March 1, 2013

Jonathan Blum, Director
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: 2014 Medicare Part C and Part D Draft Call Letter

Dear Director Blum:

Thank you for the opportunity to submit our comments on CMS’ 2014 Medicare Part C and Part D Draft Call Letter. As CMS considers revisions to the 2014 Draft Call Letter, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. In addition, 34% of our members serve an LTC facility and 48% serve an Assisted Daily Living facility. In sum, approximately 40% of the long-term care market is serviced by an independent community pharmacy.

NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans. NCPA members are a primary access point for prescription medications for millions of Part C and D beneficiaries and NCPA members comprise a critical piece of the Part C and D prescription drug distribution system. We welcome this opportunity to comment on certain proposals in the draft Part C and Part D 2014 Call Letter.

Section I – Parts C and D

Star Rating Changes

NCPA is pleased to see that our recommendations provided in an earlier response to the agency’s request for comment on proposed methodology for the 2014 Star Ratings were incorporated into the draft Call Letter and continue to support those changes. With the growth of medication therapy management (MTM) programs, we agree that it is important for plans to track success in engaging patients in such services.
In order to fully address the variations in the delivery and completion of the CMR, which can differ based on care delivery setting, we concur with CMS’ proposal to retain the status of the comprehensive medication review (CMR) completion rate as a display measure for an additional year. Adding the CMR completion rate to the Star Ratings measure in 2015 will allow for more consistency in MTM program reporting data based on CY2013 performance, and NCPA reaffirms our support of the inclusion of long-term care beneficiaries receiving a CMR in the measure calculation. Delaying the deployment of the measure as part of the Star Ratings will allow CMS an opportunity to evaluate the effect of the implementation of the new MTM requirements related to annual CMRs, including residents of long-term care (LTC) settings beginning in 2013.

Section II – Part C

Inappropriate Shifting of Drug Coverage from Medicare Part B to Part D

The Call Letter clarifies payment policies regarding billing for certain drugs under Medicare Part B and Medicare Part D depending on whether the drug is dispensed “incident to” a physician service or the enrollee elects to obtain the drug directly from the pharmacy. The Call Letter states that, “some drugs that are covered under Medicare Part B when provided incident to a physician service may be covered under Medicare Part D when dispensed upon a prescription from a pharmacy.” The Call Letter goes on to clarify that while an MA organization cannot require enrollees to pick up these drugs directly from a pharmacy, “enrollees in an MA plan offering Part D coverage may elect to have a drug dispensed from a pharmacy and bring it to their MA plan physician for administration in the physician’s office.” Furthermore, the Call Letter states that “[t]his practice is not prohibited under Part C or Part D when the beneficiary elects, as a matter of personal preference, to obtain a drug from a pharmacy under Part D that is otherwise a Part B-covered drug when furnished at a physician’s office out of the physician’s own stock.”

NCPA supports CMS’ clarification that enrollees may elect to obtain their prescriptions directly from a pharmacy. There are a number of reasons, including the relationship that a patient may share with their community pharmacist, why a patient may elect to obtain drugs directly from the pharmacist. NCPA strongly supports patient choice in allowing patients to obtain their medications directly from a pharmacy. NCPA urges CMS in the final Call Letter to continue to allow patients to obtain their drugs directly from their pharmacy under Part D even where the drugs would be covered under Medicare Part B when provided “incident to” a physician service.

Exceptions to Policies Permitting Plans to Limit DME to Certain Brands and Manufacturers

NCPA is encouraged to see that Part C is more in line with maintaining beneficiary access to care to Diabetic Testing Supplies than Part B. NCPA has concerns as to how the partial limitation on diabetic supplies will coordinate with the drastic decrease in reimbursement of DTS under the single payment amount for Part B.
For Part B, CMS recently released the National Mail Order single payment rate for diabetic strips, which drastically decreases reimbursement an average of 72% for retail pharmacies, with only 15 suppliers expected to be awarded contracts. The single payment amount for diabetic strips per box of 50 is $10.41. This is significantly lower than even the average Round 1 CBP single payment amount for a box of 50 that was $14.62, and much lower than the fee schedule amount of $37. In reality, this $37 fee schedule amount barely covers the pharmacy’s costs of goods plus dispensing and counseling for these products and services, plus the costs to pharmacies of participation in Medicare Part B, which includes surety bonding, accreditation, the costs of arduous pre and post payment reviews, separate contractors to help process Part B claims, and the audit recoveries. Now, Congress has decided to drop these rates to $10.41 per box.

While community pharmacists are currently motivated to have products that local physicians prescribe and local beneficiaries prefer, for the few community pharmacies that may choose to continue to participate in the Part B program and endure these drastic cuts in reimbursement, these community pharmacies will no longer be able to offer the customized DTS that beneficiaries and their physicians prefer. To the contrary, community pharmacies will be forced to only provide a limited range of products to beneficiaries just as mail order has done, if at all.

NCPA is encouraged to see that Part C is more in line with maintaining beneficiary access to care to Diabetic Testing Supplies than Part B. Due to Part B’s drastic cuts to DTS, NCPA is very concerned that, due to the drastic reimbursement cuts under Part B, the types of diabetic testing strips that community pharmacies will be forced to carry will not be compatible to the specific large-font monitors and large-button monitors that Part C is requiring to be furnished, further decreasing beneficiary access to care.

