NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

VIA Electronic Mail
AdvanceNotice2014@cms.hhs.gov

March 1, 2013

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

Dear Mr. Blum:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the 2014 Draft Call Letter ("Call Letter"). NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their over $1 trillion in annual sales. Every $1 spent in these stores creates a ripple effect of $1.81 in other industries, for a total economic impact of $1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit *www.NACDS.org*.

NACDS applauds the Centers for Medicare and Medicaid Services (CMS) for working with the pharmacy community to implement several important Medicare Part D policies during the previous year. As CMS looks to strengthen the prescription drug benefit, we offer our suggestions on the following Call Letter provisions and other equally important features of the Medicare Part D program.

Payment for Hospice and ESRD Beneficiaries under Part D

We commend CMS' efforts on benefit coordination, particularly in recognizing and making revisions to the current pay and chase approach used to recover erroneous payments for hospice and end-stage renal disease (ESRD) drugs by the Medicare Part D program. NACDS agrees that implementing a beneficiary prior authorization (PA) requirement on specific categories of drugs commonly used by beneficiaries in hospice or ESRD is a good first step to reducing the financial burden on beneficiaries and pharmacies, as well as reducing the possibility that drugs more appropriately covered under the per diem paid to the hospice or dialysis center will be paid by Part D.

In addition to implementing the proposed PA requirements, NACDS recommends that CMS also investigate options to ensure that the PA requirements are put in place in a timely manner. Oftentimes, the information that a patient has elected hospice or ESRD does not make it to the Part D plan until a month or more has passed. Without addressing the lag time,

the possibility still exists that the same pay and chase approach will be in effect for any claim submitted prior to the PA requirement being put in the system. This will continue to place heavy burdens on beneficiaries and pharmacies. To mitigate this potential, NACDS suggests that CMS develop and implement a strategy that would ensure that the PA requirement is put in place by the Part D sponsor immediately following a beneficiary electing hospice or ESRD and until the PA is put in place, the Part D plan and hospice would be responsible to subrogate payments between each other.

In the alternative, if the beneficiary selects hospice or ESRD, there should be a 'lag time of 7-10 days until the benefit declaration is active and available under the hospice or ESRD program. This lag time would give CMS the time to inform the Part D sponsor of the election so that the PA process can be implemented or the sponsor can reject claims identified as either hospice or ESRD. As noted in the Call Letter, beneficiaries and pharmacies should not bear the financial burden when claims are not rejected in an appropriate and timely manner.

CMS is also seeking comment on whether there is a benefit to sending a notice to a beneficiary who has had a claim rejected under the proposed approach. NACDS believes that any communication should be initiated by the Part D sponsor and should serve to provide useful information to either the pharmacy and/or the beneficiary. A simple letter to the beneficiary stating that the claim was rejected, without specific details or options for courses of action, may not be very timely and may be more confusing to a beneficiary. NACDS suggests that any communication sent by the sponsor should include detailed information on why the claim was rejected and how the prescription is more appropriately paid under the hospice or ESRD per diem amount. The communication should also state that there may be certain claims inappropriately paid at the pharmacy and request the patient to contact the pharmacy to provide additional information to help determine the correct payer.

Any communication should be delivered to the pharmacy at the time the claim is submitted to ensure that it is timely and can be of use to the pharmacy and the beneficiary. A communication sent weeks, or even days later will be after the fact and will only cause more confusion, especially in situations where the issue has already been resolved and the beneficiary has the medication in hand or, in the case of some hospice patients, the beneficiary is not in a position to read and fully comprehend and respond to the communication.

Daily Cost-Sharing Requirements

NACDS applauds CMS' decision to allow beneficiaries the option to obtain prescriptions in smaller quantities for either a trial to see how they react to the medicine, or to synchronize their prescriptions. The ability to synchronize prescriptions in consultation with pharmacists has been shown to increase medication adherence, leading to improved patient health and lower total medical costs. This is particularly true for beneficiaries taking medication to treat cholesterol, diabetes or hypertension. In fact, a recent study showed that when a patient was enrolled in a medication synchronization program, adherence for their medications was more

than twice the industry average. This means that the patient was three to six times more likely to adhere than the control patients.[1]

In the Call Letter CMS states that Part D plans must establish and apply a daily cost sharing rate to "certain medications." NACDS requests that all medications, unless specifically excluded by CMS, be deemed eligible for the daily cost sharing rate. This would allow for more beneficiaries to take advantage of the option to synchronize their prescriptions and in turn experience the benefits of doing so. In lieu of allowing a daily cost sharing rate for all medications, unless specifically excluded, NACDS requests that CMS make available a listing of those medications that will be eligible for a daily cost sharing rate.

