

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

December 8, 2009

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4085-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

***Re: CMS-4085-P: Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule***

Dear Sir or Madam:

Thank you for the opportunity to submit our comments regarding proposed revisions to the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D). As the Centers for Medicare & Medicaid Services (CMS) considers issues pertinent to these programs, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives. NCPA represents America's community pharmacists, including the owners of more than 22,700 independent community pharmacies, pharmacy franchises, and chains. Together they represent an \$88 billion health-care marketplace, employ over 65,000 pharmacists, and dispense over 40% of all retail prescriptions.

Independent community pharmacists have worked extremely hard over the past 4 years to ensure the success of the Medicare Part D program and to make sure their patients understand how to best navigate the oftentimes overwhelming aspects of a multitude of Part D plan offerings. Indeed, Department of Health and Human Services Secretary Mike Leavitt publicly stated in late January, 2006, that the efforts of pharmacists was "nothing short of heroic."<sup>1</sup>

NCPA remains committed to ensuring that their patients receive the best possible Part D coverage and care, and believes that community pharmacists have a great responsibility to inform CMS when program requirements have -- or proposed requirements will have -- problematic impact upon the delivery of Part D services.

NCPA strongly supports CMS in its efforts to implement many of the provisions of the new regulations and also the 2010 Call Letter that are designed to simplify the program for beneficiaries and allow them to make better plan choices. We further support regulations that improve payment rules and processes and promote transparency in the marketplace and help

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<sup>1</sup> *America's Pharmacist*, Volume 128, No. 4 (ISSN 1093-5401, USPS 535-410), pp. 9-10.

to make the Medicare program more efficient without sacrificing patient care. To that end, NCPA offers comments and insights into the effects of the following proposed provisions upon the ability of independent community pharmacies and pharmacists to continue to provide quality health care services to their patients.

**I. Compliance Programs Under Parts C and D, II.A.5. at 54643, (Fraud, Waste and Abuse), § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) at 54721 – 54722**

While NCPA supports efforts to curb fraud, waste, and abuse in healthcare programs, we question the need for training and education requirements for pharmacists and pharmacy staff that pose undue burdens on the ability of independent pharmacists to best serve their patients.

First, NCPA requests that any application of training for fraud, waste, and abuse to Medicare Advantage organization's first tier, downstream, and related entities that is deemed to be redundant of the certification made when these entities submit enrollment applications to become Medicare physician and non-physician practitioners, institutional providers, and suppliers, also be deemed to be redundant in relation to the downstream entities of Part D sponsors.

Pharmacies who enroll as DMEPOS suppliers in the Medicare Part B program certify to having read and understood the *Penalties for Falsifying Information* contained in the CMS 855S enrollment application. NCPA asserts that the substance of the 855S section is identical to the application used by physicians, institutional providers, and clinics and group practices to enroll in original Medicare. Therefore, the exemption CMS proposes for MA organizations' downstream entities should be applied to a pharmacy contracting with Part D sponsors if the pharmacy has provided similar certification during the Part B enrollment process.

Second, if CMS will not extend the exemption for MA organization's downstream entities to pharmacies contracting with Part D sponsors, the need for multiple trainings as now stated should be eliminated by CMS. NCPA appreciates CMS's recognition that pharmacies are contracting with multiple plans and should not have to complete duplicative training. However, we continue to be concerned that sponsors developing their own training modules may require pharmacies complete their specific program.

To best rephrase the existing language to clarify that duplicative training must be avoided while still meeting the requirement NCPA requests that CMS include language in regulation permitting downstream entities to adopt a FWA training program that meets CMS guidelines without intervention of plan sponsors. NCPA supports the concept of pharmacies providing "assurance" to plan sponsors that requirements have been met and suggests the use of an industry-accepted attestation form that could be kept on file at the pharmacy and/or submitted to plans as part of the contracting process.