Section III – Part D

**Payment for Hospice and ESRD Beneficiaries under Part D**

NCPA opposes mandating additional beneficiary-level prior authorization requirements for the categories of Hospice and ESRD drugs. While the current policy of retroactive recoupment for these drugs offers its own problems, increasing the amount of drugs subject to prior authorizations is not an adequate solution. Specifically, NCPA is opposed to the requirements in the Call Letter that, starting in January 2014, following the receipt of a transaction reply report (TRR) showing a beneficiary has either elected Hospice care or is an ESRD beneficiary receiving renal dialysis services, the sponsor must place beneficiary–level prior authorization requirements on categories of drugs that “may be” Hospice or ESRD-related.
In the Call Letter, CMS is proposing to extend the prior authorization requirements to a vast number of drugs. In regard to Hospice, the Call Letter states that the prior authorization requirement should be extended to four categories of drugs (analgesics, antinauseants, laxatives, and antianxiety drugs) as well as eight additional classes of drugs that include 54 drugs used for treating COPD and one drug used for treating ALS. In regard to ESRD, CMS is proposing to extend prior authorizations to seven additional categories of prescription drugs that “may be” ESRD-related (antiemetic, anti-infectives, antipruritic, anxiolytic, excess fluid management, fluid and electrolyte management including volume expanders, and pain management).

This is an overwhelming increase in required prior authorizations. For each drug that requires a prior authorization, CMS explains that “payment for drugs…would stop and the pharmacy would receive a reject code on the response to the pharmacy’s billing transaction indicating that prior authorization is required for adjudication the claim. The pharmacy would need to initiate dialogue between the parties to resolve payment responsibility.” 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. The Call Letter goes on to explain that, “once the sponsor, pharmacy, and prescriber have established payment responsibility; there will be no further delay in the beneficiary appropriately accessing the drug…” This delay in care that these additional prior authorizations would cause to patients in hospice care and undergoing ESRD is unconscionable.

In addition to the delay in care to patients in hospice care and those receiving ESRD treatment, there are a host of other problems with increasing the number of drugs subject to prior authorizations. Under the proposed solution in the Call Letter, the patient isn’t notified of the delay, the cause for the delay, or an estimated time when they may receive their medications.

Also, there is no guidance as to how the pharmacist, physician and sponsor are expected to communicate amongst themselves and no timeframe that this information must be provided from the physician to the pharmacy, sponsor, and beneficiary. This would most certainly lead to the community pharmacists being placed in the situation of denying the patient their vital medication. There are also no instructions as to when these drugs would not require prior authorizations, such as when a beneficiary was no longer in hospice care. Also, CMS does nothing in the Call Letter to address the real issue at hand which is the lag in real time information regarding patient’s status as a Part D patient versus a hospice or ESRD patient. The eligibility files are not real time and there is a lag in update to those files that may cause months of delay.

To justify mandating a drastic increase in the number of drugs subject to prior authorizations, CMS states, “[w]e now better understand that a hospice or ESRD dialysis facility may be uncertain about these definitions. A Part D sponsor will therefore be similarly uncertain about whether payment is the responsibility of either the hospice or dialysis facility or Part D.” NCPA is confused as to why CMS does not provide further education as to what should be included in the Medicare per-diem payment to a Hospice program and in the Part B bundled payment to an end-stage renal disease dialysis facility.
Thus, while retroactive recoupment offers its own problems, drastically expanding the number of drugs subject to prior authorizations and delaying care to Medicare’s frailest and most vulnerable populations, is not an adequate solution.

**Daily Cost-Sharing Requirements**

Although NCPA generally supports the Agency’s proposal to implement a program with daily prorated patient cost-sharing for the purpose of medication synchronization and for initial fills of a new medication, we do have several recommendations to make that are based on our experiences with the recent implementation of short-cycle dispensing in the LTC setting. In a letter dated December 18, 2012, NCPA wrote to CMS sharing information regarding reimbursement models that certain Part D plans decided to utilize related to short-cycle. The new reimbursements that certain plans are mandating for short-cycle fills punish efficient pharmacy practices and will potentially lead to increased waste.

Several of the largest Part D plan sponsors are moving forward with prorating dispensing fees, including for all generics and non-solid oral doses that will be dispensed to nursing home facilities beginning January 1, 2013. 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 is concerned that plans may impose such pro-rated dispensing fees on retail pharmacy starting January 1, 2014 whenever less than a 30 days’ supply of initial fills of new prescriptions are dispensed.

This inverse incentive that we are experiencing in relation to short cycle is in complete contravention to the preamble language in the final 2012 Part D rule published in the Federal Register on April 15, 2011: “*However, we agree with the commenter that dispensing fees will likely increase with 14-day-or-less dispensing. Although we are prohibited from intervening between negotiations between Part D plans and pharmacies, we do expect that dispensing fees will increase with the increased number of dispensing events in a billing cycle up to a point. Consistent with feedback from the LTC industry and comments on the proposed rule, we believe that drugs dispensed in shorter dispensing increments will result in fewer unused drugs. We also believe that appropriate dispensing fees that differentiate among the various dispensing methodologies could incentivize more rapid adoption of the most cost-effective technologies and effectively align facility, plan sponsor, and public interest in minimizing costs associated with unused drugs.*” “As we stated in our proposed rule, however, *nothing in the requirement prevents LTC facilities and pharmacies from extending the practice to generic drugs, and we encourage Part D sponsors to facilitate that practice.*”

NCPA requests that CMS, in the final call letter, reiterate language from the final 2012 Part D rule that the Agency expects that dispensing fees will increase with the increased number of dispensing events in a billing cycle up to a point. After all, the reason behind allowance of shorter fills is to decrease waste and improve patient adherence, and community pharmacies should in no way be punished by lower reimbursements for doing the right thing and helping the Medicare Part D program save valuable dollars.
Inappropriate Use of Prior Authorization (PA) forms

While NCPA applauds CMS in reminding plan sponsors of inappropriate use of prior authorization forms, NCPA has strong concerns that CMS has been put on notice of these egregious practices for over a year and, with the exception of releasing two reminders to plan sponsors, has done little to prevent these practices from continuing to occur.

