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

December 12, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4157-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4157-P; Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on CMS's 2013 Proposed Rule regarding the Medicare Part C and D programs. As CMS considers finalizing the proposed changes to the Part C and D program, 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. Focusing on the Medicare Part C and D programs, NCPA members are a primary access point for prescription medications for millions of Part C and D beneficiaries in both outpatient and long-term care settings, 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 2013 Proposed Rule regarding the Medicare Part C and Part D programs.

Coverage Gap Discount Program (42 CFR §§ 423.100, 423.505, 423.1000, 423.1002, and 423.2300-423.2410)

NCPA supports CMS' implementation of the statutory requirement that Part D sponsors must reimburse a pharmacy, including long-term care pharmacies and home infusion pharmacies, the amount of the applicable coverage gap discount no later than 14 days after the date of dispensing, if the claim is submitted electronically, and no later than 30 days after the date of dispensing, if the claim is submitted otherwise.

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It is important that pharmacies who provide the coverage gap discount at the point of sale be quickly reimbursed, so that they do not bear the burden of floating costs that should be borne by the Part D sponsor and manufacturer. Small community pharmacies operate on very thin profit margins, and will only continue to thrive as important health care suppliers and providers if they are promptly reimbursed for the products and services that they provide. NCPA fully supports CMS' implementation of prompt pay requirements for coverage gap discounts to retail pharmacy.

Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs (42 CFR § 423.100)

NCPA fully supports CMS' implementation of the statutory requirement that Medicare Part D provide coverage for benzodiazepines and barbiturates, when used for epilepsy, cancer, or a chronic mental health condition. These drugs play important quality of life roles for terminally ill, chronically ill, and chronically mentally ill patients. Part D beneficiaries with epilepsy, cancer, and mental health conditions should have access to these drugs under the same terms and conditions as their access to other Part D drugs. An improved quality of life and an improved mental state for these ill patients may actually correlate with improved health care outcomes and related health care spending reductions in the long run. Accordingly, NCPA endorses CMS' proposal to include benzodiazepines and barbiturates in the Part D program.

Pharmacy Benefit Manager (PBM) Transparency Requirements (42 CFR §§ 423.501 and 423.514)

NCPA applauds CMS' decision to implement the Affordable Care Act ("ACA") statutory provisions regarding PBM transparency requirements within the Part D program. We believe that some PBMs within the Part D program have been failing to pass along drug cost savings to the Part D program. The proposed PBM transparency provisions will require PBMs to disclose information regarding financial transactions involving Part D sponsors. These provisions will help to discourage PBMs from engaging in practices which enhance their profits, but decrease beneficiary and CMS access to important cost savings.

We believe that CMS should review the current information required to be reported by plans to CMS to be sure that the intent of Congress is being implemented. We believe that plans should report the rebates, discounts, and price concessions that they negotiate (minus bona fide service fees) for patient utilization, as well as the amounts that are passed through. This will give CMS a sense of how much of these rebates are being retained by the plan and how much are being passed through to beneficiaries and CMS. The types of negotiated price concessions that are to be reported are relative to patient utilization. This term should be fully defined by CMS or PBMs will find ways to rename their price concessions so they do not have to be reported. Patient utilization type rebates can be those attributable to formulary placement as well as actual use by the patient. While the law excludes the reporting of negotiated rebates, discounts, and price concessions attributable to patient utilization, there is no such limiting on reporting of those that are actually passed through. This will give CMS a sense of how much is retained by the plan, but the real loophole in our view is the ability of plans to not report negotiated price concessions other than related to patient utilization.

We also believe that for CMS to appropriately monitor whether plans are calculating their average amount paid to a pharmacy as compared to what the plan paid the PBM, that plans have to report their MAC lists to CMS no less frequently than a monthly basis.

We do not believe that CMS has full transparency into the games that PBMs play with generic MAC lists. PBMs change MAC lists on a whim, which lowers reimbursement to pharmacies. There is no indication that CMS is collecting this information.

Although the ACA requires Part D plans to exclude bona fide service fees when they report the aggregate amount and type of rebates, discounts, or price concessions, NCPA requests more guidance from CMS regarding oversight over Part D plans and PBMs to ensure that those fees claimed to be bona fide service fees are actually bona fide service fees and not rebates that should be passed through to patient and/or CMS. A March, 2011 OIG report raised similar concerns. The OIG found that PBMs were claiming certain fees as bona fide service fees, and therefore these fees were not reported to Part D plans or to CMS, provided they were paid at fair market value. However, the contracts between the Part D plans and the PBMs had only limited information about these bona fide service fees. Accordingly, neither CMS nor the Part D plans were always able to verify whether or not claimed bona fide service fees should actually have been considered rebates, in which case Part D plans would have been inaccurately reporting this information to CMS.

