours or drive-through capabilities and offer different payment terms for cost sharing levels based on these factors. We believe these characterizations would be counter to the overall intent of this section.

(iv) Must contract with any willing pharmacy able to meet *one set of the terms and conditions* offered by that plan for that type of pharmacy

NCPA further recommends that additional guidance be given around what is meant by “terms and conditions” in this context. It is possible that certain plan sponsors will attempt to establish “terms and conditions” in such a way that in practice could exclude pharmacies that are able to meet the pricing parameters but may be operationally unable to comply with other extraneous requirements based on operational capabilities such as 24-hour operating hours or the inclusion of an on-site clinic—factors that most, if not all, independently owned pharmacies would be unable to comply with. NCPA would recommend that perhaps CMS could amend this provision to read: “one set of **PRICING** terms and conditions.” Alternately, CMS could provide general language that would instruct plans that the “terms and conditions” specified for each cost sharing tier may not include any specific requirements not related to pricing that would require certain pharmacy operating procedures or the provision of any related services.

### **Prescription Drug Pricing Standards and Maximum Allowable Cost (§ 423.505(b)(21))**

Section 173 of MIPPA amended sections 1860D(12)(b) and 1857(f)(3) requiring the regular updating of prescription drug pricing standards. Later regulatory action required that sponsors’ contracts with downstream entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies and that a Part D sponsor pharmacy contract indicate the source used by the Part D sponsor for making any such pricing updates. However, one element that has been missing until the release of this proposed rule is an actual definition of “prescription drug pricing standard.” Instead, CMS provided examples of different types of drug pricing standards or benchmarks such as “wholesale acquisition cost, average manufacturer price and average sales price” and described these as “an accepted methodology based on published drug pricing.”

Based on the absence of an actual definition of “prescription drug pricing standard” and the description that references “methodology based on *published* drug pricing,” Part D sponsors/PBMs have asserted that because maximum allowable cost (MAC) pricing is not strictly based on a published benchmark but rather is based on a combination of factors, it is not a drug pricing standard and therefore not subject to the mandatory pricing updates and the disclosure of the “source” used by the Part D sponsor/PBM for making any such pricing updates.

NCPA is very encouraged by the inclusion in this proposed rule the clarification that MAC pricing is considered a “drug pricing standard”:

*“Any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of the drug, which includes, but is not limited to, drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufacturer price, average sales price, maximum allowable cost (MAC) or other costs, whether publicly available or not.”*

As noted in the proposed rule, there currently 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, Plan sponsors 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 PBM or plan sponsor 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.

Therefore, NCPA strongly agrees with the provision that CMS seeks to include in the rule that would require the PBM or plan sponsor to disclose the MAC prices before the changed prices can actually be used to reimburse the contracted pharmacies. PBM interests will argue that this will be extremely difficult to do given the fact that by the time they are able to disclose the new price(s) to the contracted network pharmacies—the price may have already changed again. It may be helpful to explain our understanding of how MAC prices are generally arrived at by the PBMs or plan sponsors.

Typically, a PBM will use one or several published pharmacy pricing benchmarks as a starting point or reference point and then employ an algorithm to arrive at the actual MAC price or prices on a list. Also, PBMs are known to vary the MAC pricing “formula” in certain ways in order to arrive either at an “aggressive” MAC pricing list or more reasonable or favorable version. Certainly it would be helpful for a PBM or plan sponsor to disclose a sample MAC list to a pharmacy prior to the signing of the contract and also disclose which published pharmacy benchmarks are used or referenced in arriving at the actual MAC pricing.

Given the nature of MAC pricing itself, such disclosures would not necessarily be definitive but would give the pharmacy an idea of the type of MAC pricing formula that would be used. This in tandem with the mandatory updating of the MAC pricing would ensure that pharmacies have some idea about the terms of the contract with regard to reimbursement for multi-source drugs and that they do not find themselves in a situation in which they are being reimbursed below cost for Part D drugs. NCPA is also very supportive of the inclusion of the phrase “includes but is not limited to” in the definition of a pricing standard. It is critical that the rule does not preclude any new or emerging pricing standards that may be used by PBMs at some point in the future.

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 spikes in the prices 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 Part D beneficiaries. In order to ensure a fair and competitive marketplace and to ensure that pharmacy providers are reimbursed fairly for providing medications to Part D beneficiaries, it is critical that this issue is addressed.

NCPA believes that CMS should also define the requirements for when a drug may be placed on a MAC list and require that sponsors disclose the methodology and sources used to determine MAC prices. Finally, it is critical that a MAC appeals process be implemented that would enable a pharmacy provider to contest a stated MAC price in circumstances in which he or she is being reimbursed below the acquisition cost of the drug. NCPA also recommends that MAC lists be provided to pharmacies in an excel spreadsheet or other similar “usable” format so that they could be downloaded for adequate analysis.