As far back as December 12, 2011, NCPA has brought examples of inappropriate use of prior authorization forms to CMS’ attention and encouraged CMS to address these violations. NCPA has alerted CMS on many occasions that beneficiaries are being forced into mail order by plan sponsors’ violation of CMS’ model transfer guidance and requested CMS to have stronger oversight of this practice. NCPA asked CMS to require Part D plan sponsors to use only the model transfer letter and to obtain patient permission before transferring a patient’s prescription to a preferred network pharmacy. NCPA further informed CMS that the attempt by some Part D plans to boost their star ratings by trying to divert their patients to their own mail order operation is serious enough for CMS to take further action.

Now, over a year later, CMS has done little to address the egregious inappropriate use of prior authorization by plan sponsors. In order to determine what good will come of CMS’ notice to plan sponsors of these egregious practices and request that plan sponsors discontinue these practices immediately, one doesn’t have to look much further than the actions that resulted from the HPMS memo that CMS released on May 4, 2012 entitled, Reminder of Prescription Transfer Requirements. The HPMS memo was released over 10 months ago, and as CMS states in the Call Letter, “CMS continues to receive complaints that beneficiaries have not been able to obtain medications which required prior authorization at the pharmacy of their choice, but were ultimately dispensed by the sponsor’s and/or PBM’s own mail-order pharmacy.”

The abuses in prior authorization forms being utilized to divert Medicare beneficiaries to mail order are especially concerning in light of NCPA’s new study of millions of Medicare Part D prescription drug event (PDE) data that found that community pharmacies provide 90-day medication supplies at lower cost than mail order pharmacies and that local pharmacists substitute lower-cost generic drugs more often when compared to mail order pharmacies. Specifically, reviewing PDE records for 2010 supplied by CMS, the study found for 90-day prescriptions filled by local pharmacies, costs per unit of medication, as compared with mail order pharmacies, were lower for total costs ($0.94 vs. $0.96), Medicare costs ($0.59 vs. $0.63), and all third-party payer costs ($0.64 vs. $0.72). Because of co-pay differentials set by health plans to incentivize mail order usage, patient costs at retail were higher for patients ($0.31 vs. $0.24 at mail order) even though the total cost of those prescriptions was less at retail.

Thus, it is unacceptable that CMS continues to receive complaints from beneficiaries after CMS has released prior notice to plan sponsors that such actions violate CMS requirements. It is clear that such notices are not adequate action to cease these egregious practices. These actions are unacceptable and are stripping beneficiaries of their choice in pharmacy.
NCPA strongly encourages CMS to take further action and to stop these egregious practices once and for all and as one proposed solution, NCPA recommends that CMS mandate that plans use a **specific written standardized transfer letter** that is approved by CMS and must be used by all plans with no adjustments allowed.

**Auto-Ship Refill Programs in Part D**

The automatic refilling of medications can provide convenience for patients, and may be a tactic to help facilitate adherence. However, the proper use of medications needs to be a shared decision among the prescriber, pharmacist, and most importantly, the patient. The growing chorus of beneficiary complaints CMS is receiving sheds light on the consequences of automatic shipment of refills without patient awareness, and should lead to serious concerns about patient safety and potential fraud and abuse when medication refills are never requested by the patient but are shipped out anyway and paid claims are not reversed.

NCPA members can provide first-hand experience of the vast amounts of waste that they see being generated through mail order auto-ship programs when patients drop-off their unused or expired medications. Through NCPA’s Dispose My Meds program, community pharmacists have collected over 100,000 pounds in unused or expired non-controlled medications, with many of these participating pharmacies noting returns that include thousands of dollars in returned medication from mail order pharmacies that continued to ship medications despite patient protests to stop. These pictures and anecdotes from our members demonstrate a significant amount of unnecessary waste that counteracts any efforts to provide safe, effective, and affordable care.

The misalignment of payment incentives and profit motives of pharmacy benefit managers only serve to encourage greater utilization of mail order and the practice of automatic shipment of refills. An example is within the current structure of the Medicare star quality ratings for plans. The incentive for plans to improve their quality ratings is the ability to market their plans on a broader basis. One such component is related to medication adherence, which NCPA has contended is based solely on prescription claims data with no tie or correlation to outcomes. We reiterate our concerns that simply shipping the product every 30 or 90 days without proper clinical assessment of the patient for therapeutic appropriateness is not true adherence and in fact, can generate more waste. If these ratings are calculated on how many fills a patient receives without factoring true clinical improvement, plan sponsors are motivated to ensure that patients are always receiving their refills. A consequence of this is seniors can find themselves advancing through the Part D benefit phases prematurely if they truly did not need those extra refills but were billed anyway.

In addition to the increased costs to the Federal government by the rampant waste produced by auto shipping, according to NCPA’s new study of millions of Medicare Part D prescription drug event (PDE) data, community pharmacies provide 90-day medication supplies at lower cost than mail order pharmacies and local pharmacists substitute lower-cost generic drugs more often when compared to mail order pharmacies.
Therefore, with higher cost for 90-day medication supplies and rampant waste, mail order is certainly not less costly than community pharmacies. In fact, reviewing PDE records for 2010 supplied by CMS, the study found for 90-day prescriptions filled by local pharmacies, costs per unit of medication, as compared with mail order pharmacies, were lower for total costs ($0.94 vs. $0.96), Medicare costs ($0.59 vs. $0.63), and all third-party payer costs ($0.64 vs. $0.72). Because of co-pay differentials set by health plans to incentivize mail order usage, patient costs at retail were higher for patients ($0.31 vs. $0.24 at mail order) even though the total cost of those prescriptions was less at retail.