Additionally, NACDS requests CMS to clarify that pharmacies that fill a prescription under the new daily cost-sharing requirements are still entitled to receive the dispensing fee associated with providing the prescription as the time and effort to dispense is still the same, regardless of the number of pills dispensed.

Auto-Ship Refill Programs in Part D

NACDS commends CMS for addressing the issue of fraud and waste attributable to the automatic delivery of medications to beneficiaries who may not want nor need the prescription. Requiring patient consent prior to the delivery of any prescription, whether a new or a refill prescription should help reduce waste as well as confusion for beneficiaries caused by receiving unwanted and unexpected medication. NACDS also appreciates that CMS has specifically clarified that this recommendation will not affect refill reminder programs that require the patient to pick-up the prescription. These programs have been useful in increasing medication adherence leading to improved health and lower overall healthcare costs.

Incremental Fills of Schedule II Controlled Substances Prescriptions

CMS is encouraging the industry to promptly address the known limitations of the current HIPAA prescription drug billing standard with respect to distinguishing partial or incremental fills on an original prescription from refills. CMS notes that the limitation may currently result in partial fills of Schedule II controlled substances being billed in a manner that cannot be distinguished from refills.

The National Council for Prescription Drug Programs (NCPDP) has identified an industry approach which would allow for the transmittal of the quantity prescribed and the monitoring of the number of pills dispensed versus that prescribed amount. This data would be available to validate whether or not there are inappropriate fills in excess of the quantity prescribed. The NCPDP recommended approach was provided to the Department of Health and Human Service's Office of e-Health Standards and Services (OESS) and is pending approval. NACDS recommends that CMS reference the NCPDP recommended approach in the final Call Letter.

[1] Holdford, David and Inocenio, Timothy. Appointment-Based Model (ABM) Data Analysis Report, Virginia Commonwealth University School of Pharmacy (Prepared for Thrifty White Pharmacy), December 2012

Additionally, because such a major change would not only affect Part D claims, but the industry as a whole, and, in order to mitigate the risks for patients and pharmacies at the point of sale, NACDS recommends that CMS delay any systemic monitoring of this issue until January 1, 2015. This would allow the industry time for system development, testing and coordination of implementation.

Applicability of Rewards and Incentives in Part D

CMS is requesting comments on how it could successfully design and utilize rewards and incentives to improve care under the Part D program, including any discriminatory impacts or other unintended consequences.

It is not uncommon for Part D Plan Sponsors to seek funding for beneficiary rewards and incentives from participating pharmacies. These participating pharmacies are required to operate in compliance with the federal anti-kickback statute and federal civil monetary penalties law (which generally prohibits offering inducements to Medicare beneficiaries). CMS is considering implementing guidance, similar to that for Medicare Advantage plans, which states that awards and incentives may exceed $50 per year as long as each individual award does not exceed $15. The implementation of a similar reward and incentive program by CMS for Part D beneficiaries would be at odds with current HHS OIG enforcement guidance on offering inducements to beneficiaries, which states that the limit per item should be no more than $10 in retail value and no more than $50 per year. Participating pharmacies may be asked by Part D Plan sponsors fund rewards and incentives in excess of the HHS OIG maximum dollar amount. This discrepancy in program rules and guidance places pharmacies in a difficult legal position given that the pharmacies may risk legal fines and penalties for the funding of rewards and incentives that exceed the HHS OIG dollar amount maximums.

CMS must ensure that the implementation of any reward and incentive program does not have the unintended consequence of placing providers, such as retail pharmacies, in jeopardy of facing fines and penalties because of discrepancies between various guidance documents.

Payment of Extemporaneous Compounds from Compounding Pharmacies

The 2014 Call Letter states that if a Part D sponsor covers a compound, in addition to the dispensing fee, it may only pay for the ingredient cost of those ingredients that independently meet the definition of a Part D drug. NACDS disagrees with CMS' plan for line item exclusions for compounded medications. A compounded medication should be covered in its entirety.

If CMS decides to implement a policy to limit the kinds of compounded medication reimbursable under Part D, including the implementation of a prior authorization (PA) requirement, there must be in place a mechanism for waiving the PA requirement in times of drug shortages. A PA waiver is especially important in certain situations, such as for patients who are unable to take an oral medication, due to difficulty swallowing, and need specially compounded medications or when there are drug shortages of medications that require timely administration. For example, in response to a shortage of liquid Tamiflu in 2009, chain

pharmacists helped to meet the need in reaction to the H1N1 flu outbreak through their ability to compound the liquid product from Tamiflu capsules. Pharmacists were able to act quickly in response to the liquid Tamiflu shortage. Requiring a patient to wait for a prior authorization in that situation would have been detrimental to the health and well-being of the patient.

