Submitted electronically via www.regulations.gov

February 13, 2023

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4201–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications [Docket No. CMS–4201–P]

Administrator Brooks-LaSure,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback on CMS' proposed rule: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Medication Therapy Management (MTM) in Part D

As medication experts, community pharmacists are critical to helping patients stick with and get the most out of their prescription drugs. Yet so much more can be done to improve medication adherence and achieve better health outcomes at lower overall costs. That is where medication therapy management, or MTM, services can play a vital role and it is why NCPA strongly supports the increased application of MTM. NCPA believes that prevention is the best medicine, and whether it's catching a medication error before it leads to a hospitalization or effective chronic

disease management, MTM services present an opportunity to improve patient care while providing greater efficiencies within the healthcare system.

NCPA has long supported the expansion of MTM services. In 2006, we partnered with GlaxoSmithKline on a pilot program examining how medication therapy management can help patients with uncontrolled asthma. We supported the expansion of MTM services in legislative efforts in 2010, 2013, and 2015. NCPA also supported the expansion and extension of the Center for Medicare & Medicaid Innovation (CMMI)'s Part D Enhanced Medication Therapy Management Model.[1]

CMS is proposing to make several changes to MTM eligibility criteria beginning in plan year 2024. These include: 1) adding HIV/AIDS to the list of core chronic diseases,[2] and requiring plan sponsors to include all core chronic diseases previously identified by CMS in their targeting criteria; 2) lowering the maximum number of covered Part D drugs a sponsor may require from eight to five drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and 3) revising the methodology for calculating the cost threshold ($4,935 in 2023) to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020). With these proposed changes, CMS estimates that the MTM program size will be approximately 23 percent of the Part D population.

NCPA supports the intent of these changes in that they will increase the number of beneficiaries eligible for MTM services. However, NCPA provides the following comments below.

Broadening chronic disease class to "neurodegenerative diseases"

CMS solicits comment on whether it should consider including additional diseases to the list of chronic diseases. NCPA supports CMS adding all 10 core chronic diseases identified by CMS in its MTM targeting criteria, **and requests that CMS expand "Alzheimer's disease" to "neurodegenerative diseases."**

Pharmacists should be properly compensated for MTM

NCPA opposes further broadening coverage of MTM services without increasing payment to pharmacies, as doing otherwise will create an "unfunded mandate" on pharmacy. It is crucial that Part D plans increase payment for these services, as the existing payment rates are insufficient for pharmacies. If low payments continue, pharmacists will not invest the time in providing MTM services. Part D plans should recognize the role and value of the pharmacist and what they provide for MTM services, and compensate them accordingly.

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[1] See "Extending the CMMI Enhanced Medication Therapy Management Model to Ensure the Safety of Medicare Beneficiaries," July 28, 2021. *NCPA.* Available at: extension-emtm-letter.pdf (ncpa.org).

[2] The current core chronic diseases are: diabetes, hypertension, dyslipidemia, chronic congestive heart failure, Alzheimer's disease, end stage renal disease (ESRD), respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders), bone disease-arthritis (osteoporosis, osteoarthritis, and rheumatoid arthritis), and mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions).

Furthermore, MTM payments should be commensurate with the care and expertise provided to the patient, not based on generating additional revenue for the plans and the PBMs. NCPA opposes Part D plans utilizing MTM to generate cost savings, such as formulary management tools that arbitrarily seek to move patients to the PBM's preferred formulary medication or transitioning to an extended-day supply of medication. Often patients that qualify for MTM are not ideal candidates for extended-day supplies, such as 90-day fills. Additionally, extended day supply can often lead to less clinically appropriate in-person, pharmacy-patient contact. MTM payments should emphasize the professional services and relationships that pharmacists provide to patients. MTM should not arbitrarily limit time and engagement with patients.

Additionally, NCPA supports CMS requiring Part D contracts to contain "any willing pharmacy" language to allow pharmacies to participate in MTM services. Such participation in MTM should be based on pharmacies' capacities and willingness to handle MTM cases. Plans should not be allowed to have performance scores, fees or payment withholds contingent on the number of MTM beneficiaries a pharmacy has.