Furthermore, when medications are being automatically filled without prior consent from the patient, this presents the possibility of overbilling to payers, including government programs such as Medicare. NCPA urges CMS to establish clear policies and parameters surrounding auto-ship refill programs. While we support the requirement that retail and mail pharmacies obtain patient consent prior to the delivery of each refill or new prescription, we have concerns that mail order facilities may try to fulfill this requirement by creating a blanket consent agreement for patients to sign that further authorizes future refills to circumvent the patient affirmation needed each time. Given the opportunities for increasing their star ratings, plans could be moving patients without their consent over to mail-order (often the PBM’s own facility), potentially violating CMS’ model transfer guidance, to place them on an auto-ship refill program.

Again, we maintain that proper medication management needs to be a shared activity among the care triad of patient, prescriber and pharmacist. Not all patients are candidates for enrollment in an auto-ship refill program, nor are all medications appropriate to be on an automatic shipment schedule. The determination to place a patient on any such program should be made by a clinician, not a plan sponsor with motives other than improved patient outcomes. Given the incentives plans have to ensure patients are refilling their medications on a regular basis, we believe such methods employed by plans that are quantity and not quality driven should be closely examined. NCPA encourages CMS to place greater scrutiny of adherence measures based on proportion of days covered, especially in relation to mail order benefits and the automatic shipment of refills. One such recommendation is to explore the possibility of re-configuring the calculations for star ratings to account for the fact that patients are enrolled in an auto-ship refill program, and possibly assigning a different weight for scoring.

**Incremental Fills of Schedule II Controlled Substances Prescriptions**

NCPA strongly agrees with CMS’ encouragement to the industry to promptly address the known limitation of the current HIPAA prescription drug billing standard with respect to distinguishing between partial or incremental fills of an original prescription and refills. NCPA also agrees with CMS that the September 2012 OIG report that found that three-quarters of Part D sponsors inappropriately paid $25 million for Schedule II controlled substances failed to take into account that some of these drugs may have been inaccurately billed as refills instead of partial fills.
In addition, NCPA further agrees with CMS that with the implementation of LTC short-cycle dispensing beginning January 1, 2013, the issue of partial fills versus illegal refills will become more apparent. Thus, this issue must be promptly addressed.

NCPA understands that NCPDP is addressing this issue and in the process of developing a solution. In a letter dated November 15, 2012, NCPDP recommended that HHS allow the Telecommunication Standard Implementation Guide to specify the conditional use of field Quantity Prescribed which is currently not in use in the claim billing transaction. NCPDP also requested OESS to publish a notice by December 31, 2012 regarding approval of the use of the requested field. NCPA supports the efforts by NCPDP to provide a solution to eliminate the misinterpretation of partial fills dispensed to patients in LTC facilities and asks that this issue be promptly addressed.

**Applicability of Rewards and Incentives in Part D**

NCPA has concerns regarding the potential consequences of allowing rewards and incentives in Part D. While Section 70.3 of the Medicare Marketing Guidelines provides that rewards and incentives must not “be used to target potential enrollees (e.g., used in pre-enrollment advertising, marketing, or promotion of the plan) and must not be structured to steer enrollees to particular providers, practitioners, or suppliers,” NCPA is aware of current incentive programs in Part D where community pharmacies cannot meet current parameters and thus cannot participate. Not allowing community pharmacies to participate eliminates beneficiary choice of provider.

In addition, NCPA has strong concerns that incentives and awards within Part D could advertently or inadvertently be tied to a particular provider further limiting beneficiary choice. NCPA also has strong reservations that these incentives and rewards could be used as egregious marketing tactics in order to steer enrollees.

**Payment of Extemporaneous Compounds from Compounding Pharmacies**

While NCPA is committed to working with FDA, CMS, and Congress to make certain that safe, compounding products are provided to the public, it is essential to also preserve patients’ access to these customized and safe compounded medications.

The Call Letter states that 50% of Part D compounds were from either a LTC or home infusion pharmacy and that more than 80% of sterile compounds were from LTC and home infusion pharmacies. Thus, it’s worth noting that CMS requires network LTC pharmacies (NLTCPs) via Long Term Care Guidance issued on March 16, 2005, to be “capable of providing specialized drug delivery formulations as required for some LTC residents.”

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Furthermore, the Long Term Care Guidance states that, NLTCPs must be capable of providing these compounding and alternate forms of drug composition where, “residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms to facilitate effective drug delivery.”

In addition to mandating that NLTCPs have the capacity to provide compounded medications to LTC patients, CMS also requires “NLTCPs to possess the capacity to provide IV medications to the LTC residents as ordered by a medical professional.” Furthermore, the CMS Long Term Care Guidance provides that, “NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.”

Thus, by CMS’ own guidance, LTC pharmacies must have the capacity to provide compounded medications and IV medications to LTC residents. As such, NCPA is very concerned with the direction that CMS takes in the Call Letter regarding compounded medications. NCPA is concerned that this direction does not preserve beneficiary access to essential compounded medications. To the contrary, the Call Letter states, “[f]or instance, in order to ensure that Part D only covers medically necessary Part D compounds, we would require Part D plans to consistently obtain justification via prior authorization from the prescriber as to why no FDA approved product is clinically suitable for the patient, for example, during drug shortages, or because the individual prescription requires a medication tailored to meet a patient’s special medical needs.” NCPA strongly urges CMS to remove the above language from the final Call Letter. This is significant Federal interference into medical practice and the practice of pharmacy.

