NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Submitted VIA: https://www.regulations.gov

March 5, 2018

Demetrios Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare
7500 Security Boulevard
Baltimore, MD 21244

Dear Principal Deputy Administrator Kouzoukas:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the 2019 Draft Call Letter ("Call Letter"). NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit www.NACDS.org

As CMS looks to strengthen the prescription drug benefit, we offer our suggestions on the following Call Letter provisions.

New Measures for 2019 Star Ratings (Page 107)

A. Statin Use in Persons with Diabetes (SUPD) (Part D)

CMS is proposing to add the SUPD measure to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year. In subsequent years, CMS proposes a weight of 3 as an intermediate outcome measure, as prescription fills are a proxy for patients taking their prescribed medications, and adherence is necessary to reach clinical/therapeutic goals.

NACDS strongly supports the CMS plan to add the SUPD measure to the 2019 Star Ratings. Due to their accessibility, education, and training, pharmacists are uniquely positioned to improve health outcomes by ensuring that patients properly receive a statin medication.

B. Statin Therapy for Patients with Cardiovascular Disease (Part C)

NACDS supports the proposal to include this measure in the 2019 Star Ratings as a process measure with a weight of one.

Changes to Measures for 2019 (Page 108)

A. Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D)

NACDS supports the proposal to concatenate consecutive stays to create a single admission and discharge date for the Proportion of Days Covered (PDC) adjustment for inpatient (IP) stays and hospice enrollment for MA-PDs and PDPs, and skilled nursing facility (SNF) stays for PDPs.

Changes to Existing Display Measures (Page 141)

A. High Risk Medication (HRM) (Part D)

NACDS supports the continued reporting and evaluation of the HRM measure on the display page for 2019 and adoption of a change made by the PQA to measure specifications for the numerator (beneficiaries with at least two fills of the same HRM drug on different dates of service) for the 2019 display measure.

B. Drug-Drug Interactions (DDI) (Part D)

NACDS supports the proposal to implement the revised PQA DDI measure drug list for the 2019 display measure using 2017 performance and PDE data.

C. Antipsychotic Use in Persons with Dementia (APD) (Part D)

CMS proposes to display the rates for the two population breakouts on the 2019 display page and to assess adding the APD measure to the Star Ratings in the future. NACDS urges CMS to move this display measure to a Star Rating in the future to highlight the role of the pharmacist in advancing the quality of care for patients in this population.

D. Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D)

NACDS supports the non-substantial changes recommended by PQA, including changing "morphine equivalent dose" to "morphine milligram equivalents" and their proposed implementation beginning with the 2017 Patient Safety Reports and addition to the 2019 Part D display page based on 2017 data. NACDS also supports the CMS proposal to add *Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP)* to the 2019 Part D display page. Further consideration is needed to fully understand how performance among these measures can be tracked in a more real-time manner to affect change.

NACDS believes that development of measures that focus on use of opioids can be a key component in addressing the incidence of abuse and diversion of opioids in the Medicare program. Such a complex epidemic requires a comprehensive and collaborative response that includes the development and implementation of relevant quality measures.

Potential Changes to Existing Measures (Page 145)

A. Telehealth and Remote Access Technologies (Part C)

In response to the CMS solicitation for feedback on telehealth and/or remote access technology encounters, NACDS believes telehealth services should be considered equivalent to an in-person encounter, if the telehealth provider has access to peripherals that measure the patient's vitals necessary to assess the patient relative to the quality measure.

B. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D)

NACDS supports adoption for the 2020 Star Ratings of the updated PQA measure to include new denominator exceptions for patients eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program.

Potential New Measure for 2020 and Beyond (Page 148)

A. Opioid Overuse (Part C)

In response to the request for feedback from stakeholders about the value of including NCQA collected data on the *Use of Opioids and High Doses* and the *Use of Opioids from Multiple Prescribers*, NACDS believes CMS should refrain from including these HEDIS measures on the display page. Intermingling HEDIS measures and Part D measures, especially when they are similar in scope, could lead to confusion. CMS should limit reporting to the established Part D measures.