In addition, we urge CMS to issue a guidance stating that a training program will be deemed as satisfactory if it contains the following elements identified in the August 2009 CMS memorandum on fraud, waste and abuse training:

- Laws and regulations related to MA and Part D fraud, waste and abuse (i.e., False Claims Act, Anti-Kickback statute, HIPAA, etc.)
- Obligations of the first tier downstream, and related entities to have appropriate policies and procedures to address fraud, waste, and abuse
- Process for reporting to the MAO or PDP sponsor suspected fraud, waste and abuse in first tier, downstream, and related entities
- Protections for employees of first tier, downstream, and related entities who report suspected fraud, waste and abuse
- Types of fraud, waste and abuse that can occur in first tier, downstream, and related entities

Lastly, NCPA requests that FWA training and education should be required one-time only unless changes in the laws and regulations related to FWA are significantly changed. We believe that time spent training pharmacists and their staff on an annual basis could be better applied to the direct provision of patient care in the pharmacy setting.

**II. Beneficiary Communications Materials Under Parts C and D, II.B.2. at 54655, § 422.2260, 422.2262, 423.2260 and 423.2262 at 54725-54726**

CMS proposes to eliminate “plan notification materials that are often either situational materials or beneficiary specific customized communications” from the definition of “marketing materials”, in order to “streamline the review and approval of beneficiary communication notices to current members.”

While NCPA supports efforts to sensibly simplify the Part D program, NCPA urges CMS to ensure that these types of “non-marketing” communications -- particularly Part D explanations of benefits (EOBs) and other one-time or situational, beneficiary specific letters to current enrollees -- clearly not steer patients toward certain pharmacies or mail order prescription services.

In our October 30, 2009, response to CMS’s request for comments to its mail order model letter (*NCPA response letter attached*), we objected to considerable leeway given in the model letter to allow plans to state their beliefs that mail order is more convenient, is a value-added service, and saves money. In order to ensure a level playing field between retail community pharmacy and mail order operations, NCPA believes that any communication that is placed outside of the “marketing communications” category must still clearly not promote mail order beyond stating that mail order is one of many options available for the beneficiaries’ consideration, as is retail pharmacy.

Provider choice is a key component of the Medicare Part D program. In order to make that choice meaningful, beneficiary communications should inform beneficiaries of their rights, including informing them of options that are available at both mail and retail, such as a 90 day supply of medications, without steering them toward mail order.

### **III. Maximum Allowable Cost Sharing Amount for Medicare Parts A and B Services and Prescription Drugs, II.B.6. at 54657, § 422.100, § 423.104 at 54728**

Part D plans may offer zero cost prescription co-pays in various manners. Examples are plans that offer zero cost co-pays for generics, while some plans only offer zero cost co-pays to beneficiaries that order an extended (90-day) supply of generics via mail order. In fact, NCPA has received numerous calls from our members of recent regarding certain plans that are offering long-term generic drugs via mail order at zero co-pay, leaving their long-time patients with a tough choice to make when they are accustomed to receiving pharmacy services from their independent pharmacist and want to continue to do so. These cost sharing structures are discriminatory against those who want to continue to utilize valuable services offered by their independent pharmacist. In general, offering a zero co-pay structure for prescriptions delivered via mail order creates an intra-plan discriminatory structure steering the beneficiary away from retail pharmacies. Offering the zero co-pay at mail order can lead to an imbalance of higher co-pay costs at a retail pharmacy.

NCPA asserts that the allowance of preferred pharmacy networks, especially those that offer patients lower cost-sharing and co-pays can have the effect of steering patients to these pharmacies and stifling competition. Further, when these pharmacies (whether mail order or retail) are owned by the pharmacy benefit manager (PBM) that administers the plan, the PBM is reaping the benefits of self-dealing by artificially manipulating the incentives faced by patients and plan sponsors. In such situations a strong conflict of interest occurs in that the pharmacy benefit manager is able to not only set prices for their pharmacy operations where the PBM has a direct financial interest at stake; but the PBM is also able to set the prices that must be paid for using a non-preferred retail pharmacy that is in competition with PBM owned pharmacies for patients. PBMs are the only companies that have the anticompetitive power to set prices for their rivals, thereby preventing competition that benefits patients and health plans.