Million Hearts Initiative

NACDS applauds the early success of Department of Health and Human Services (HHS) Million Hearts Initiative and looks forward to continuing to be partners with the Department on this important campaign. CMS' suggested actions that MA and PDP sponsors can take to improve access and increase adherence to anti-hypertensive medications will help with the campaign's stated goal of preventing one million heart attacks and strokes by 2017.

NACDS agrees that improving access and adherence to anti-hypertensive medications for Part D beneficiaries will help in reducing the number of heart attacks and strokes. More and more evidence is supporting the fact that improved adherence, and therefore improved health outcomes, can be achieved through increased access to medication therapy management (MTM) services and NACDS agrees with CMS' plan to encourage MA and PDP sponsors to offer MTM services to beneficiaries who fill one or more anti-hypertensive medication.

Pharmacist-provided services such as MTM are an important tool in the fight to improve medication adherence and patient health, and reduce healthcare spending. The Call Letter states that CMS will encourage Part D sponsors to offer MTM to beneficiaries who fill one or more prescriptions for anti-hypertensive medication. Poor medication adherence costs the U.S. healthcare system $290 billion annually (New England Healthcare Institute, 2009).

The recent CMS report has demonstrated the impact MTM services can have on Part D beneficiaries. The report found that Medicare Part D beneficiaries with congestive heart failure and COPD who were newly enrolled in the Part D MTM program experienced increased medication adherence and discontinuation of high-risk medications. The report also found that monthly prescription drug costs for those beneficiaries were lowered by approximately $4 to $6 per month and that they had nearly $400 to $500 lower overall hospitalization costs than those who did not participate in the Part D MTM program.

The Congressional Budget Office (CBO) has also recently acknowledged that medication use reduces healthcare costs in other parts of the Medicare program. The CBO recently revised its methodology for scoring proposals related to Medicare Part D and found that for each one percent increase in the number of prescriptions filled by beneficiaries there is a corresponding decrease in overall Medicare medical spending. When projected to the entire population this translates to a savings of $1.7 billion in overall healthcare costs, or a savings of $5.76 for every person in the U.S. for every one percent increase in the number of prescriptions filled.

A study published in the January 2012 edition of *Health Affairs* identified the key role retail pharmacies play in providing MTM services. The study found that a pharmacy-based intervention program increased patient adherence for patients with diabetes and that the

benefits were greater for those who received counseling in a retail, face-to-face setting as opposed to a phone call from a mail-order pharmacist. The study suggested that interventions such as in-person, face-to-face interaction between the retail pharmacist and the patient, contributed to improved behavior with a return on investment of 3 to 1.

Encouraging sponsors to provide more access to beneficiaries who fill one or more prescription for anti-hypertensive medications will lead to better health outcomes and reduce overall healthcare costs at the same time.

Expansion of Part D Policy on Improving Utilization Review Controls

NACDS applauds CMS' goal of addressing the very serious issue of overutilization in CY 2014. As CMS considers expanding the Part D policy on improving utilization review controls to drugs such as anti-psychotic drugs, amphetamine derivatives, benzodiazepines and non-benzodiazepine sleep aids, NACDS urges CMS to take a deliberative approach to making drug changes to ensure legitimate beneficiary access to needed medications is not impeded. Polices to reduce overutilization must be balanced with maintaining access to prescription medications by the beneficiaries who need them most. Mechanisms must be in place to allow a pharmacy, in consultation with the prescriber, to fill legitimate prescriptions without delaying treatment for beneficiaries.

Additionally, some Part D plans are sending after-the-fact utilization notices that require the pharmacist to consult with the patient on the risks of taking too much of a particular medication. We believe that consultation about the overutilization of certain medications should occur as part of an MTM session, rather than as a separate consultation after receipt of a utilization notice, with appropriate reimbursement to the pharmacy.

Drug Class Quantity Limits

NACDS has concerns with CMS' plan to implement quantity limits (QLs) based upon cumulative daily morphine equivalent doses (MED) across the opioid class. NACDS supports actions to curb the abuse of prescription medications so long as they are implemented in a manner that does not limit access to beneficiaries legitimately needing the medication.

Since individuals experience pain differently, we fear that an objective QL based on MED would merely be an arbitrary standard. In addition, it would lead to the sickest patients suffering pain the most. It is common for pain patients to develop tolerance to opioid pain medications, thus requiring higher daily doses of these medications. The risk of overdose should be controlled by good prescribing practices and patient monitoring. Only opioid-tolerant patients should receive higher doses of opioid medications.