Whether a compounded medication is prescribed and is thus in the best interest of the patient is a matter that is determined between a patient and their physician. By prescribing a customized medication in the form of a compounded drug, the physician has already taken into account the drugs available to the patient and weighing these options, elected to prescribe a compounded medication. Thus, the physician has decided that a compounded medication is the best solution for the needs of their patient. By requiring Part D plans to obtain justification via prior authorization from the prescriber why no FDA approved product is clinically suitable, CMS will only delay essential care to the beneficiary, cause confusion on behalf of the beneficiary, and interfere with the patient–doctor relationship and right of the physician to elect to prescribe the medications that a physician deems to be within the patient’s best interest for their well-being.
No other justification or prior authorization is needed from the physician and should not be required. Any such interference of the authority of the physician to prescribe to their patient an essential medication, would only delay care to beneficiaries and not address the actual concern of making certain that safe compounded medications are being provided to patients. While NCPA appreciates the intent of CMS efforts to make certain that safe compounded medications are being given to patients, the method that CMS proposes in the Call Letter requiring justification via prior authorization is an inadequate solution and only provides further concerns for decreased and delayed access to beneficiary care.

**Medication Therapy Management and Million Hearts™ Initiatives**

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. As noted in the CMS interim report, *Medication Therapy Management in a Chronically Ill Population*, not only did Medicare beneficiaries with congestive heart failure and chronic obstructive pulmonary disease (COPD) who were enrolled in MTM programs and received their annual CMR experience significant improvements in the quality of their drug regimens compared to beneficiaries who did not receive any MTM services, but there were also significant cost savings tied to all-cause hospitalizations. Although these early findings suggest that MTM services are a cost-effective care delivery model that provides enhanced quality to those that qualify, the low eligibility rate of beneficiaries who qualify for a CMR as currently determined by plan sponsors suggests there is room for improvement in expanding MTM to more beneficiaries.

We commend CMS for the agency’s efforts to promote beneficiary awareness of MTM programs through the “Medicare & You” handbook and Medicare Plan Finder, and applaud the proposed requirement for plan sponsors to have a dedicated MTM program page on the plans’ website. We share the agency’s concerns that the Part D sponsors are restricting their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs. Given the low participation rates within the MTM program today, all stakeholders, from CMS to plan sponsors to providers should work together to enhance the MTM benefit that Medicare beneficiaries receive. At the same time, a viable business model needs to exist for all involved parties to have a vested interest in participating.

While NCPA continues to support efforts to build a more robust MTM benefit, we were perplexed to see that CMS would encourage plan sponsors to offer MTM and a CMR to targeted beneficiaries on at least one anti-hypertensive medication to advance the goals of the Million Hearts™ Initiative, but that these services would not result in additional payment under Medicare Part D. We believe that CMS is taking the right step in suggesting that patients on an anti-hypertensive medication should receive a targeted medication review, and that this would expand the population of patients eligible for MTM.
However we have difficulty understanding why CMS would propose an additional MTM service without offering a corresponding payment mechanism. Pharmacists are well-poised to provide comprehensive medication reviews to patients with cardiovascular disease, but if done under the auspices of MTM per CMS definition, we seek clarification on why these services would not result in additional payment.

Since the Million Hearts™ campaign launched in September 2011, NCPA has communicated this significant public health initiative to our members, many of whom indicate that they provide patient care services such as blood pressure and lipid screenings, as well as smoking cessation counseling. Research confirms the positive impact pharmacists can have in assisting their patients with hypertension management. In the Hypertension Outcomes Through Blood Pressure Monitoring and Evaluation by Pharmacists (HOME) study, community pharmacists provided patient specific education about hypertension, including: (1) disease process and complications, (2) medication use and adherence, (3) lifestyle modification, and (4) home self-blood pressure monitoring techniques. Hypertensive patients receiving interventions from community pharmacists in the HOME study experienced blood pressure reductions that were clinically meaningful. Four other studies found that blood pressure control improved when community pharmacists assisted with patient education, blood pressure monitoring, drug therapy management and medication adherence.6,7,8,9

With so much of the population with uncontrolled hypertension, and medication non-adherence as a cause, pharmacists can help fulfill an unmet need. Pharmacists serve a critical role in team-based care by engaging patients in their health care through counseling and education about medication and the importance of adherence (to medications and other lifestyle modifications). A recent CDC Prevention Task Force found that patients’ blood pressure control improved when provided by a team of health care professionals – a primary care provider supported by a pharmacist, nurse, dietician, and social worker – not just a single physician.10 There was strong evidence from over seventy studies examining team-based care organized primarily with nurses and pharmacists working in collaboration with primary care providers, patients, and other health professionals.

One method which NCPA strongly believes can facilitate improved patient adherence is through a personalized, coordinated medication refill program to identify adherence barriers, decrease therapy gaps, improve outcomes and lower costs.

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10 Cardiovascular Disease Prevention and Control: Team-Based Care to Improve Blood Pressure Control. May 2012.
The coordination of refills decreases regimen complexity which can help boost adherence, and provides an opportunity for the community pharmacist to review all of a patient’s medications to ensure safe and appropriate use. The design of such high touch, patient care programs reduces not only the potential for gaps between refills, but can also improve the care transition process and address the critical issue of medication-related hospital admissions. Such adherence programs dovetail with the Million Hearts initiative, as the monthly medication review by the community pharmacist that’s part of NCPA’s Simplify My Meds synchronization program, provides a great opportunity to discuss cardiovascular health, and offer blood pressure checks or other appropriate screenings. Therefore, we question CMS’ rationale that there should not be additional payment under Part D for MTM services that enhance medication adherence and improved outcomes related to hypertension control and other cardiovascular conditions.