### **Any Willing Pharmacy Standard Terms & Conditions (§ 423.120(a)(8))**

NCPA is strongly supportive of allowing network participation by any willing pharmacy able to meet either the standard or preferred cost sharing rate terms and conditions and the extended days’ supply addendum. To date, independent community pharmacies have not been afforded the opportunity to participate in the vast majority of preferred pharmacy networks in the Part D program. Instead, they have been relegated to participation only in the broader, standard network, at the highest level of beneficiary cost sharing. In this way, many Part D beneficiaries have been forced away from their pharmacy of choice due to large co-pay differentials in spite of the fact that their pharmacy of choice was in fact, ready and willing to accept the terms and conditions of the preferred pharmacy network.

Also, many NCPA member pharmacies have numerous examples in which elderly beneficiaries have been forced to drive long distances to utilize a “preferred” pharmacy which raises significant access issues. Effectively, pharmacies that wish to participate in these limited networks must agree to charge no more than the contract’s ceiling price to qualify for offering the lower preferred cost sharing.

Undoubtedly, certain plan sponsors or entities that are currently offering these “preferred” or exclusionary network arrangements will argue that the current structure provides significant cost savings to beneficiaries that will be compromised by the proposed changes. However, we are encouraged to note that CMS has noticed, as we have as well, that these preferred networks currently do not demonstrate consistent savings.

According to a cost comparison using the Medicare Plan Finder website, NCPA found that many times the Medicare Part D program and taxpayers often pay more when prescription drugs are obtained through “preferred pharmacy” networks and mail order pharmacies than they would if the same prescriptions were filled through other “non-preferred” pharmacies.

NCPA staff chose one commonly purchased PDP, the AARP Medicare Preferred drug plan and entered into Plan Finder four of the most-prescribed drugs; generic version of Lipitor—atorvastatin calcium Tab 20 mg 90-day supply; generic version of Plavix—clopidogrel 75 mg 90-day supply; Diovan 80 mg 90-day supply; and Nexium Capsule 40 mg 90 day supply. The costs were then compared between preferred, mail order and non-preferred pharmacies in nine cities across the country. According to the NCPA analysis:

- 89 percent of the time, preferred pharmacy costs to Medicare were higher than those of non-preferred pharmacies;

- 100 percent of the time, mail order costs to Medicare exceeded those of non-preferred pharmacies.

NCPA also conducted another analysis using CMS plan finder data that examined six PDP plans that have both a preferred network plan option (where preferred pharmacies have preference to network pharmacies) and an open network plan option (where all pharmacies are equally preferred). Within each PDP, NCPA compared costs to Medicare and costs to the consumer for both plan options, allowing for a comparison of whether preferred network plans have equal or lower cost to open network plans.

The analysis was conducted in six states using a “market basket” of commonly prescribed medications used for the following conditions: osteoporosis, high blood pressure, high cholesterol and diabetes Type II. NCPA collected data using the Medicare Plan Finder web site that was established to help seniors evaluate and choose a drug plan. Furthermore, NCPA accounted for deductibles and yearly premiums associated with each plan option.

NCPA analysis shows that:

- In 9 out of 13 instances Medicare paid more for preferred network plan options than for open network plan options.
- In 11 out of 13 cases the consumer paid more for open network plan options than for preferred network plan options.
- In 6 out of 13 instances preferred network plan options had higher total cost.

The analysis clearly shows that lower overall costs that may attract beneficiaries to preferred network plans are paid for by shifting costs to Medicare and taxpayers. By law, Medicare costs associated with a preferred network plan must not exceed cost associated with a comparable open network plan. **[For additional detail and results please see Attachment #2]**

Undoubtedly those business entities that have reaped significant profits under the current exclusionary “preferred network” system will claim that the proposed changes to open networks to any willing pharmacies will result in increased prices.

NCPA has retained the services of an antitrust economist who has prepared a detailed economic analysis of this issue which we have attached with our comments. Essentially the attached study will demonstrate contrary to what opponents to the rule have claimed, that CMS’ proposed “any willing pharmacy” provision may reduce or leave drug prices unchanged. **[Please refer to Attachment #3]**

Also, we are encouraged to note that CMS feels that those “preferred cost sharing” pharmacies that are permitted to offer the greatest level of beneficiary cost sharing savings should also be less expensive to the plan and to the federal government itself. Therefore we agree with the approach that would require each plan sponsor that offers both standard and preferred cost sharing under any of its benefit packages to provide in its contracts for network retail pharmacies not only the terms and conditions for standard cost sharing but also the terms and conditions for preferred cost sharing ---stating the negotiated pricing levels that must be agreed upon to qualify for offering the preferred cost sharing. We also agree that retail pharmacies would have to choose to participate in either the standard terms and conditions or the preferred cost sharing terms and conditions—but not both.

NCPA requests clarification in this section of the proposed rule for the following item.