Cost threshold

NCPA is concerned that revising the methodology for calculating the cost threshold ($4,935 in 2023) to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020) may have negative unintended consequences for pharmacies. NCPA believes that ensuring a more equitable reimbursement for MTM would allow pharmacies to be able to accept more MTM cases and increase the positive impact on health outcomes for these patients. If CMS increases the number of MTM cases with the new thresholds, without ensuring the MTM requests from plans (more than changing to their formulary drugs and 90 day fills) are outcome based and appropriately compensated, CMS will not get the results they are seeking. **NCPA requests clarity from CMS as to how it anticipates the cost threshold will impact payment to pharmacies.**

Plan software

NCPA also argues that pharmacies should have flexibility to choose the documentation system(s) they prefer instead of the one(s) required by the Part D plans and PBMs. It is difficult for pharmacies to manage multiple patients on multiple platforms, which includes redundant data entry and significant administrative burden. Interoperability of the platforms would help remedy this situation. While some payers want pharmacies to capture MTM in a given platform, pharmacies should have flexibility and choice in their software for documenting and billing MTM interventions to provide the most efficiency at the point of care. NCPA also supports these platforms' ability to provide real time calculation and provision of data/payment impact information.

Star Ratings Program in Medicare Part D and Medicare Advantage

CMS proposes to add the following measures to the 2026 Star Ratings (2024 measurement year: Concurrent Use of Opioids and Benzodiazepines (COB); Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS).

NCPA opposes any factors that CMS and Part D plans take into consideration in Star Ratings that would have downstream effects on pharmacists' scope of practice or patients' clinical benefit. For example, pharmacists should be able to dispense both opioids and benzodiazepines where clinically appropriate, appropriately dosed and through communication with the beneficiary's doctor. Furthermore, some community pharmacies dispense a higher percentage of opioids due to their patient mix, or due to the fact that they are located near pain clinics, and should not be penalized from high dispensing alone.

These principles apply beyond opioids as well. For example, not every diabetic should be put on a statin (for example, an 85-year-old diabetic that has never been on a statin). Under the proper management and monitoring by a pharmacist, drug combinations are less risky to the patient.

CMS also proposes to change the weight of patient experience/complaints and access measures from four to two to further align with other CMS quality programs. **NCPA opposes this, as it undermines the importance of beneficiary care.** NCPA believes that this provision is a boon to plans, and a bust for beneficiaries.

New Drug Substitutions Allowed in Part D

In the proposed rule, CMS will permit Part D sponsors to immediately substitute 1) a new interchangeable biological product for its corresponding reference product; 2) a new unbranded biological product for its corresponding brand name biological product; and 3) a new authorized generic for its corresponding brand name equivalent. According to the proposed rule, Part D sponsors may charge the applicable cost sharing based on the therapeutically equivalent drug's or interchangeable biological product's formulary status and plan benefit design for claims. **NCPA seeks feedback from CMS if it anticipates these drug substitutions to negatively affect beneficiary cost-sharing. NCPA opposes this provision if it adds significant out-of-pocket costs.**

Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth

NCPA supports the proposed requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital literacy to assist them with accessing medically necessary covered telehealth benefits, especially when the provider and enrollee are not in the same location using "electronic exchange." NCPA agrees with CMS that this would be a first step for MA organizations to assess health inequity in telehealth in their plans and help enrollees navigate telehealth.

Many types of medication management services (MMS)[3] provided by pharmacists are clinically appropriate for telehealth, including: medication therapy management, chronic care management (e.g., diabetes, hypertension), medication reconciliation, transitions of care, pharmacogenomics, interpretation of diagnostic tests and providing test results, and consultations with patients and health care providers. In many instances, especially in rural and underserved areas where telehealth would be invaluable, pharmacists are the first point of

[3] "Medication Management Services (MMS) Definition and Key Points," Joint Commission of Pharmacy Practitioners, https://jcpp.net/wp-content/uploads/2018/05/Medication-Management-Services-Definition-and-Key-Points-Version-1.pdf

contact by patients and their caregivers. **NCPA believes CMS should pay pharmacists for the telehealth services they provide, much like they do for physicians and other health care providers and practitioners.**

Standards for Electronic Prescribing

NCPA supports the NCPDP SCRIPT Standard Version 2023011 for the e-prescribing standard for transmitting prescriptions and prescription-related information for Part D drugs for Part D eligible individuals. NCPA also supports the transition for the eventual retiring of NCPDP SCRIPT standard version 2017071, which should be replaced by NCPDP SCRIPT Standard Version 2023011 and the recommendations being made by NCPDP.