*Optimizing the Delivery of MTM in LTC Settings*

We understand through previous guidance that CMS encourages plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC. Such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor’s MTM vendor or PBM and LTC consultant pharmacists (or their intermediaries). In addition to these arrangements, NCPA recommends that plan sponsors allow independent consultants to bill independently for their MTM, including comprehensive medication review (CMR) services. If CMS were to require plans set up a system to allow other billing methodologies (such as NPI or license number) this could allow an independent pharmacy the ability to provide MTM without having to incur additional costs.

*Expansion of Part D Policy on Improving Utilization Review Controls*

NCPA opposes efforts to expand the Part D Policy of Improving Utilization Review Controls to other drugs or classes of drugs, such as anti-psychotic drugs, amphetamine derivatives, benzodiazepines, and non-benzodiazepines sleep aids. CMS just recently within the Final CY 2013 Call Letter and the HPMS memo dated September 6, 2012 applied the Improving Drug Utilization Review Controls in Part D to overutilization of opioids. Thus, it’s too soon to know the outcome of applying these Controls to opioids, learn from this implementation, and expand the application of Controls. As such, NCPA strongly encourages CMS to focus on the application of Improving Utilization Review Controls to opioids in CMS’ recent Call Letter and not expand these Controls.

*Change in Part D Barbiturate Coverage*

NCPA supports allowing barbiturates that otherwise meet the definition of a Part D drug to be covered beginning January 1, 2014 under Part D for any medically accepted indication. This expansion of allowing all barbiturates to be covered under Part D instead of those just used to treat epilepsy, cancer, or chronic mental health disorder as under current law, will allow providers and pharmacies to work together to provide a broader spectrum of care.
PDE Guidance on Post-Point-Of-Sale Claim Adjustments

We applaud the fact that CMS has recognized that it is wrong for Part D plan PBMs to hire bounty hunting auditors to comb through pharmacy files to find the slightest of clerical errors so they can recoup the monies paid for a legitimate prescription claim and then turn around and not accurately report their gains to the Medicare program. These are the most egregious of abusive auditing practices, and we applaud the fact that CMS has blown their cover. We have attached multiple examples of these types of practices which are unfair to pharmacies that are trying to serve Medicare patients, which were tabulated as part of a NCPA member survey from 2012 (Attachment 1). CMS also recognizes that this is a “growing practice” among Part D plans because small independent pharmacies are at the mercy of the giant Part D plans and PBMs. Moreover, because the PBMs have been reporting this as DIR, CMS has likely been overpaying plans. Thus, plans have had every incentive to use this insidious scheme to bilk pharmacies for millions of dollars over the past several years. CMS should force plans to pay back pharmacies for every claim that was recouped on a technical error. In an era of focus on fraud waste and abuse, the PBMs have taken every opportunity to try and abuse and distort the Part D payment system.

Community pharmacists understand and support legitimate auditing practices that uncover true fraud waste and abuse. However, there is no negotiating with these plans over the appropriate nature and scope of audits. As CMS notes, plans are recouping total payments “when non-financial data on the claim transaction, such as prescription origin codes or prescriber identifiers, are determined to be erroneous. The increasing incidence of these adjustments for ‘routine clerical errors’ rather than incorrect payment amounts (financial errors) may be related to the incentives in contingency reimbursement arrangements with claim audit vendors.”

These concerns raised by CMS mirror the same auditing issues which have greatly affected NCPA members over the years. NCPA’s members have informed us of widespread disparity in how clerical, typographical and related prescription errors are treated by Part D plans during audits. Last fall, NCPA conducted a survey of small business community pharmacies regarding challenges that they face with regard to both commercial and Part D audits. The results include reporting by almost 77% of respondents that PBMs apply inconsistent auditing standards across various plans. Not only are the auditing standards inconsistent, but over 82% of respondents reported that PBM auditors always or often require recordkeeping requirements above and beyond state and federal law requirements. Most significantly, almost 87% of respondents reported that PBM auditing practices have a significant to very significant impact on respondents’ ability to provide patient care and remain in business, which can lead to decreased access to care.

That is why we are so pleased with CMS statement that “…we believe that full claim recoupment…should only take place if a plan learns that a claim should not have been paid under Part D at all; for example, because it is fraudulent.” The call letter also states, “…the practice of recoupment of claims costs for administrative errors is not compatible with existing PDE guidance…”
The Part D plans PBMs have to-date recouped tens of millions of dollars in legitimately-dispensed prescriptions from pharmacies for administrative and technical violations where there was no intent to commit fraud. These practices have to stop, and we believe that CMS takes an important first step with this call letter. NCPA asks that CMS make clear in the final call letter that recoupments can only occur when true fraud has occurred. Given existing inconsistencies and the administrative nature of these errors, NCPA requests that CMS introduce a consistent standard across Part D plans regarding audit practices and that CMS instruct plans to not recoup for clerical and typographical errors without providing pharmacies an opportunity to correct such errors.

We urge that CMS follow existing law as well and require that Part D plans disclose the source of and the actual Maximum Allowable Cost (MAC) payment rates to pharmacies before asking pharmacies to sign contracts, and per law, require that these be updated every seven days. Consistent with the need to have transparency with the PDE data, Part D plans are playing games with the MAC rates, and making them transparent to CMS and pharmacies would help reduce the waste and abuse in this part of the program.

**Post Point-Of-Sale Per Claim Administrative Fees**

NCPA agrees with CMS’ assessment that per-claim fees deducted after point-of-sale is an overstatement of negotiated prices. Any payments back to the plan sponsor do not represent the true amount paid to the pharmacy, and therefore would be a violation of the CMS definition of negotiated price. We can confirm that such arrangements of plan sponsors charging pharmacies $1.00 (or more) per claim to participate in a preferred pharmacy network exist, and believe this current practice in the Part D market is more the rule rather than the exception. Such DIR fees are fairly common for preferred pharmacy network participation. Not only does NCPA feel that these practices go against CMS’ interpretation of negotiated price by altering the final price paid to the pharmacy, but we are adamantly opposed to any sort of “pay-to-play” scenarios where plan sponsors charge per-claim administrative fees to pharmacies to participate in a preferred pharmacy network. This also raises the question of how and to what extent these pharmacy payments back to the plans are being reported and per 42 C.F.R §423.100 are being passed on to the beneficiary.