B. Polypharmacy Measures (Part D)

NACDS supports the PQA developed and endorsed measures that identify potentially harmful concurrent drug use or polypharmacy and the evaluation of them for potential

inclusion in Patient Safety reporting, display page, or Star Ratings in the future. However, NACDS believes CMS should use either the *Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)* measure or the *Concurrent Use of Opioids and Benzodiazepines* measure, or another appropriate measure as utilizing multiple measures would be repetitive and unnecessary.

C. Additional PQA Medication Adherence Measures (Part D)

Although declining to adopt additional PQA medication adherence measures at this time (Adherence to Non-Warfarin Oral Anticoagulants (ADH- NWOA and Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis (ADH-MS)), CMS does note that given the high cost of these medications and the importance of adherence for achieving positive outcomes, CMS may consider including these measures within the quarterly outlier reports to Part D contracts through the Patient Safety Analysis Website in the future, along with the beneficiary level data so contracts can focus adherence improvement efforts for these members.

NACDS supports this strategy and urges CMS to consider the importance of adopting applicable measures for specialty pharmacy to address their increasing use and high costs. Also, the adoption of specific measures for specialty pharmacy could contribute to the development of meaningful performance-based agreements, further lowering program costs.

Part D Enhanced MTM Model (page 167)

NACDS has long been supportive of exploring new and innovative approaches to improve the Part D program, such as the Center for Medicare and Medicaid Innovation's (CMMI) ongoing Enhanced MTM Model pilot. This pilot allows Part D plans the opportunity to utilize new and innovative approaches to MTM, such as more efficient outreach and targeting strategies and tailored levels of services that better meet beneficiaries' needs. NACDS believes the Enhanced MTM Pilot program presents an opportunity to create better alignment of program incentives and has the potential to lead to improved access to MTM services for beneficiaries as well as greater medication adherence.

Medications are the primary intervention to treat chronic disease and are involved in 80% of all treatment regimens.[1] Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, have 50 different prescriptions filled per year, account for 76% of all hospital admissions, and are 100 times more likely to have a preventable hospitalization.[2] Yet medication management services are poorly integrated into existing healthcare systems. Poor medication adherence alone costs the nation approximately $290 billion annually—13% of total healthcare expenditures—and results in avoidable and costly health complications.[3] Thus, given the importance of medications in achieving patient care outcomes and lowering

[1] http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf
[2] Ibid.
[3] "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease;" New England Healthcare Institute, Cambridge, MA, 2009.

overall healthcare costs, it is critical that policies are implemented to encourage greater care integration across the healthcare continuum and promote financial accountability for safe and appropriate medication use.

A growing body of evidence suggests that when physicians, nurses, pharmacists, and other healthcare professionals work collaboratively, better health outcomes are achieved. Pharmacies provide access to highly-trained and highly-trusted health professionals. The unique reach and access points of pharmacy provide a means of continuous care and oversight between scheduled visits. Medication related 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, assist with hospital readmission cost avoidance goals, and enable patients to be more actively involved in medication self-management. Examples of the value of these services include:

- A 2013 CMS report found that Medicare Part D MTM programs consistently and substantially improved medication adherence for beneficiaries with chronic diseases. This included savings of nearly $400 to $525 in lower overall hospitalization costs.[4]

- A study of published research on medication adherence conducted by Avalere Health in 2013 concluded that the evidence largely shows that patients who are adherent to their medications have more favorable health outcomes such as reduced mortality and use fewer healthcare services, especially hospital readmissions and ER visits. Such outcomes lead to less expensive healthcare costs, relative to non-adherent patients.[5]

- How and where MTM services are provided also impact its effectiveness. A study published in the January 2012 edition of *Health Affairs* found that a pharmacy-based intervention program increased 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 interventions were cost-effective, with a return on investment of approximately $3 for every $1 spent. These findings highlight the central role that pharmacists can play in promoting the appropriate initiation of and adherence to therapy for chronic diseases.[6]

NACDS strongly recommends CMS and the CMMI look at ways to increase the use of pharmacist-delivered MTM as a component of the Part D Enhanced MTM Model as a key strategy to improve patient outcomes while reducing the overall cost of healthcare.