As a result of its findings, the OIG had a number of recommendations for CMS. First, the OIG encouraged CMS to work with sponsors to gain a better understanding of the circumstances under which some sponsors are reporting these fees as rebates and others are not. Second, OIG further requested that CMS clarify when these fees should be reported as rebates. Finally, OIG indicated that CMS should monitor the fees and ensure that they were reported appropriately, including targeting certain sponsors to audit in order to assess whether these fees should actually be considered rebates and therefore should be taken into account in reconciliation.

The 2013 Proposed Rule does not address a number of the concerns raised by the OIG. Although the Proposed Rule defines bona fide service fees and discusses monitoring the reporting of such fees to ensure compliance, CMS should provide further guidance on the issue. More specifically, CMS should provide guidance on how it will determine whether the fees are being paid at fair market value, and therefore do not need to be reported as a rebate or related discount.

Additionally, CMS should set out guidance explaining when a fee paid to a PBM should be deemed to be a bona fide service fee and when it should be deemed to be a rebate or similar discount to be passed onto the beneficiary or CMS. The proposed definition lists examples, but also states that such examples are "not limited to" those listed, which allows PBMs too much leeway to wrongfully claim certain fees as bona fide service fees. Therefore, CMS should include in any guidance on this section examples of fees that would not be considered bona fide service fees. Furthermore, CMS should explain how it intends to monitor compliance in terms of appropriate reporting of bona fide service fees, and should promulgate regulatory guidance regarding CMS' proposals for auditing sponsors and PBMs to ensure compliance. NCPA does not believe that CMS' proposed guidance is strong enough to deter PBMs from wrongfully claiming certain fees as bona fide service fees.

With regard to defining a bona fide service fee, NCPA is also concerned that the phrase "patient care programs" is too vague. In the preamble, CMS states that bona fide service fees include "patient care programs (such as medication compliance programs and patient education programs)." As phrased, the phrase "patient care programs" contains no boundaries or limitations.

NCPA remains concerned that PBMs will use the vagueness of the phrase to include as patient care program fees certain fees, which should not be considered as such. PBMs will likely engage in such conduct to avoid the requirement of having to make transparent their payment for such fees. Accordingly, NCPA requests that CMS more strictly define what is and is not included in a fee related to a patient care program.

Lastly, as the intent of the inclusion in the ACA of these requirements for PBMs under Part D is to provide greater transparency around the complex issues of rebates and to ensure that the federal government has adequate and relevant data to ensure that rebate amounts are being returned to the Part D program, NCPA encourages CMS to focus the highest level of scrutiny in ensuring these requirements are properly reported and analyzed. CMS should provide an annual report on the best and worst plans with respect to the metrics required to be reported under the law.

Independence of LTC Consultant Pharmacists (§483.60)

NCPA strongly opposes CMS' considerations to require a LTC facility to employ or directly or indirectly contract for the services of a licensed pharmacist who is independent of any affiliations with that LTC facility's LTC pharmacy, pharmaceutical manufacturers and distributors, or any affiliates of these entities. NCPA does not dispute that some large chain LTC consultant pharmacists and pharmacies participated in the improper and allegedly unlawful practices as outlined in the proposed rule. However, such wrongdoing was perpetrated by a small group of entities, all of which appear to be large LTC pharmacies. The entire industry, especially small, independent LTC pharmacies, should not be punished or completely changed for the actions of others.