In addition, NCPA is very concerned that these pay-to-play models do not fit the business models of independent community pharmacies. Unlike large pharmacies that are able to participate in these pay-to-play models because they can make up lost revenue from getting more patients into their pharmacy and increasing front-end sales, independent community pharmacies cannot make up lost revenue by increased foot traffic and increased front end sales. To the contrary, the pay-to-play models eventually force community pharmacies out of business which is not good for patient care services or competition.
Preferred/Non-Preferred Pharmacy Networks

NCPA appreciates the strides CMS has taken in attempt to reduce beneficiary confusion regarding their prescription benefits and choice of pharmacy. We commend CMS for recognizing previous concerns NCPA has shared about misleading marketing practices, and reminding sponsors that beneficiary communications regarding preferred pharmacy networks must not be misleading, and that any marketing to LIS beneficiaries must be differentiated. In addition to customer service representatives from the plans, NCPA also encourages CMS to continue working closely with State Health Insurance Assistance Program (SHIP) representatives to ensure that they are fully aware of the Part D benefit, including the nuances affecting LIS patients, in order to offer accurate, unbiased counseling and assistance to Medicare beneficiaries. Results from a 2013 survey of community pharmacists on the impact of preferred pharmacy networks on patients and pharmacies reveal that beneficiaries are still very confused about the differences between preferred and non-preferred (or "network") pharmacies, with three-quarters of respondents attributing the patients’ confusion to the plan's marketing activities.

We remain concerned about preferred network adequacy requirements and question whether drug costs in preferred prescription drug plans (PDPs) are lower compared to costs in PDPs without preferred networks, and ultimately increase CMS payments to such preferred pharmacy networks – the antithesis of the allowance of such networks. These so-called “preferred” network plans are actually restrictive plans and pose challenges for many seniors living in rural communities. Although minimum access standards do not apply to the formation of preferred pharmacy networks, CMS should be concerned about the great disparities in the locations of preferred and non-preferred pharmacy locations. Some beneficiaries from the NCPA survey who enrolled in a preferred plan report that not only were they unaware they could no longer fill their prescriptions at their local, trusted community pharmacy, but that they have to travel 20 miles or greater to fill their prescriptions at a preferred pharmacy, bypassing several network pharmacies along the way just to benefit from lower co-pays.

NCPA conducted its own analysis (Attachment 2) of a comparison of drug costs in preferred vs. network pharmacies as well as of the situation of preferred pharmacy locations in relation to the rest of network pharmacies for several large preferred PDPs. To conduct the analysis of the comparison of drug costs in preferred vs. network pharmacies, NCPA selected four commonly dispensed brand drugs in the senior population and compared the full cost of these drugs at a preferred network pharmacy and mail order versus the full cost at a non-preferred network pharmacy, for two large preferred pharmacy network plans. The analysis was carried out for eight zip codes in the Midwest and Western regions of the country, with a population mix of both large urban cities and small rural towns. Across the eight cities, the preferred network pharmacy was more expensive relative to the non-preferred network pharmacy 75% of the time. Furthermore, when comparing mail pharmacy to non-preferred network pharmacy, the comparable figures were again higher 94% of the time. Our findings appear to corroborate the initial results from CMS’s own analysis as well. While these results represent just a cross-section of beneficiaries for a short list of drugs, they send a strong signal that preferred pharmacy networks may be violating the requirement not to increase CMS payments to such plans and warrant further investigation by the agency.
In addition, seniors enrolled in the Humana Wal-Mart Preferred Rx plan, and residing in Helena, Montana, have the option to choose between fifty network pharmacies to fill their prescriptions, yet only four of these pharmacies are part of the preferred network. Relying on GPS coordinate data, NCPA was able to identify the precise location of each participating network pharmacy. NCPA went on to calculate the distance a senior residing by a network pharmacy would have to travel to reach a preferred network pharmacy. In many cases the distance was more than thirty miles. As an example, seniors residing by a network pharmacy located by point A (see Attachment 3) would need to travel sixty four miles to reach the nearest preferred network pharmacy. Seniors participating in the AARP Medicare Rx Preferred plan would need to travel forty miles to reach the nearest preferred pharmacy, if they resided by a network pharmacy located by point A (see Attachment 4).

While NCPA is happy to see CMS is concerned with LIS marketing and cost-differentials associated with preferred pharmacy networks, we strongly encourage CMS to pursue more thorough analyses on access, costs and marketing associated with these preferred networks.

Conclusion

The draft Call Letter takes significant steps toward addressing Part D PBM abuses that have been plaguing beneficiaries and pharmacies. NCPA commends CMS for recognizing them for 2014. NCPA urges that the final Call Letter retain these sections addressing Part D PBM abuses to protect the interests of beneficiaries, further promote pharmacy competition, and most importantly provide true patient choice.

Sincerely,

John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs/
Director NCPA Advocacy Center

Attachments
ATTACHMENT 1

Survey of Community Pharmacies
Impact of Pharmacy Benefit Manager (PBM) Contracting and Auditing Practices on Patient Care

National Results
September 2012

The Medicare Pharmacy Transparency and Fair Audit Act of 2012 (H.R. 4215) would make several reforms to the unregulated Pharmacy Benefit Management (PBM) marketplace. These reforms would help community pharmacies serve patients and assure that there is a strong, accessible community pharmacy network.