There has never been a single peer-reviewed study demonstrating the potential for savings from mandating or incentivizing the use of a pharmacy that is owned by a PBM. NCPA has collected numerous letters from Medicare patients, whom have complained that after being forced by CVS Caremark to utilize a CVS pharmacy, they found themselves paying more than they previously had to pay at their local independent community pharmacy. Other studies have demonstrated that incentivizing the use of mail order is simply a way of shifting higher costs onto the health plan,<sup>2</sup> while another study has demonstrated that the conflict of interest

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<sup>2</sup> Norman V. Carroll; Ilia Brusilovsky; Bryan York; Robert Oscar. "Comparison of Costs of Community and Mail Service Pharmacy." *Journal of the American Pharmacists Association*, June 2005.

inherit with PBMs owning mail order pharmacies leads to higher health care costs due to reduced generic utilization.<sup>3</sup>

Not only does mandating and steering patients to a pharmacy owned by a PBM stifle competition, but research shows that inadequate utilization of medication, including waste and poor adherence, costs our health system \$290 billion annually.<sup>4</sup> Steps to minimize prescription drug waste include providing patients access to their preferred choice of pharmacy for acquiring prescription drugs. When patients receive their prescriptions via mail order, waste can abound. One study has demonstrated that mandatory mail order prescription drug plans create 3.3 times more prescription drug waste than plans that allow patients to choose their own pharmacy for acquiring prescription drugs.<sup>5</sup> This is often due to the fact that mail order pharmacies encourage patients to purchase medications in bulk that they may not use.

CMS intends to add a new paragraph (iii) to § 423.104(d)(2) to specify that tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. Because of the concerns raised in this section of our comments, however, NCPA respectfully requests that in drafting this new paragraph, CMS consider the system-wide discriminatory effects of allowing zero cost co-pays to induce the use of specific retail or mail order pharmacies upon all facets and beneficiaries of the Part D program. Specifically, if a plan sponsor offers zero cost co-pays for certain mail order prescription drugs, then it should be required to offer them at retail pharmacies, also. The information stated above shows that the mere existence and technical compliance with the 25% equivalency requirement is not enough to prevent discriminatory practices and ensure a level playing field.

#### **IV. Enrollment of Full Subsidy Eligible Individuals and Other Subsidy Eligible Individuals Under Part D, II.B.9. at 54659, § 423.34 at 54726**

NCPA continues to have concerns about the reassignment process that affects millions of low-income Medicare patients each year, a large majority of whom represent our patient base. These patients represent the most vulnerable beneficiaries served by the Medicare Part D program. And yet, each year, a large segment of this patient population is annually subjected to reassignment to a new plan. In 2009, 1.3 million LIS beneficiaries were reassigned to a new plan because their existing plan bid above the 2009 benchmark. For 2010, that number remains high at 1.2 million beneficiaries. While those figures are trending down from 1.6 million reassignments in 2008, it still presents a significant disruption to this vulnerable population.

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<sup>3</sup>James Langenfeld & Robert Maness. "The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit." September 2003.

<sup>4</sup>New England Healthcare Institute. "Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Medication Adherence for Chronic Disease." August 2009.

<sup>5</sup>Daniel Halberg, Erin Smith, and Kevin Sedlacek. "Effect of Mail-Order Pharmacy Incentives on Prescription Plan Costs", University of Arkansas for Medical Sciences College of Pharmacy, October 2000.