NCPA has strong concerns with data CMS is relying on to consider separation of LTC consultant pharmacists from LTC pharmacies

Moreover, CMS relies on questionable data in justifying the need to alter the structure of the entire industry of LTC consultant pharmacy. Specifically:

- The proposal states that "industry estimates indicate that three LTC pharmacy organizations have 90 percent of the market. Based on these estimates, the LTC pharmacy industry is highly concentrated, and we believe, therefore, these arrangements are widespread." Other studies refute CMS' premise and conclusion. For example, a study conducted by Harvard Medical School for CMS' own MedPAC indicates the market is composed of two LTC pharmacy organizations (Omnicare and PharMercia) and the rest of the industry is held by local and regional LTC pharmacies.[1] Current estimates indicate that the two large chain pharmacies may only control up to 60% of the senior care market.[2],[3]

- The preamble also states that "despite the serious safety concerns, researchers reported nearly 1 in 3 nursing home residents in the U.S. received antipsychotic drugs in 2007." In the preamble, CMS neglects to mention that this same report contains a number of limitations, including the fact that "the [report] data c[a]me from a single long-term care pharmacy provider with a large nationwide sample." [4] The report specifically stated that "our results may not be generalized to all Medicare enrollees."[5]

- The preamble further states that "prior research examining potentially inappropriate prescription drugs among nursing home residents found half of the almost 3,400 study residents were prescribed a potentially inappropriate prescription medication. Forty percent of these residents had medication that was identified as both inappropriate and generally to be avoided among older LTC residents; a third of these medications posed a potential for severe harm. The therapeutic class most prevalent was antipsychotic agents." The prior research cited by CMS is extremely outdated. The Medical Expenditure Panel Survey Nursing Home Component, upon which CMS relies, was conducted in 1996, some 15 years ago, and the report was published in 2004. Moreover, both the study and the publication took place before the 2005 Food and Drug Administration warning against the use of antipsychotic medications in older persons with dementia.[6] Given the FDA changes, one cannot rely on such outdated data to claim the widespread inappropriate use of antipsychotic drugs.

- The preamble cites to another report that "states that 54 percent of the 79 pharmacy directors interviewed for the study reported that their pharmacy receives rebates from pharmaceutical manufacturers that are frequently based on market share or volume. However, only three of the pharmacy directors reported providing rebate information to the LTC facility. Thus, in delegating responsibility for avoiding use of unnecessary drugs to consultant pharmacists, nursing homes generally are unaware of any financial interests that can bias the pharmacist's drug recommendations." Once again, CMS failed to note the limitations of this report. The report expressly states that, "…estimates derived from medical directors' and pharmacy directors' responses are limited to the sample respondents. We did not project these estimates to the population due to the low response rate and low useable sample size, respectively."[7] In other words, it is questionable whether these findings are applicable to larger populations.

- In the preamble, CMS, referencing the same report above, also stated that "…the OIG noted that when a consultant pharmacist recommended a medication change during the drug regimen review, the recommendation was accepted by the prescribing physician about 74 percent of the time." However, again, CMS did not explain that OIG also stated that "…estimates derived from medical directors' and pharmacy directors' responses are limited to the sample respondents. We did not project these estimates to the population due to the low response rate and low useable sample size, respectively." [8] Moreover, the 74% statistic may not even be accurate, as other studies have cited a broad range of accepted recommendations by prescribers from 46% to 52.6% to 68% to as high as 80%.[9]

NCPA strongly disagrees that potential large scale changes to the LTC consultant pharmacy industry are being considered based on anecdotal evidence and not empirical data

CMS' preamble also relies on data that lacks rigor or is speculative. CMS is using such questionable data and speculations to justify changing the structure of the entire LTC consulting pharmacy industry. For example, with emphasis added:

- CMS relies on **verbal conversations with industry representatives** to conclude "that LTC pharmacies typically provide the consultant pharmacists to nursing homes at rates that are well below the LTC pharmacy's cost and below fair market value."
- The preamble concedes that CMS has "**no evidence directly linking [current LTC consulting pharmacy] arrangements to adverse outcomes."**

- The preamble further concedes that **CMS' "findings do not directly connect LTC pharmacy relationships with consultant pharmacists to these research findings and survey results."** Rather, CMS believes it reasonable "**to presume** that the incentives present in the relationships among consultant pharmacist, LTC pharmacies and drug manufacturers can influence the prescribing practices reflected in these data."
- CMS' preamble also states that "it is our understanding that LTC pharmacies typically have been providing consultant pharmacists to LTC facilities at rates below fair market value." However, CMS does not explain how it reaches such a conclusion.
- Similarly, the preamble also states that CMS understands "that the subsidized rates are typically $1 per resident per month for the conduct of each resident's drug regimen review." Again, CMS does not explain where this data comes from.

In light of the concerns raised above, NCPA believes a more robust analysis of the current LTC pharmacy marketplace and current LTC pharmacy practice, supported by substantial, empirical data, is warranted before altering an entire sector of pharmacy practice.