1. In the proposed rule, CMS states:

*Sponsors could not offer preferred cost sharing for higher negotiated prices than the ceiling price listed in the T & C, but would be free to negotiate even deeper discounts from individual pharmacies in the limited network.*

NCPA is concerned that the italicized portion above could mean that individual pharmacies participating under preferred cost sharing terms and conditions could be allowed to provide even deeper discounts to plans and lower copayments to beneficiaries. If so, NCPA is concerned that this would simply result in creating an additional sub-network of pharmacies, thereby replicating the issues that CMS is trying to remedy with this proposed rule in terms of eliminating barriers to access and increased costs to the Medicare program.

### **Specialty Pharmacy/Specialty Drugs as a Potential Area of Concern**

NCPA encourages CMS to carefully consider the issue of “specialty pharmacy” or specialty drugs during the deliberation of this rule. Specialty pharmaceuticals are the fastest growing segment of the pharmaceutical industry as a whole and are generally defined as high-cost medications that treat complex conditions and typically require special handling or administration.

According to many health care insiders, specialty drugs are poised for a long run of expansion and increased utilization. It has been estimated that specialty drugs will account for the majority of new drug approvals in coming years and will consume approximately 40% of a health plan’s drug spending by 2020.<sup>7</sup> In spite of these expected quantum leaps in specialty drug utilization, there is no standardized industry definition of what constitutes a specialty drug.

At the present time, CMS simply makes reference to “specialty tier” medications –those medications that have a monthly cost of \$600 or more. The lack of a clear and workable definition has created a situation in which Pharmacy Benefit Managers (PBMs) are able to label virtually any high- cost medication as a “specialty drug” and insist that these drugs be directed to the PBM-owned mail order pharmacy.

NCPA is concerned that in light of the new CMS interpretation of “any willing pharmacy” that would presumably prevent Part D plan sponsors and PBMs from constructing exclusionary pharmacy networks in order to maximize their own profits, that these entities will make further use of the specialty arena to prevent all willing pharmacies from providing these high cost medications to patients.

While it is true that many, if not most, specialty medications are expensive, cost should not be the only deciding factor when considering whether a particular drug is truly a “specialty” drug or not. If any willing pharmacy will be allowed the opportunity to participate in cost sharing networks—it seems probable that PBMs and plan sponsors will shift even more drugs into a “specialty category” and then require that these drugs only be dispensed in “specialty pharmacy networks” or through the PBM-owned mail order specialty pharmacy.

NCPA would encourage that CMS consider stipulating or providing a more detailed definition of “specialty drug” than simply referring to the specialty tier drugs. It should be noted that this is an issue of concern that exists in all federally supported prescription drug programs and that a comprehensive look at this issue is warranted.

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<sup>7</sup> Specialty Pharmacy Whitepaper, URAC 2011.



### **Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))**

NCPA is supportive of CMS' proposal to require physicians and eligible professionals enroll in the Medicare program in order to prescribe covered Part D drugs. As was the case with implementation of the requirement that every PDE record contain NPIs, NCPA expects there may be implementation challenges of this new requirement at point-of-sale. For that reason, we would ask that CMS delay implementation of this requirement until such time that data elements can support validations of this information at point-of-sale in a pharmacy. Systems must be in place to allow for real-time reporting of prescriber information to the pharmacy from the plan sponsor/PBM. Until these systems are in place and adequately tested, pharmacies should not be responsible for prescriptions filled that are based on information they receive that may be in error.

Related to CMS' solicitation of comments on whether pharmacies should enroll or maintain enrollments in the Medicare FFS program in order to dispense covered Part D drugs, NCPA is opposed to any such requirement at this time. Instead, NCPA asks that CMS take the appropriate step-wise approach, as outlined in this proposed rule, by requiring all prescribers to maintain enrollments or valid opt-outs. Currently, Part D plan sponsors/PBMs perform their own internal verifications before allowing pharmacies to participate in their networks.

There is a very large expense for small business independent pharmacies to be enrolled in the Medicare FFS program, including application fees and screening requirements, in addition to the associated administrative burden. Requiring pharmacies to enroll may prove disruptive to patient care, as the process is lengthy. NCPA estimates that many independent pharmacies would be impacted by this change, as many of our members do not process FFS claims, but would need to enroll in order to process Part D claims only. If a pharmacy is inactive in the Medicare FFS program they would be dis-enrolled and have to go through the reenrollment process all over again in order to participate in the Part D program, thus leading to additional costs, burdens and impact to patient care.

### **Improper Prescribing Practices (§ 424.535)**

NCPA stands in strong support of proposed provisions that would give CMS the authority to deny a physician or eligible professional's Medicare enrollment application based on specific circumstances as well as the authority to revoke a physician or eligible professional's Medicare enrollment. We also support CMS' proposal to revoke enrollment if there is a pattern or practice of prescribing Part D drugs that is abusive and represents a threat or fails to meet Medicare requirements.

### **Broadening the Release of Part D Data (§ 423.505)**

In general, NCPA is supportive of the proposed regulation that would broaden the release of Part D data. Releasing unencrypted prescriber, plan and pharmacy identifiers to external entities can provide needed detail and clarity about the overall quality of healthcare services being provided and enable legitimate researchers to bring greater transparency to the overall process.