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[4] "Medication Therapy Management in Chronically Ill Populations: Final Report;" Centers for Medicare and Medicaid Services (CMS); August 2013 (http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf).
[5] "The Role of Medication Adherence in the U.S. Healthcare System;" Avalere Health; June 2013 (http://www.avalerehealth.net/research/docs/20130612_NACDS_Medication_Adherence.pdf).
[6] "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients;" *Health Affairs,* January 2012 (http://content.healthaffairs.org/content/31/1/120.full).

New Medicare Card Project (formerly the Social Security Number Removal Initiative, SSNRI) (Page 167)

NACDS appreciates CMS recognizing the importance of ensuring a smooth transition to the new Medicare cards and use of the Medicare Beneficiary Identifier (MBI). NACDS, along with other stakeholders have expressed concerns related to the ability of pharmacies and other providers to crosswalk patient data between the old and new identifier to ensure accurate billing and maintenance of historical patient data.

While CMS has indicated that the MBI will be returned within the 835 Electronic Remittance Advice, this is not a viable solution for pharmacy providers. In addition to the need to reference patient history to effectively apply compliance edits, there is also a 30-day average time lag of the Part B 835s and extensive system coding would be needed to incorporate the MBI from the payment system into the claim billing and intermediary systems. Moreover, the MBI will not be available on the 835 until October 2018. By this time, the workflow impact will already have been realized, resulting in undue resource and financial cost to providers.

As an alternative to using the 835, we respectfully request the Health Insurance Portability and Accountability Act Eligibility Transaction System (HETS) support the return of the MBI within the 271-eligibility response. The Part B intermediaries/system vendors run a 270/271 on every transaction request from the pharmacy. If the MBI and HICN are both returned in the 271 responses, the necessary crosswalks can be developed to provide historical data information to the pharmacy, where it is needed most, at point of service. The 271 is used extensively by the industry to obtain Part B eligibility information and appears to be the most viable solution. We recommend that if the beneficiary has been mailed their new Medicare card and the provider submits the HICN on the 270, that the HETS system return the beneficiary's MBI in the 2100C NM109 of the 271, the submitted HICN in the REF02 with REF01 qualifier "Q4" (Prior Identifier Number), along with the INS segment, much like CMS supports active/cross-referenced HICNs currently. This approach also is consistent with guidance in the X12 270/271 005010X279 Technical Report Type 3 (TR3).

If the MBI cannot be returned in the HETS eligibility workflow as allowed and expected within the X12 270/271 TR3, we request that CMS provide intermediaries/system vendors access to crosswalk files for the Medicare beneficiaries that they support to maintain established business processes without disruption.

We appreciate and support the work you are doing to implement this major change and look forward to working with you on this issue to ensure a smooth transition from the HICN to the MBI in a manner that does not disrupt existing and crucial provider workflow logic and beneficiary access and treatment.

Expanding the Part D OTC Program (Page 196)

NACDS supports CMS allowing additional flexibilities for Part D plan sponsors to offer access to OTCs to make them more accessible to beneficiaries while potentially lowering prescription drug costs. However, to protect patient access, such a policy should not include additional utilization management requirements be imposed on OTC products. Additionally,

CMS should consider enhancing the OTC policy to include coverage of preventive OTCs, such as aspirin and smoking cessation products.

Improving Access to Part D Vaccines (Page 199)

NACDS appreciates the encouragement by CMS for Part D sponsors to either offer a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing. It has been shown that high cost is the primary barrier contributing to low immunization rates. Beneficiaries receiving Part B-covered vaccines are not subject to cost sharing, while beneficiaries receiving a Part D-covered vaccine can be subject to a variable cost-sharing amount. A report by Avalere Health found between 47 and 72 percent of the 24 million Medicare beneficiaries with Part D coverage had some level of cost sharing for vaccines, ranging from $35 to $70 in 2015.[7] Additionally, the variable payment structure for vaccines within Medicare only confuses beneficiaries and in some cases, providers. This undoubtedly impacts the simple act of recommending a vaccine, which is another major factor affecting whether patients receive vaccinations.