NCPA strongly believes that it is important to limit the amount of re-assignment of low-income beneficiaries. We urge CMS to consider looking at additional approaches that might be used to minimize the numbers of beneficiaries that get automatically randomly re-assigned. Re-implementing the de minimus rule may be one option. Implementing random intelligent assignment might be another. It seems there should be some “acceptable” premium difference that, when factored against the burden to the patients, providers, and even CMS, would still result in an overall favorable result for all parties and reduce the number of reassignments.

In addition, the random nature of the process currently used during the reassignment process does not take into account the patient's medications or attempt to match these medications to a plan's formulary to make the best match. We would encourage CMS to look for ways to use low income patients' claims data to try to match them with a plan that covers all of the patient's medications on its formulary to limit disruption to these patients' care.

**V. Transition Process Under Part D, II.B.11. at 54660, § 423.120(b)(3) at 54728-54729**

NCPA supports the requirement for plans to allow transition fills for the first 90 days a patient is in a new plan and that transition fills be allowed for not only non-formulary medications but also those formulary medications that require a prior authorization or step therapy. We further support that these transition fills should include a 30-day supply, to allow sufficient time for the patient and/or pharmacist to contact the prescriber to make the necessary medication changes. In addition, NCPA requests that CMS review the written notice that sponsors provide enrollees regarding their transition process. NCPA is concerned that the notice may be used to steer patients unknowingly to mail order pharmacies.

**VI. Use of Standardized Technology Under Part D, II.B.14. at 54665, § 423.120 at 54729**

NCPA appreciates CMS' proposed requirement that all sponsors must assign a unique "Part D BIN or RxBIN and Part D processor control number (RxPCN) combination to its Medicare line of business." However, it should be emphasized that the PCN and RxBIN numbers should be assigned and differentiated at the sponsor level, since many sponsors may contract with a common downstream entity to handle the claims processing.

NCPA also appreciates that CMS recognizes that enrollees may have personal reasons for not wanting specific prescription claims processed through their Part D sponsor (or intermediary) and upholds the enrollees' right to make such decisions. However, Part D plans may have to modify these requirements to conform with new provisions included in the Health Information Technology for Economic and Clinical Health (HITECH) Act passed as part of the American Recovery and Reinvestment Act of 2009 (ARRA). These provisions allow an individual to request that a covered entity restrict the disclosure of their protected health

information when the purpose of the disclosure is for carrying out payment or health care operations and the information pertains solely to a health care item or service for which the provider involved has been paid out of pocket in full.

**VII. Collection of Additional Part D Claims' Elements for Nonpayment-Related Purposes, II.E.4. at 54683, § 423.505 at 54732**

NCPA respectfully questions CMS' conclusion that it may, under the authority it claimed in its May 28, 2008 Part D Claims Data final rule (73 FR 30664) in which it interpreted its authority under Section 1860D-12(b)(3)(D) of the Social Security Act, add new elements to the PDE record without undertaking rulemaking for each additional element added in the future.

First, as CMS notes, interested parties were not afforded an opportunity to comment to the proposed rule (71 FR 61447, October 18, 2006) on whether new elements that were added to the PDE record for 2008 (or any PDE elements that might be added in the future) should be collected under that section of the Act, and, consequently, used or disclosed to other parties for non-payment related purposes.

Second, it is clear from CMS statements in this section of the preamble of the current proposed rule that CMS is predisposed to rapidly add elements to the PDE record. There are costs that are born by different sectors of pharmacy when a PDE element is added. Particularly for pharmacies, submitting such information to PBMs has both immediate and longer term costs and policy implications. NCPA strongly believes that a full rule-making process should attach with any attempt to add elements to the PDE record.

**VIII. Medication Therapy Management Programs Under Part D, II.G.5. at 54692, §423.153(d) at 54729**

We support that the proposed rule establishes regulatory codification (through the Code of Federal Regulations) of the 2010 Call Letter provisions, especially the promotion of more consistent enrollment, targeting, intervention and outcomes-reporting requirements. We support the opt-out method of enrollment, quarterly targeted enrollment, specifying the maximum number of diseases and drugs plans use as a minimum threshold, the lowering of the cost threshold, the annual comprehensive medication review, quarterly targeted medication reviews, and an increased focus on continuity of care between plan years.