The increased availability of this type of data will enable CMS and other outside researchers to conduct in-depth comparisons of medications provided through different outlets, which could enable CMS to take proactive measures to impact cost savings. NCPA believes that the factors that CMS is proposing in order to mitigate any concerns regarding access to potentially sensitive data including minimum necessary, legitimate researcher and aggregation policies are sufficient to provide some common sense parameters for the release of this type of data.

## **MA-PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§422.112)**

NCPA supports CMS' efforts to ensure that Part D drug benefits and drug benefits under Part A and B should be coordinated by MA organizations offering MA-PDs so that enrollees receive timely access to medications. We support CMS requiring MA-PDs to establish adequate messaging and processing requirements with network pharmacies to ensure that payment is assigned at point-of-sale and when coverage is denied under Part D, such Part A or B coverage is authorized in a timely manner.

NCPA has historically opposed mandating additional beneficiary-level prior authorization requirements for the categories of Hospice and ESRD drugs. Previous proposals to require prior authorizations for vast quantities of drugs are overwhelming on the pharmacy. The drastic increase in drugs subject to prior authorizations would certainly lead to beneficiary confusion, undue burden on community pharmacies, and delays in care to Medicare's frailest and most vulnerable populations. We have concerns that within the prior authorization process the patient isn't notified of the delay, the cause for the delay, or an estimated time when they may receive their medications.

Community pharmacists are placed in the situation of denying the patient their vital medication. Problems with prior authorizations also include the fact there are no instructions as to when these drugs would not require prior authorizations, such as when a beneficiary was no longer in hospice care. NCPA supports the Part D sponsor recovering payment from the responsible party without involving the pharmacy. NCPA greatly appreciates CMS clearly stating that payment recovery should occur without recouping funds from the pharmacy or requiring the pharmacy to reverse the original claim when the plan discovers that a claim was incorrectly adjudicated. To ensure claims are billed to the correct Medicare program, appropriate tools providing real-time access to all beneficiaries' Medicare eligibility information are needed.

### **Conclusion**

As you finalize plans for release of the 2015 Final Rule for the Medicare Part C and Part D programs, NCPA respectfully urges you to consider these issues. We appreciate the opportunity to share our concerns and recommendations with you.

Sincerely,



Steve Pfister  
Senior Vice President, Government Affairs

### **Attachment(s)**

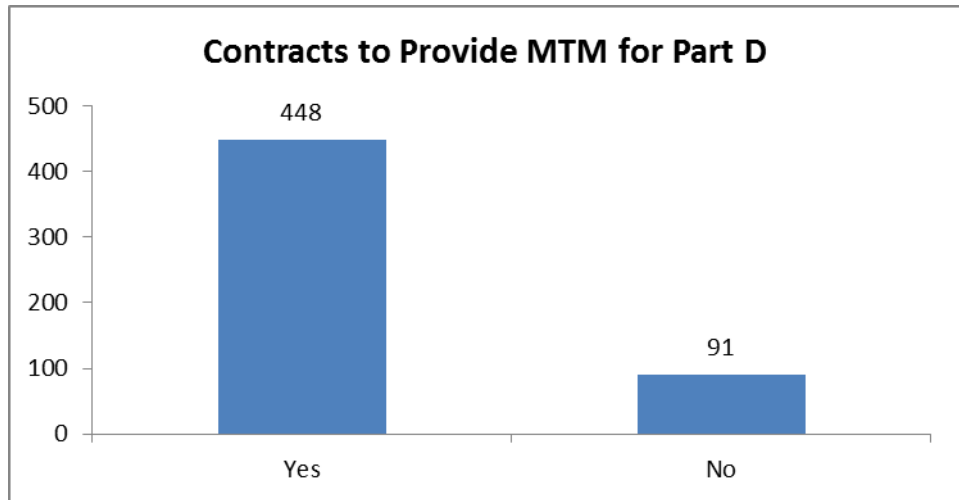
- 1. NCPA Survey on MTM, conducted February 2014**
- 2. NCPA Analysis on Open vs. Preferred Networks and costs to federal government, consumer and total costs**
- 3. MiCRA Analysis on Any Willing Pharmacy**

## Attachment 1: NCPA Member Survey on Medication Therapy Management (MTM)

The survey was conducted in February 2014, and received a total of 539 responses. The second half of the survey focused specifically on MTM conducted in long-term care settings.

Do you have contracts to provide MTM for Part D beneficiaries?