Among other provisions, the bill would require PBMs to disclose the source of maximum allowable costs (MACs) for generics and update them no less than every seven days. The bill would also make PBM auditing practices more focused on fraud rather than administrative and technical issues and make these audits more consistent among PBMs.

This survey provides important information to policymakers regarding the challenges that over 350 pharmacies report having with PBMs. This survey was conducted in August, 2012.

- 96.2% of independent community pharmacies stated that a typical PBM contract has minimal or no transparency on how generic pricing is determined.
- 20% of the time, PBMs set reimbursement for generics below the acquisition cost to the pharmacy.
- 76.6% of independent community pharmacies stated that auditing requirements across Part D PBMs is not consistent at all.
- over 58.7% of independent community pharmacies stated that PBM reimbursement and auditing practices are very significantly affecting their ability to provide patient care and remain in business.
I - A provision of H.R. 4215 would require PBMs to disclose more information to pharmacies in contracts regarding MAC reimbursement for generics. In a typical PBM/pharmacy contract, how much information or specificity is usually given regarding either how MAC pricing is determined (methodology) or how often these prices will be updated?

II - How often is it the case that PBMs set reimbursement for generics below the acquisition cost to your pharmacy?

<table>
<thead>
<tr>
<th>Percent of Time MAC Pricing Below Acquisition Cost</th>
<th># of Respondents</th>
<th>% of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% or less</td>
<td>188</td>
<td>51%</td>
</tr>
<tr>
<td>Between 11% and 20%</td>
<td>104</td>
<td>28%</td>
</tr>
<tr>
<td>more than 20%</td>
<td>78</td>
<td>21%</td>
</tr>
</tbody>
</table>

III - It has been suggested that PBMs reduce their MACs faster for products that have gone down in price rather than increasing MACs for products that have gone up in price. Do you believe that this statement is true?
IV - Several provisions of H.R. 4215 would reform the manner in which PBMs could conduct audits. How consistent are the auditing requirements across Part D PBMs?

![Consistency of Auditing Requirements](image)

V - How often is extrapolation used in a Medicare Part D PBM pharmacy audit?

![Frequency of Extrapolation in Audit Process](image)
VI - How often do Medicare Part D PBM auditors require (and accordingly harshly penalize pharmacies for even minor noncompliance) recordkeeping requirements that go above and beyond what is required under state or federal law?

![PBM Recordkeeping Requirements in Excess of State/Federal Law](chart)

VII - How significantly are PBM reimbursement and auditing practices affecting your ability to provide patient care and remain in business?

![PBM Audit Practices Impact on Patient Care](chart)
Open-Ended Responses

Please provide examples of contentious Medicare Part D auditing practices that are affecting your ability to provide patient care and remain in business:

- Audits take 4 to 5 hours of my professional time in addition to 4 to 5 hours to pull Rx hard copies to prepare for the audit. Then I spend my 16 to 24 hours of staff time rebutting the audits, and prescriber time, for what are mostly clerical errors.
- One audit required invoices be pulled on hundreds of products to prove we had bought them. It took my main tech at least 12 hours over several days to pull and copy all the paperwork.
- We fill a monthly prescription for Provigil 200mg (#90) for a patient. Every time a new prescription is issued by the physician, we are audited by the PBM. Twice they have claimed that we did not respond to audit and that it would result in an automatic charge back (one month is approximately $3000).
- Minor recordkeeping errors like missing a doctors ID number on the face of Rx that they won't let us correct.
- Requiring pharmacy to obtain written documentation from physician for a prescription that was telephoned in 8 or more months in the past.
- Require NPI and we have to constantly look them up because not on hard copy or e-script.
- The NPI lookup website had the wrong # for an md and we were penalized
- Reversing claims for entering script for md name on top of hard copy, instead of the one who signed
- Auditing records from 5 or 6 years ago prior to us having electronic records. It is very hard to find paper copies from that long ago.

Please give examples of drugs for which MAC pricing was set below acquisition cost:

- Over 600 drugs were identified. Some of the most commonly identified drugs included: Budesonide (Asthma), Atorvastatin (Cholesterol), Clarithromycin (Antibiotic), Fentanyl Patches (Pain), Hydrocodone (Pain/Inflammation), Methylprednisolone (Steroid)
**ATTACHMENT 2**

<table>
<thead>
<tr>
<th>Location</th>
<th>Preferred Pharmacy</th>
<th>Non-PREFERRED Pharmacy</th>
<th>Mail Pharmacy</th>
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<td><strong>Helena, MT</strong></td>
<td>$359.38</td>
<td>$327.73</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>non-preferred pharmacy</td>
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<td>$369.97</td>
<td>$368.98</td>
</tr>
<tr>
<td>Mail</td>
<td></td>
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<tr>
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<tr>
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<td></td>
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<td>$368.98</td>
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<tr>
<td>non-preferred pharmacy</td>
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<td>$367.47</td>
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<td>non-preferred pharmacy</td>
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<td>$368.98</td>
<td>$367.47</td>
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<tr>
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<tr>
<td>Mail</td>
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</table>
ATTACHMENT 3

Humana Walmart-Preferred Rx
Helena, Montana
2013

- 50 Pharmacies in open network (stars)
- 4 Pharmacies in preferred network (arrows)
- Senior living near "A" would need to travel 64 miles to reach nearest preferred network pharmacy
ATTACHMENT 4

AARP Medicare Rx Preferred
Helena, Montana
2013

- 43 Pharmacies in open network
- 3 Pharmacies in preferred network (arrows)
- Senior living near "A" would need to travel 40 miles to reach nearest preferred network pharmacy