Additional opportunities for patients to benefit from MTM should include upon discharge from the hospital and anytime 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.

Evidence continues to show that pharmacist provided MTM services produce a high level of patient quality outcomes and cost saving benefits for the Medicare Part D program. NCPA

urges CMS to continue to recognize these benefits and continue to increase accessibility to this valuable benefit. To that end, MTM services should be defined to include those based on a referral by a pharmacist, as community pharmacy interventions deliver the greatest documented cost savings.<sup>6</sup> The annual comprehensive medication review and quarterly targeted interventions should be provided by a pharmacist with an existing relationship with the beneficiary, preferably the beneficiary's local community pharmacist. This is especially important for the beneficiaries of the Medicare program.

As you know Part D plans must allow any willing pharmacy to participate in a network if the pharmacy agrees to meet the plans' terms and conditions. To date, the access standards for retail pharmacies have not been extended by CMS to MTM services. We believe that this is an oversight on CMS' part and one that should be clarified.

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. These measures will give further definition to MTM programs, distinguish among different pharmacy providers and the types of MTM provided and appropriately compensate pharmacists that are able to improve quality of care.

**IX. Formulary Requirements—Development and Revision by a Pharmacy and Therapeutics Committee, II.G.6. at 54693, § 423.120(b)(1)(ix) at 54727**

NCPA supports CMS' decision to require plans to have their P&T committee review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug. As CMS stated, these utilization management tools have the same, if not more, impact on a beneficiary's ability to obtain needed medications as the drug's inclusion on the plan's formulary. These cost-reducing tools can severely restrict patient access to medications, and we appreciate CMS' recommendation to require these critical clinical decisions to be approved by an objective review committee.

**X. Access to Covered Part D Drugs, II.G.8 at 54694, § 423.120 at 54727-54728**

The Social Security Act at sections 1860D-4(1)(b)(C) and 1860D-21(c)(1) requires that the sponsor of a PDP shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access consistent with rules established by the Secretary, and as long as they are no less favorable than the TRICARE pharmacy access standards. Those minimum standards are: Urban areas: a pharmacy within 2 miles of 90 percent of the beneficiaries; Suburban: 5 miles and 90 percent; and Rural: 15 miles and 70 percent.

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<sup>6</sup> Shelly Winston and Yu-Shen Lin. "Impact on drug cost and use of Medicare Part D of medication therapy management services delivered in 2007." Journal of the American Pharmacists Association, Nov/Dec 2009.

The agency's discussion of the changes to the Part D access requirements is somewhat confusing. It indicates that it intends to conduct the analysis of the aforementioned requirements at the Part D sponsor level rather than the plan level. We believe that the standards were developed so that beneficiaries can have access to pharmacies. As such, we believe that the analysis should be conducted at the individual plan level. Moreover, if a plan exists in more than one state, the analysis should be conducted within each state in the plan.

Based on the experience of its independent community pharmacy members and recent research conducted related to beneficiary access to services performed by community pharmacists in rural areas, NCPA asks CMS to undertake any regulatory authority, or to support Congressional efforts, to apply more favorable access standards of increasing the urban and suburban percentages to 95 percent, and to increase the rural standard to 10 miles and 85 percent.

Independent community pharmacies play an influential role in preserving patient access to a community pharmacist, especially in rural and traditionally underserved areas. Many studies have documented the financial challenges faced by independents that are operating as sole providers, often defined as any pharmacy located in a rural community where there are no other pharmacies located within a 10 mile radius. Whenever such a pharmacy closes it has a substantial impact on the patients of its community, severely jeopardizing the ability of patients to gain their medications and have access to the professional knowledge offered by local community pharmacists. The standard of requiring 70 percent of all rural patients to be within 15 miles of a pharmacy is in particular too lax and needs to be strengthened in order for a larger number of rural patients to have access to the health care services that they need.