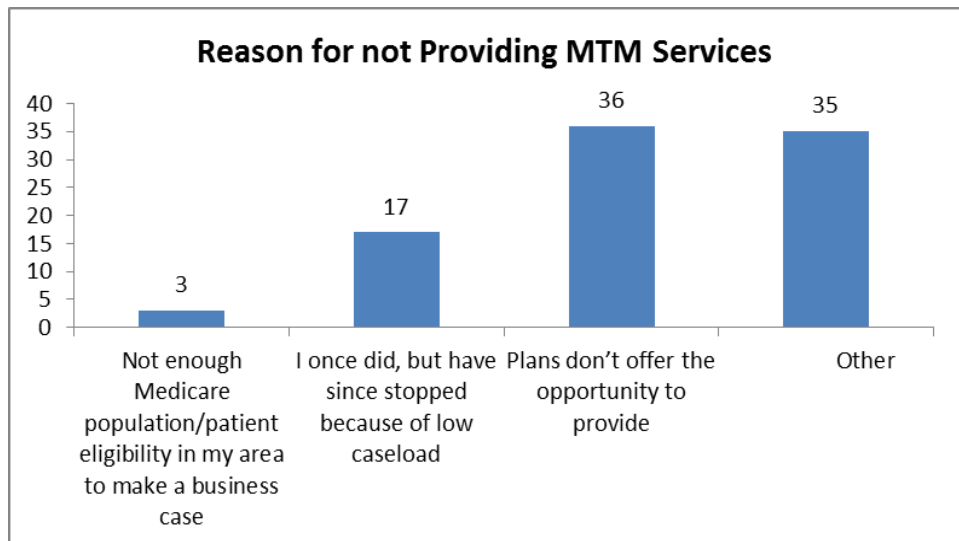
83% (448 out of 539) of survey respondents have contracts to provide MTM for Part D beneficiaries.



Why do you choose not to provide MTM for Part D beneficiaries?

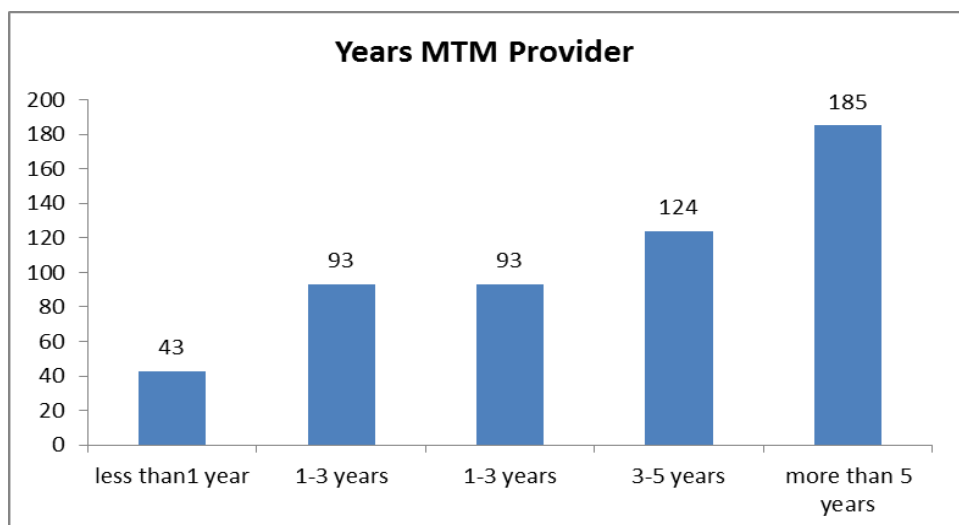
Of those who indicated they do NOT offer MTM for Part D beneficiaries, 78% (71 out of 91) say it is due to lack of opportunity from plans or another reason.

22% (20 out of 91) do not offer MTM because of lack of patient population or caseload opportunities.



How long have you been a Part D MTM provider?

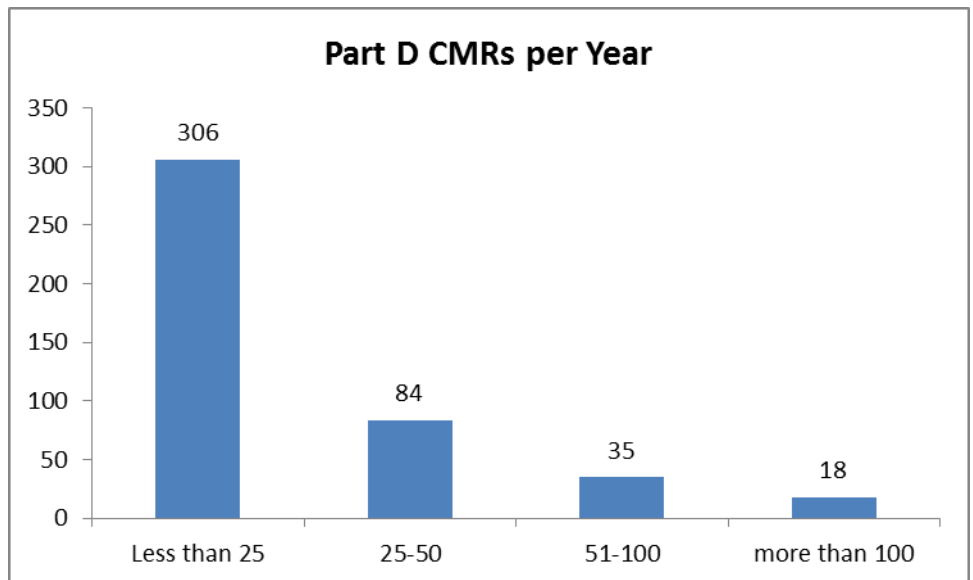
57% (309 out of 538) of respondents have been a Part D MTM provider for 3 or more years



On average how many Part D CMRs are being conducted by your pharmacy per year?