NCPA concerns with LTC consultant pharmacist separation proposal also include timing considerations, access to rural providers, and conflicts that may arise from independence of consultants

Along with questioning the foundation and support for CMS' proposed change to LTC consulting pharmacies, NCPA is also concerned with the timing of implementation of this proposed change. As of January 1, 2013, skilled nursing facilities and LTC pharmacies will already be implementing new 14-day-or-less dispensing cycles. Implementing the LTC consulting pharmacy proposal at the same time has the potential to create confusion, problems with communication, and may affect patient care. Should CMS decide to implement the proposed LTC consulting pharmacy change, we strongly urge CMS not to implement this rule at the same time as the new dispensing regulation.

The proposed rule also solicits comments about implementation of LTC consulting pharmacy changes for rural LTC facilities. NCPA is concerned that the proposed rule will change the profession in such a way that rural LTC facilities will not be able to find or afford an independent consultant pharmacist. A survey of NCPA membership conducted in November 2011 indicates that 80% of the facilities they serve are located in small town or rural communities. Furthermore, 57% of respondents are aware of shortages of consultant pharmacists in the area that their pharmacies reside and 53% are aware of shortages of consultant pharmacists in the area that their facilities reside. NCPA believes that these existing shortages will become much worse if consultants are forced to sever ties with current employers and become independent consultant business owners without the benefits of employment by a larger entity. Another important factor is facilities may not be able to find pharmacists willing to travel to their location because of the distance to get there. A pharmacist working at a retail/LTC combination pharmacy may be the only pharmacist in the local area. NCPA is agreeable to sharing more information contained in our survey results with CMS.

In addition, NCPA has concerns that if LTC consultants were to be employed by the nursing home, conflicts of interest could exist. As an example, a patient is admitted to the facility on brand name drugs and costs the facility money. The nursing home in this instance might instruct the consultant to make recommendations to change everything to a generic versus leaving them on a brand drug. In the case of an antibiotic or other agent, this may not be the best for the patient.

NCPA has been made aware of examples where the facility insisted on using a lower cost antibiotic even though the infection was not susceptible to the less expensive product and the patient had to go back to the hospital costing the system more money.

NCPA suggestions for entities in the private sector that should be exempt from any efforts regarding LTC pharmacist separation from LTC pharmacy

As stated above, NCPA does not believe that the data cited in the proposed rule sufficiently justifies the proposal requiring independence of the consultant pharmacist from the dispensing pharmacy. The choice of the relationship should be between the LTC facility, the dispensing pharmacy, and the consultant pharmacist.

However, as the proposed rule solicits comments related to unique situations, such as Tribal ownership of the facility and pharmacy, wherein entities should be exempt from a rule of this nature as the risk of conflict is limited, NCPA requests that CMS consider exemptions from the independence requirement for the following categories if such a proposal is to move forward, where either the undue hardships of separation would be too great or the risk of conflict is limited:

- Rural pharmacies, for the reasons stated above.
- Pharmacies that are a combination of community retail sector, and long-term care sector. These pharmacies are not strictly long-term care providers, or "closed-door" pharmacies, and as such they would not have access to the rebates referred to in this proposal due to trade restrictions.
- Non-publically traded, non-publically owned independent LTC pharmacies. As reasoning for this category, the proposed rule indicates concerns related to reducing prescription drug costs for LTC residents. It is worth noting that one report indicates a significant difference between the average cost per prescription dispensed by corporate-owned LTC pharmacy providers and independently-owned LTC pharmacy providers. From 2004 through 2009, the average cost increased almost 40% (from $50.96 to $70.92) for corporate-owned entities and during the same time period the increase for independently-owned entities only increased 5 percent (from $59.60 to $62.84).[10] NCPA views this report as worth noting due to our contention that the entire industry should not be changed for the actions of others. These numbers signify that the large, chain pharmacies have certain incentives to move market share for more expensive products, unlike the small independents. Therefore, it should not be assumed that unscrupulous practices by some are being committed by the entire industry, nor should such a separation proposal be imposed on the entire industry. In addition, NCPA contends that any manufacturer incentives to independent community pharmacies related to atypical antipsychotics were terminated based on the black-box warning from the FDA. Long-term care independent pharmacies do receive rebates on other products but they are small discounts amounting to less than 2% of their total drug purchases. These rebates are discounts that take into consideration the formularies within the Medicare Part D program and are designed to work with formularies to decrease costs.