Examples of such studies include a recent study by the Rural Policy Research Institute (RUPRI) regarding the effect of the Medicare Part D program among rural pharmacies. The study found that among the 998 independently owned rural pharmacies that closed from May 1, 2006 to sometime before the July 2008 publication of the study, 158 were the only pharmacy serving their community at the time, and no other pharmacy replaced them.<sup>7</sup> The study referenced two 2006 and 2007 studies that reported cash flow concerns since the introduction of the Part D program for rural independent pharmacies located at least 10 miles from the nearest alternative. Other studies include several linked at the Office of Rural Health Policy<sup>8</sup> and a presentation before the National Rural Health Association in September (studying independent pharmacies located 10 or miles from the nearest pharmacy).<sup>9</sup>

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<sup>7</sup> <http://www.unmc.edu/ruprihealth/Pubs/b2008-2%20Independently%20Owned%20Pharmacy%20Closures.pdf>.

<sup>8</sup> [http://www.ruralhealthresearch.org/search\\_results.php?topic=pharmacy](http://www.ruralhealthresearch.org/search_results.php?topic=pharmacy).

<sup>9</sup> A Profile of Sole Community Pharmacists: Their Role in Maintaining Access to Medications & Community Pharmacy Services in Rural Communities, the second link at <http://www.ruralhealthweb.org/go/left/programs-and-events/nrha-conferences/medication-use-in-rural-america-conference/medication-use-in-rural-america-conference-handouts>, or directly at <http://www.ruralhealthweb.org/download.cfm?downloadfile=4DAABEDF-3048-651A-FE4F1A5D40DEC140&typename=dFile&fieldname=filename>.

NCPA is concerned about the access standards raised by these studies. In addition to the mileage standards discussed above, it should be noted that there are many communities in which the straight distance between pharmacies is significantly less than the actual distance that must be traveled on winding roads to reach the destinations. In order to avoid under serving the residents of large geographic regions, NCPA urges CMS to move to the more access-sensitive standards enumerated above.

## **Conclusion and Recommendations**

In conclusion, NCPA supports CMS' efforts to address significant Part D issues, but in these comments has offered the following recommendations to address its concerns:

- Avoid unnecessarily burdensome fraud, waste and abuse requirements by eliminating repetition where the requirements are already met;
- Do not allow beneficiary communications excluded from the definition of marketing materials to contain statements that steer beneficiaries toward mail order;
- Consider the system-wide discriminatory effects of allowing zero cost co-pays to induce the use of specific retail or mail order pharmacies upon all facets and beneficiaries of the Part D program. If a plan sponsor offers zero cost co-pays for mail order prescription drugs, then it should be required to offer them at retail pharmacies, also;
- Limit the amount of re-assignment of low-income beneficiaries and create ways to use low-income patients' claims data to try to match them with a plan that covers all of the patient's medications on its formulary in order to limit disruption to these patients' care;
- Provide for clear assignment and differentiation of PCN and RxBin numbers at the sponsor level;
- Undertake separate rule-making and public comment process to any attempt to add elements to the PDE record;
- Full promotion of the benefit of community pharmacists in the Medication Therapy Management program; and
- Consider ways to apply appropriate network access standards, such as a network requirement of 95 percent of beneficiaries to be within 2 miles of a pharmacy in urban areas and 5 miles of a suburban area, and within 10 miles of 85 percent of pharmacies in rural areas to maintain access to sole providers.

NCPA appreciates the opportunity to comment on *CMS-4085-P: Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule*. If you have any questions, please contact me at (703) 683-8200 or [john.coster@ncpanet.org](mailto:john.coster@ncpanet.org).

Sincerely,

*John M. Coster*

John M. Coster, Ph.D., R.Ph.  
Senior Vice President, Government Affairs

Attachment