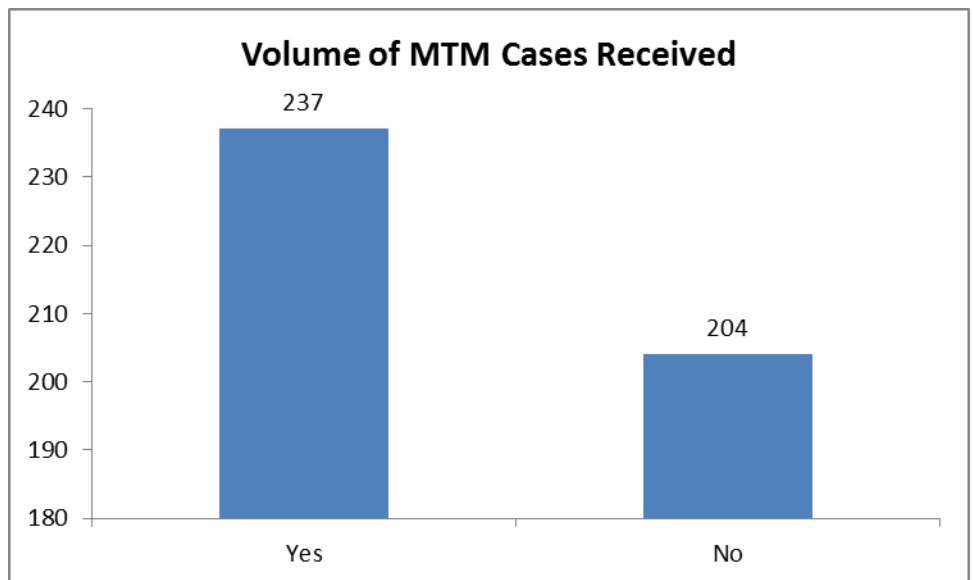
69% conduct less than 25 CMRs annually

31% conduct more than 25 CMRs per year



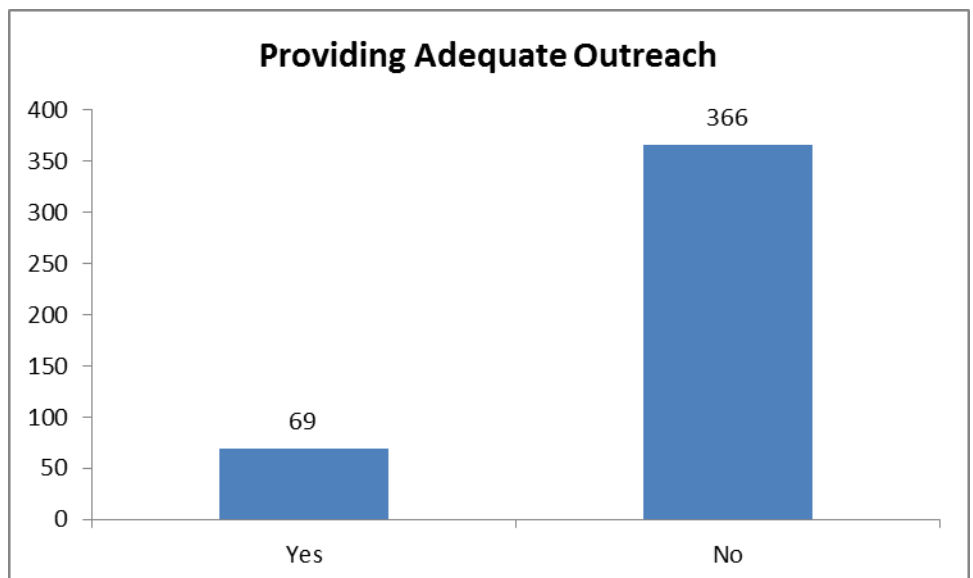
Have you noticed any changes in the volume of MTM cases you've received?

54% of respondents noticed changes in the volume of MTM cases they have received.



Do you feel plan sponsors are providing adequate outreach to beneficiaries regarding their MTM benefit?

84% do NOT feel plan sponsors are providing adequate outreach to beneficiaries regarding their MTM benefit.