Independence of LTC Consultant Pharmacists - Comments Regarding Additional Information Collection Requirements

The analysis should include a study to estimate the average time it takes to conduct appropriate drug regimen reviews. NCPA believes that significant omissions were made in CMS' calculation of the time a consultant pharmacist takes to complete drug regimen reviews in a 100 bed facility (33 hours).

The proposed rule only takes into account the time required to provide drug regimen reviews. It fails to take into consideration the provision of other pharmacy services required by §483.60 (a) and (b)(1), and in Quality Assessment and Assurance Activities required by §483.75. An additional 20--25% of time must be accounted for these activities.

A thorough analysis of the time it takes to conduct appropriate reviews and also an impact study to predict the effects of consultant pharmacists changing employers or becoming independent business owners as consultants should be conducted. If a facility with 100 beds takes approximately 33 hours by the proposed rule estimate, one consultant will need to find work at 4-5 facilities to obtain full time employment status.

Independence of Long-Term Care Consultant Pharmacists – Comments Regarding Regulatory Impact Analysis

NCPA urges CMS to develop data to support the broad, sweeping effects that this proposal is expected to create in LTC pharmacies. Pharmacists do not prescribe medications, therefore it seems impudent to assume that the separation of the consultant pharmacist "would result in more appropriate prescribing, leading to reductions in all of the following: absolute number of drugs prescribed; unnecessary use of high price, brand name drugs; and use of antipsychotics and other drugs that should be generally avoided among older LTC residents."

The proposal indicates that one outcome will be the use of fewer drugs and fewer brand name drugs which would lower costs for LTC residents. NCPA believes there are more global factors which contribute to medication use than simply the relationship between a consultant pharmacist and the dispensing pharmacy. The IMS Institute for Healthcare Informatics report *The Use of Medicines in the United States: Review of 2010* indicates that the overall number of prescriptions dispensed by location has increased each year for the previous four years across all sectors, including community retail, mass market, mail service, and long-term care pharmacies.[11] LTC is not unique in this regard and it should not be expected that fewer prescriptions will be prescribed by requiring consultant pharmacists to be independent. Further, it is likely that fewer brand name drugs will be prescribed overall for patients in the near term as the number of brand name drugs going off patent increases through 2014.[12]

It should also be noted that consultant pharmacists often work in tandem with the dispensing pharmacy to identify and recommend medications which are within the formulary restrictions of the resident's prescription drug plan and they work with the facility to keep costs down, particularly as it relates to residents covered under Medicare Part A.

NCPA also has concerns about the impact that the proposed rule will have on LTC facility staff and overall patient care. Based on survey guidelines, the consultant pharmacist is the pharmacist of record and is responsible for managing drugs and services within the facility. Separating the consultant from the pharmacy will lead to operational disconnect between the pharmacy and facility as well as disrupt the continuum of care. The aforementioned NCPA membership survey supports these concerns. Respondents indicated that they believe that the independence of the consultant pharmacist would be detrimental to the following: facility efficiencies (66%), continuity of care (63%), timeliness of care and services (61%), and communication between health care providers (65%).

NCPA does not believe that the estimated reduction of LTC costs by $423 per beneficiary per year will be realized as the proposed rule suggests. The 2008 Part D data referenced in regard to this reduction indicates that the most expensive regions for a LTC National Drug Code (NDC) drug basket and for a LTC Pharmaceutically-equivalent Product (PEP) drug basket includes the state of New Jersey as one of the most expensive states.[13] The state of New Jersey has required LTC consultant pharmacist independence since the early 1980s.

Furthermore, the proposed rule indicates that beneficiary costs were 23% higher in the LTC setting than in the community setting. It is unclear in the preamble whether this difference takes into account the increased dispensing fees for LTC pharmacies (8-9 % pts additional to low prices, 12-13 % pts to typical prices, and 21-23 % pts to high prices).[14] Dispensing fees for LTC beneficiaries are higher due to the additional services required for this group, including: unit-dose packaging, medication delivery, and emergency drug supplies, among other special considerations.[15] In other words, higher costs in the LTC setting may not have anything to do with a lack of consultant pharmacists being independent and more to do with inherent additional costs within the LTC system. Therefore, NCPA recommends a much more thorough analysis of the estimated savings before implementing the proposal.