Zero-dollar or low cost-sharing tiers for Part D vaccinations would improve beneficiary access and utilization.

Improving Drug Utilization Review Controls in Medicare Part D (Page 202)

A. ***Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at a dosage level of 90 MME per day, with a 7 days supply allowance.***

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

   Any policy limiting a beneficiary to a single 7-day supply when reaching a predesignated threshold needs to be constructed and implemented in a manner that does not create barriers or unnecessarily delay access to needed medications. As such, the exception process for beneficiaries in hospice care, with cancer diagnoses, or for other medically necessary reasons, needs to be seamless and prompt. Beneficiaries falling within an exception should not need to endure delays in treatment due to additional administrative processes slowing down the process.

[7] http://avalere.com/expertise/managed-care/insights/medicare-has-the-potential-to-avoid-preventable-illnesses-by-encouraging-br

Additionally, those subject to a 7-day supply limit due to reaching a MME threshold need to be informed of such by the Part D Sponsor in a timely and consistent manner to avoid confusion and maximize time needed to address the issue and maintain any treatment regimen. To most effectively achieve this, communications to patients related to 7-day supply limits should be standard across all plans.

B. ***Implementing a days supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME per day).***

NACDS supports policies establishing a 7-day supply limit for initial opioid prescriptions written for acute pain. This policy aligns with the *Guideline for Prescribing Opioids for Chronic Pain* developed by the Centers for Disease Control and Prevention (CDC) and serves to reduce the incidence of misuse, abuse, and overdose of these drugs.

A clinical evidence review performed by the CDC revealed that a greater amount of early opioid exposure is associated with a greater risk for long-term use and addiction.[8] Notably, the average day supply per opioid prescription has increased in recent years, growing from 13.3 to 18.1 days per prescription between 2006 and 2016.[9] Considering this trend and the risk of early exposure to higher amounts of opioids, it is imperative that policymakers adopt provisions to promote careful prescribing practices for prescription opioids. Notably, over 20 states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain (with appropriate exemptions, such as patients with pain due to cancer, hospice, or other end-of-life care, etc.)

For these reasons, NACDS believes CMS should finalize the proposed policy to establish a 7-day supply limit for initial prescriptions written for acute pain.

C. ***Expecting all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and request feedback on concurrent prescription opioid and benzodiazepine soft edits.***

NACDS supports the CMS proposed expectation that Part D sponsors implement a soft duplicative LA opioid therapy POS edit. A soft POS safety edit will allow the pharmacy to address and resolve potential issues at the point-of-sale, thereby reducing unnecessary delay in treatment for beneficiaries.

November 2017

[8] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*. CDC.gov. https://www.cdc.gov/drugoverdose/prescribing/guideline.html

[9] Centers for Disease Control and Prevention, *Annual Surveillance Report of Drug-Related Risks and Outcomes*. United States, 2017. https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf

In addressing how best to manage multiple opioid POS edits that may be triggered by a single prescription, NACDS suggests the "duplicative" edit be given a higher priority than the "MME" edit; the reason being that if the duplication is not valid, then it should not impact the calculation of MME.

Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs (Page 218)

NACDS generally supports the proposed changes related to making coverage determinations for immunosuppressants and inhalation drugs. However, NACDS asks CMS to clarify that the determination whether a prescription should be covered under Part B or Part D should rest solely in the hands of the Part D sponsor, who should relay that determination to providers and pharmacies via adjudication systems edits. Providers and pharmacies do not have access to the necessary data to make such a determination and must rely on information received from the sponsor.

CMS is also proposing that in instances when the Part D sponsor discovers new information indicating Part B coverage is appropriate, that no changes need to be made by the sponsor to prior Part D claims. We ask that if CMS finalizes this proposal, it clarify that in addition to no changes needing to be made by the Part D sponsor, no changes in reimbursement to pharmacies shall be required for past paid claims.

Conclusion

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

Sincerely,

Eric P. Juhl
Director, Federal Public Policy
National Association of Chain Drug Stores