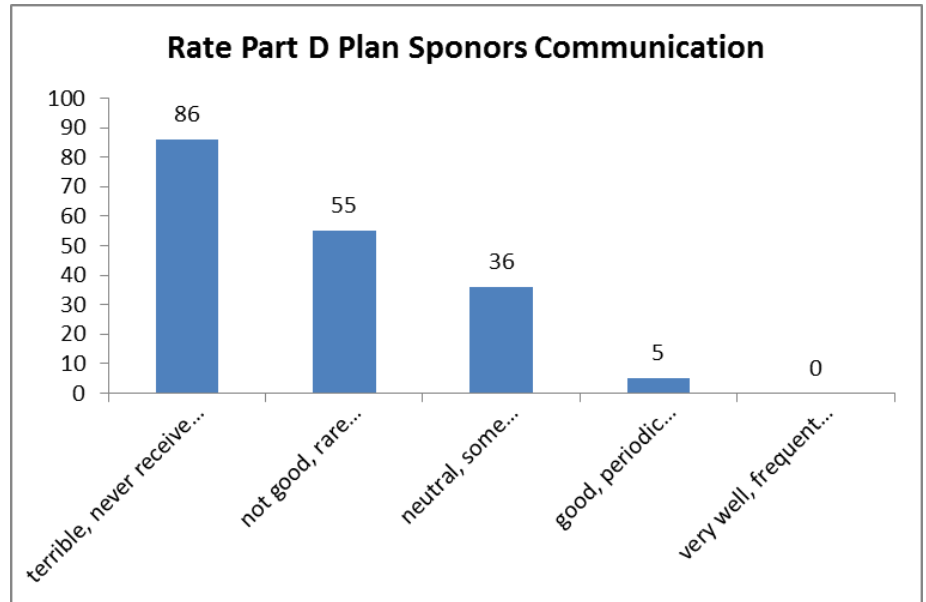


## Long-Term Care Specific Questions

On a scale of 1-5, how well do you feel Part D plan sponsors have communicated and/or implemented the new CMR requirements for LTC since January 1, 2013?

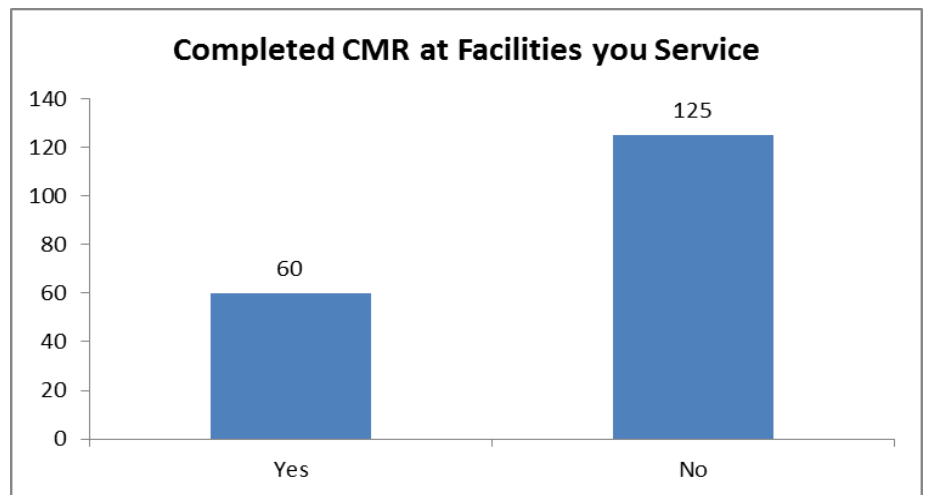
Of the 182 respondents who offer long-term care, 77% do NOT feel plan sponsors have communicated and/or implemented the new CMR requirements for LTC, while only 3% feel they have.

20% are neutral.



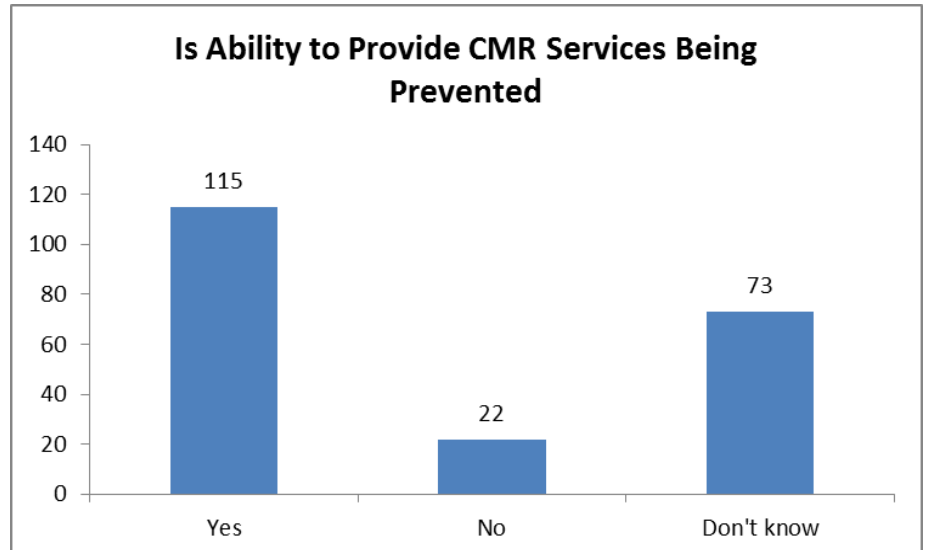
Have you seen CMRs being completed at the facilities you service?