Lastly, NCPA is disappointed that CMS has used the forum of a proposed regulation to question the integrity and professionalism of all pharmacists based on the actions of others and based on insufficient data as outlined above. The proposal states that "LTC facilities must use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based solely on what is in the best interests of the resident. We believe this can be achieved only if the consultant pharmacist is working without the influence of conflicting financial interests that might otherwise encourage overprescribing and overutilization, which creates health and safety risks for residents." Thousands of pharmacists work tirelessly on a daily basis to care for their patients, they work with the patient's health and safety in mind, and they do it without the interests of financial incentives in mind.

In summary, requiring independent LTC consultant pharmacists may not be as advantageous as CMS claims. Accordingly, CMS should conduct additional, thorough studies regarding the likely impact of independent LTC consultant pharmacists on drug costs and patient care within the LTC setting.

Plan Performance Ratings (42 CFR §§ 422.504, 422.510, 423.505, and 423.509)

NCPA supports a number of the plan ratings measures, which CMS proposes to use in determining the star plan ratings for Part D plans and whether those plans maintain satisfactory administrative and management arrangements to avoid termination or non-renewal of a Part D contract. Specifically, NCPA endorses the measures related to hold times for pharmacists' calls to the sponsor, ensuring that the data used by pharmacists to determine a customer's Part D plan enrollment is accurate and up to date, ensuring the plan members' LIS status is accurate, efforts to direct plan members away from drugs with a high risk of side effects and ensuring that members with diabetes are treating their high blood pressure with appropriate medication.

Focusing on the accuracy of enrollment status, NCPA believes that having up to date enrollment status is particularly important, given that, in the future, Part D plans will likely recoup from pharmacists who bill a patient's claim to Part D, when the patient was actually enrolled in hospice as one example.

Pharmacists will be unable to identify whether a patient is a Part D patient or a hospice patient, unless the enrollment files are up to date. Accordingly, it is important that Part D plans be penalized when they do not maintain up to date Part D enrollment records.

For purposes of promoting better health care outcomes for Part D beneficiaries and reducing spending, it is also important to promote medication therapy management (MTM) and disease management within the Part D program. Accordingly, the measures related to avoiding medicines with a risk of side effects and appropriately treating diabetes patients' high blood pressure are very valuable.

Clarifying Coverage of Durable Medical Equipment (42 CFR §§ 422.100 and 422.111)

CMS' proposal to allow Medicare Advantage (MA) plans to limit DME supply coverage to certain manufacturers raises serious concerns. More specifically, such a proposal, while capitalizing on efficiencies through negotiated bulk discounts, may also lead to unintended consequences. In other words, MA plans may seek to limit patient access to the least expensive DME products available, regardless of quality. For example, in the context of diabetes testing supplies, MA plans in an effort to save money may drive all of their patients towards the least expensive diabetes testing supplies, but those supplies may not be as effective as more expensive brands in terms of monitoring diabetes. These lower quality products and the resulting decrease in effectively monitoring a patient's diabetes can lead to more diabetic complications and more costly measures to address those complications. In short, the least expensive diabetes testing supplies may not save money if the end result is increased health care costs to address diabetes complications. Accordingly, NCPA encourages CMS to revisit this policy and study the potential negative impacts of such a policy before finalizing it.

In light of our concerns, NCPA supports CMS' efforts to provide for beneficiary protections under the DME supply limitation proposal, including ensuring that patients who demonstrate a medical necessity for non-preferred brands have access to those brands, allowing for a transition period for new enrollees from non-preferred to preferred brands, and prohibiting MA plans from eliminating preferred coverage of a particular brand mid-year. NCPA encourages CMS to adopt the strongest beneficiary protections possible, particularly to ensure that those beneficiaries who medically need non-preferred brands have access to those brands. Otherwise, CMS may end up eliminating any savings generated by the proposal through Part A costs expended later because patients did not have access to high quality DME and developed complications as a result of such lack of access.

Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (42 CFR §§ 423.104 and 423.153)

For the most part, NCPA supports CMS' 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. By reducing patient cost-sharing for short-cycle fills, more providers and patients will participate leading to a reduction in waste from unused medications and better medication adherence through medication synchronization.

NCPA commends CMS for its recognition of the benefits of trial fills and prescription synchronization, not only for beneficiary convenience but more importantly in the provision of better patient care, healthier outcomes, and ultimately lower overall health costs.

We appreciate the foresight from CMS and the consideration of daily cost-sharing for beneficiaries to take advantage of, should they elect to have trial fills of new medications or have their prescription refills synchronized.