Implementation should not impose an arbitrary QL that will prohibit a health care provider from treating a patient's pain. Adopting an arbitrary limitation assures the ineffective treatment of many patients or assumes that the limitation will be ignored by health care providers whenever necessary to properly treat patients' pain. Unless suitable pain treatment alternatives to opioid medications are found, imposing a QL would deprive patients who

benefit from such therapy, thus leading to ineffective treatment of many patients or an expectation that health care providers will ignore the limitation.

NACDS believes that policy solutions should focus on striking a necessary balance to curb the abuse of prescription medications, while also ensuring access for legitimate patients.

PDE Guidance on Post-Point-of-Sale Claim Adjustments

NACDS applauds CMS' recognition that retrospective audits of claims should not result in the complete recoupment of the claim amount for clerical errors or non-financial data errors on the transaction, such as the prescription error codes or erroneous prescriber identifiers. NACDS thanks CMS for clarifying the requirements for the submission of PDE data with respect to corrections of financial, administrative, and coverage errors.

In addition to these clarifications, NACDS requests that CMS provide additional clarification—that any recoupment should only be for the amount of the financial harm caused to the plan by the error. This is in keeping with the requirement that full recoupment should only occur in specific circumstances and not for clerical errors, but will provide greater clarification for those circumstances when partial recoupment of the claim is being determined. Pharmacies should be given an opportunity to correct administrative errors without incurring penalties or fees.

Point-of-Sale Per Claim Administrative Fees

The 2014 Call Letter states that any post-point-of-sale claim adjustments, specifically the imposition of per-claim administrative fees, violate the current guidance on negotiated prices. NACDS is seeking clarification on the definition of the "post-point-of-sale" as used in this section by CMS, as well as clarifying that the imposition of such fees by Part D sponsors is not allowed.

Additionally, NACDS asks CMS to clarify that the restriction on the imposition of administrative fees also applies to any claims processing fees charged by the Part D sponsor or their intermediaries and that claims processing fees violate the guidance on negotiated prices.

Medication Therapy Management

NACDS supports CMS' efforts to increase awareness of MTM services provided by community pharmacists, and we encourage CMS to continue outreach and education on the benefits of MTM.

Pharmacists are the most highly trained professionals in medication management. As highly trained and accessible healthcare providers, pharmacists are uniquely positioned to play an expanded role in ensuring patients take their medications as prescribed. MTM services provided by community pharmacists improve patient care, enhance communication between providers and patients, improve collaboration among providers, optimize medication use for improved patient outcomes, contribute to medication error prevention and enable patients to be more actively involved in medication self-management. Retail pharmacist-provided MTM

services are one of the many ways of using a pharmacist's clinical skills to improve patient outcomes. Pharmacists already have the training and skills needed to provide MTM services and currently provide many of these services in their day-to-day activities.

NACDS applauds CMS' plan to promote further beneficiary awareness by enhancing the information available in the *Medicare & You* handbook and on Medicare.gov. NACDS also applauds the requirement that Part D sponsors maintain certain information on their Medicare drug plan website.

Updates to the Qualification Process for Fully Integrated Dual Eligible (FIDE) Special Needs Plans

CMS is updating the process by which a Special Needs Plan (SNP) can become a Fully Integrated Dual Eligible (FIDE) SNP. NACDS applauds actions that make it easier for the dual eligible population to receive services.

However, NACDS also recommends that CMS develop and implement a strategy that would streamline the coordination of benefits between payers for dual eligible individuals, such as a FIDE/SNP and Medicaid. For example, increased coordination between payers will eliminate the current gap that exists due to Medicaid plans not supporting a point of service claim for the Part B co-insurance amount. Better coordination of benefits will contribute to better care and reduced waste in the treatment of the dual eligible population.

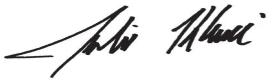
Preferred/Non-Preferred Pharmacy Networks

NACDS applauds efforts by CMS to ensure beneficiaries are fully educated when making plan selections and do not make selections based on ambiguous information. NACDS recommends that all beneficiaries be given clear instructions that, regardless of plan selection, they still retain the right to have a prescription filled at the pharmacy of their choosing and are not required to obtain their prescriptions at a preferred network. Ensuring beneficiary awareness of this policy will lead to less confusion and will allow beneficiaries to continue to utilize the pharmacy of their choice.

Conclusion

Thank you for the opportunity to comment and we look forward to working with you on these important issues.

Sincerely,



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