68% have NOT seen CMRs being completed at the facilities they service, while only 32% have.



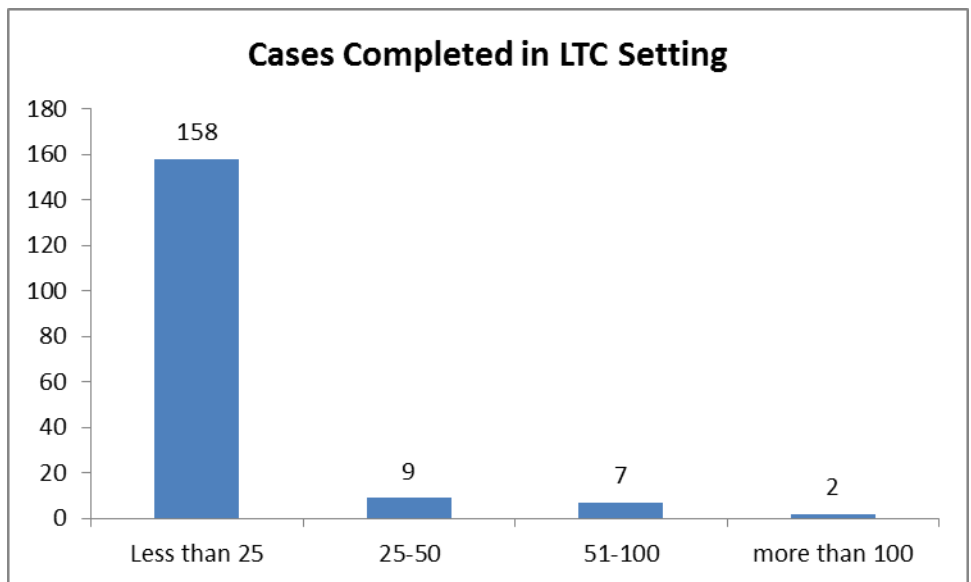
If not seeing cases, do you feel your ability to provide CMR services are being prevented by any third party offering these services (i.e. sponsor call centers)?

55% feel their ability to provide CMR services is being prevented by any third party offering these services (i.e. sponsor call centers), while 35% were not sure. 10% do not feel their ability is being prevented.



How many cases would you estimate have been completed in the LTC setting in 2013?

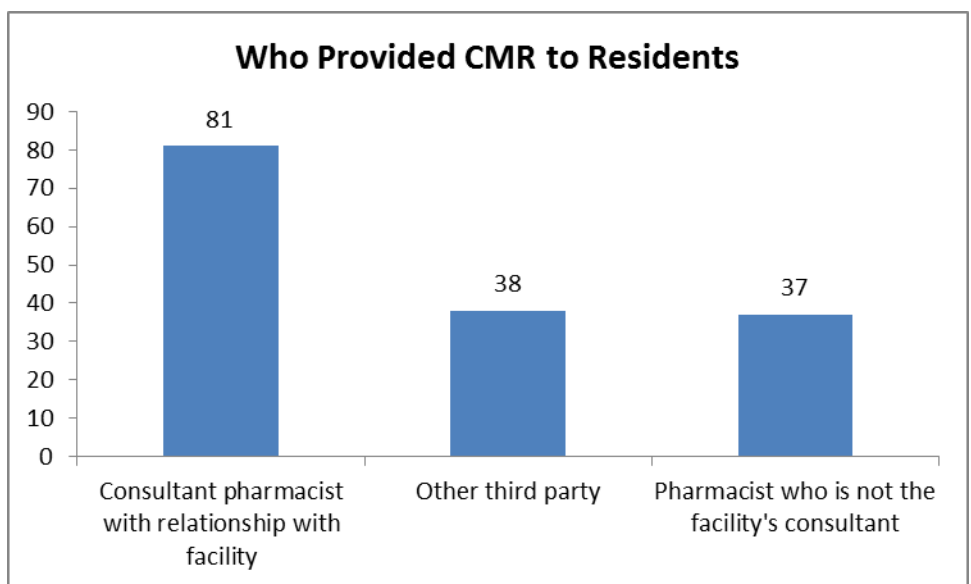
90% estimate that less than 25 cases have been completed in the LTC setting in 2013.



Who have you generally observed providing the CMR to residents?

52% (81 out of 156) observe a consultant pharmacist with relationship to the facility provide CMR to residents.

24% observe other third parties, and 24% observe pharmacists who are NOT the facility's consultant, providing the CMR.



Have you observed coordination amongst MTM providers and other health professionals in the facility in relation to the results and recommendations from the CMR and the monthly drug regimen reviews (DRR)?

29% have observed coordination amongst MTM providers and other health professionals in the facility in relation to the results and recommendations from the CMR and the monthly drug regimen reviews (DRR), while 71% have not.