Specifically focusing on refill synchronization, NCPA is pleased to share the experiences of its members who have implemented refill synchronization programs, and address the issues raised by CMS in the proposed rule. Community pharmacists around the country have begun offering refill synchronization programs to better coordinate the care of their patients, reduce the potential for gaps in therapy, and improve medication adherence. This in turn can potentially prevent hospitalizations due to improper medication use.

Patients enrolled in such programs are very satisfied with the convenience of reduced trips to the pharmacy and the personalized medication reviews from their pharmacist. Although there are many benefits associated with refill synchronization, the greatest challenge with synchronization of patient refills is often coverage for "short fills", or billing for a certain quantity dispensed in order to bring the patient in line with the designated synchronization date. Currently these fills are not recognized by payers and many patients have to pay out of pocket for these short fills. Therefore, daily cost-sharing rates would greatly facilitate the synchronization process and ensure that beneficiaries are able to take full advantage of such programs.

CMS requested specific comments on its assumption that the generation of two prescriptions (when appropriate) during a single office visit would be most convenient for both the prescriber and beneficiary in the instance of a trial fill. NCPA's guidance to pharmacists who are short filling is to contact the patient's physician, explain the purpose of the refill synchronization model, and request two prescriptions for each "synchronized" medication: one for the quantity required for synchronization and a second for the normal monthly quantity. This would also satisfy the scenario of an initial or trial fill.

NCPA also understands the rationale from plan sponsors who want to monitor the prevalence and appropriateness of the dispensing of prescriptions less than 30 days to ensure that a pharmacy is not doing so in increments to increase dispensing fees. We are hopeful that the proper alignment of interests from stakeholders with a focus on improving the quality of patient care while reducing waste and lowering health care costs will alleviate those concerns, especially with the associated savings of daily cost-sharing to the Part D program (CMS has estimated savings of $180 million in 2013 alone and over $2.5 billion by 2018).

NCPA also strongly believes that the industry has the capability to work towards the coding necessary in pharmacy transactions for network pharmacies to communicate to sponsors the purpose of a short fill for less than 30 days. NCPA's recommendation is the development of submission clarification codes through the NCPDP standards process to delineate whether a short fill is to align refill dates, or for purposes of an initial or trial fill. Having a standardized code set will also help plan sponsors and CMS track the frequency with which the different dispensing methodologies are being employed.

Regarding a daily cost sharing rate in the context of LTC pharmacies, NCPA strongly encourages CMS to apply CMS' quoted guidance in the preamble of the April 2011 final rule that states that due to the relatively small copayments for LIS beneficiaries, copayments for LIS beneficiaries should be billed with the first or last dispensing event of the month.

NCPA LTC members have expressed strong concerns with the implications of a daily cost-sharing rate for this population. First, LTC pharmacies would literally be chasing quarters, expending staff time to try and collect LIS fees, many of which go uncollected today. In addition, CMS must take into account the fact that our members incur costs each and every time they must generate a paper invoice for these amounts. Creating paper invoices for extremely nominal amounts is an unwise use of valuable staff time. Again, NCPA strongly recommends that CMS revert back to the previous quoted guidance concerning LIS cost-sharing.

Valid Prescriptions (42 CFR §§ 423.100 and 423.104)

NCPA supports CMS' proposal to provide coverage for only valid prescriptions in accordance with state law. NCPA appreciates CMS' encouragement that states define valid prescriptions to include only those prescriptions with valid individual NPI numbers. Given that CMS, in the future, will be requiring valid individual NPI numbers on Part D prescriptions, it is important that there is stringent enforcement that all prescribers have individual NPI numbers.

If states begin to require valid individual NPI numbers on prescriptions, then that will add another layer of enforcement and incentive for all providers to have individual NPI numbers. However, at this time as there is no requirement for a prescription to include an individual NPI to be valid at a state level, NCPA has serious concerns with requirements to include only an individual NPI on Part D claims staring January 1, 2013 (see below). Without heavy emphasis on the NPI requirement, pharmacists will be faced with too many prescriptions using no NPI numbers, invalid NPI numbers, and/or group NPI numbers.

In addition, CMS states in the preamble that it would like to underscore that it does not intend to impose any state law requirements that do not otherwise apply regarding valid prescriptions. If it is indeed CMS' intent that all prescriptions comply with applicable state law requirements, NCPA contends that if a Part D prescription does indeed comply with all state law requirements, then that prescription can under no circumstances be audited by Part D plans using more strict guidelines than what state law requires. In other words, CMS must instruct the Part D plans to immediately stop egregious audit practices against pharmacies for violations of requirements that are not in state law.