NCPA also recommends that CMS adopt the NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13 as the standard for prescriber RTPBs supported by Part D sponsors.

Additionally, NCPA agrees with CMS' approach to update and align e-prescribing standards 45 CFR 170.205(b) by cross-referencing Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards for electronic transactions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Standards for Eligibility Transactions

NCPA supports CMS' proposal that eligibility transactions should comply with 45 CFR 162.1202, and as recommended by NCPDP, with continued use of the NCPDP Operating Rules for the ASC X12 270/271 Transactions in Electronic Prescribing.

Adoption of Health IT Standards

As noted above, NCPA supports the adoption of NCPDP SCRIPT standard version 2023011, NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13, and the eventual retiring of NCPDP SCRIPT standard version 2017071, as well as the aligned approach for adopting standards in a single location for the Department of Health and Human Services (HHS) use.

Concerning the retirement date for NCPDP SCRIPT standard version 2017071, NCPA agrees with NPCDP's recommendation (and additional suggestions) that both the 2017071 and 2023011 versions be available for HHS until January 1, 2026, instead of January 1, 2025 as CMS proposes.

Replacing the "Reasonable Diligence Standard" with the "Knowingly" Standard

CMS proposes to revise its current overpayment rule, at 42 C.F.R. Sec. 401.305(a)(2), to eliminate the reasonable diligence provision, which expressly allows for the identification of an overpayment after one has or should have exercised "reasonable diligence" to make that determination and calculation. Under this provision, the payment recipient is allowed 6 months to exercise its reasonable diligence, upon credible information of a potential overpayment, before the 60-day repayment clock starts running. CMS proposes substituting instead the False Claims Act definition of "knowingly." **NCPA opposes this proposed revision, and strongly encourages CMS to maintain the current "reasonable diligence" language.**

The existing six-month time period is beneficial in helping providers identify potential CMS program overpayments. Pharmacies need significant time and resources to identify and correct overpayments. Truncating the six-month time period to 60 days would contribute undue burden on pharmacies, and not provide them with sufficient time to appropriately investigate alleged overpayments.

Access to Covered Part D Drugs During Drug Shortages

CMS proposes that for Part D drugs on a Part D plan's formulary that is subject to a shortage (on the Food and Drug Administration drug shortages list), a Part D sponsor must, for at least the duration of the shortage, permit enrollees affected by the shortage to obtain coverage of: 1) a therapeutically equivalent non-formulary drug or interchangeable biological product, if any, without requiring enrollees affected by the shortage to meet formulary exception requirements; or 2) a therapeutically equivalent formulary drug or interchangeable biological product, if any, that requires prior authorization or step therapy without requiring enrollees affected by the shortage to meet prior authorization or step therapy requirements. **NCPA supports this proposal.**

DEA Numbers

CMS proposes that a Part D sponsor must confirm the prescriber's DEA registration number on a prescription drug claim for a controlled substance, and if the DEA registration number is not on the claim, then the sponsor must cross-reference the prescriber's Type 1 NPI on the claim to any associated individual prescriber DEA number. CMS further proposes that if the DEA registration number is not valid or active or the DEA registration number does not have an associated Schedule that is consistent with the drug for which the claim was submitted, then the Part D sponsor must reject the claim and provide the pharmacy with the electronic reason code when rejecting the claim. Further, if the pharmacy confirms the validity of the DEA registration number via electronic override code, or the sponsor is not able to cross-reference the Type 1 NPI to a prescriber DEA registration number, the sponsor must process the claim under the applicable benefit rule.

NCPA requests that CMS not automatically require sponsors to reject all claims for controlled substances for which they cannot validate the DEA registration number and Schedule. Having sponsors reject all claims for controlled substances for which they cannot validate the DEA registration number and Schedule could lead to perfectly valid prescription claims being rejected, which would harm beneficiary access and increase administrative burden. Additionally, pharmacies often have access to DEA registration number information that is more current and accurate than the information from the Part D sponsor.

Conclusion
NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

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