Medication Therapy Management (MTM) Comprehensive Medication Reviews (CMR) and Beneficiaries in LTC Settings (42 CFR § 423.153)

NCPA appreciates CMS' proposal, which recognizes that, within the LTC setting, some patients are not lucid enough to participate in MTM and CMRs. NCPA supports the proposed clarification that when a patient is unable to participate, the pharmacist can perform the CMR without the beneficiary's assistance. To require otherwise would be futile, disruptive to the patient, and unnecessarily burdensome for the pharmacist. However, NCPA asks that CMS provide clarification regarding differences between a MTM, CMR, and a drug regimen review and ultimately who is supposed to be providing the service(s).

Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs) (42 CFR § 423.120)

Despite the existing rules that valid prescription claims are claims including a valid prescriber NPI, prescriber UPIN, prescriber DEA number of prescriber state license number, NCPA members have examples that some Part D plans are recouping pharmacy reimbursements unless the underlying claims contain only valid individual NPI numbers. These Part D plans are imposing requirements above and beyond those required under current federal regulations.

Unless certain changes are made, there will be implementation problems with the new 2013 proposed rules for use of only valid individual NPI numbers on prescription claims. One problem is that some Part D prescriptions come to pharmacies from an individual prescriber who uses a group NPI number on the prescription. It appears that CMS is working to eliminate the use of group NPI numbers on Medicare claims. However, unless group NPI numbers are prohibited from being used on prescription claims, it will be very difficult for pharmacies and Part D plans to ensure that a valid individual NPI number is on each Part D prescription.

Similarly, NCPA is aware that most medical interns and residents do not have individual NPI numbers. Accordingly, interns and residents usually put their supervisor's individual NPI number or a group/hospital NPI number on their prescriptions. Neither the 2012 Part D Call Letter nor the 2013 Part D Proposed Rule appears to address this issue. Again, unless interns and residents are required to obtain and use individual NPI numbers on their prescriptions, pharmacies and Part D plans will be unable to ensure that prescription claims from intern and resident prescriptions contain the individual NPIs of those interns and residents.

More generally as to the NPI issue, NCPA is unaware of the existence of a single thorough, complete and accurate database that contains all prescriber NPIs. If CMS' *National Plan and Provider Enumeration System* (*NPPES*) were completely thorough and accurate there would be no need for the commercial vendor lists that pharmacies must pay very high fees to access. Moreover, access to such commercial lists is prohibitively expensive for small business independent community pharmacies.

With regard to the 2013 plan year, it is unrealistic for CMS to expect that mandating submission of valid NPIs, and only valid NPIs, on prescription claims will be a smooth process. The inaccurate and missing data within both the NPPES and commercial vendor lists will create substantial and unfair auditing burdens on independent community pharmacies. Moreover, such a requirement may also curtail patient access to necessary drugs if pharmacists are unable to find a prescriber's NPI or accurately verify that a prescriber's NPI is valid. In sum, it is extremely unrealistic for CMS to require the use of an individual NPI on Part D prescriptions when in reality not all individuals authorized to prescribe are required to have one.

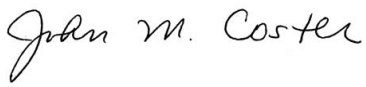
For these reasons, we request that CMS delay the 2013 NPI requirement until CMS has a valid and thorough NPI database that pharmacy providers can use to access and check NPIs and CMS has notified all prescribers that pharmacies cannot fill prescriptions unless they provide a valid NPI. Also, it is extremely important that CMS instruct plans they are not allowed to mandate the use of individual NPI's on Part D prescriptions per the reasons stated above.

Nonetheless, NCPA appreciates and supports CMS' preamble language stating that CMS expects that pharmacies will be permitted to correct any invalid NPI numbers before payment for a claim is reversed. NCPA also supports CMS' statement that it expects that any requirement by a plan sponsor or its contracted PBM for a pharmacy to acquire and utilize its own automated validation capability will be arrived at only through mutual agreement, since such a requirement may be unaffordable for many smaller pharmacy organizations. Such efforts go a long way toward minimizing the compliance burden on small community pharmacies.

Conclusion

As you finalize plans for release of the 2013 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,



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