Submitted electronically to: www.regulations.gov

September 6, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1770-P
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amount (CMS-1770-P)

Dear Administrator Brooks-LaSure:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its *Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amount* proposed rule (CY 2023 PFS proposed rule).

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 $67 billion healthcare marketplace, employ 215,000 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. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1 and GYYY2)
CMS is proposing to create separate coding and payment for chronic pain management (CPM) services beginning January 1, 2023. Specifically, CMS is proposing two new codes that would be analogous to Chronic Care Management (CCM) services. **NCPA advocates that CMS should allow at least two add-on codes with GYYY2 because these patients can be complex and some require intense coordination.**

NCPA strongly supports that CMS adopt provisions for pharmacist participation in CPM as auxiliary personnel. We also support using consistent terminology in that CMS should use "clinical staff" as it does for similar programs. NCPA strongly supports the general supervision requirement, which would allow community pharmacists to partner with physicians.

NCPA also supports that the initiating visit be able to be delivered via telehealth and well as monthly follow-up visits. NCPA prefers that video be the modality for the initiating visit.

We have some concerns that the documentation of this service could be onerous and impact providers, including pharmacists' ability to participate. We ask that CMS ensure that documentation requirements not be overly burdensome.

Proposed Revisions to the ''Incident to'' Physicians' Services Regulation for Behavioral Health Services
CMS is proposing to amend the direct supervision requirement under its ''incident to'' regulation at § 410.26 to allow behavioral health services to be furnished under the general supervision of a physician or NPP when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. **NCPA supports this proposal.**

Request for Information: Medicare Potentially Underutilized Services
CMS is seeking comments on ways to identify specific services and to recognize possible barriers to improved access to these kinds of high value, potentially underutilized services by Medicare beneficiaries. CMS is also seeking comment regarding how it might best mitigate some of these obstacles, including for example, through examining conditions of payment or payment rates for these services or by prioritizing beneficiary and provider education investments.

Some services that CMS mentions by name in the RFI which pharmacists provide include: annual wellness visits, "diabetes management training," screening for diabetes, immunizations/vaccinations, and the Annual Wellness Visit (AWV). NCPA provides policy suggestions below on how to improve access to diabetes self-management training (DSMT), continuous glucose monitoring (CGM), the Medicare Diabetes Prevention Program (MDPP), and the AWV.

Diabetes self-management training (DSMT)
NCPA recommends that CMS address challenges for pharmacists and pharmacies to deliver diabetes self-management training ("DSMT") services. Diabetes is a growing epidemic in this country, and community pharmacists are key in managing the disease. We appreciated CMS' recognition of pharmacists as instructors "who actually furnish DSMT services...," in the CY 2017

PFS proposed rule.[1] Section 1861(qq)(2)(A) of the Social Security Act states that DSMT services can be provided by "certified providers," which include "individual[s]" who meets "quality standards established by the Secretary..." "...for furnishing these services." While pharmacists and their services are not listed under §1861, accredited pharmacies are able to provide such services upon meeting certain requirements.

Our members continue to experience barriers to providing DSMT services due to lack of awareness that accredited pharmacies can bill for DSMT services and that pharmacists are recognized DSMT instructors. For example, it took one community pharmacy 9 months to receive an NPI to bill for DSMT services primarily because of MAC assertions that a pharmacy should only be requesting an NPI for Part D services. In addition, our members have had claims rejected when submitting bills from a DSMT accredited pharmacy because a pharmacist signed the billing paperwork and not a Part B DSMT certified provider.[2] Policies that allow a pharmacist to be an instructor for an accredited DSMT pharmacy, but not sign the bills for DSMT services is illogical and inconsistent with CMS' policies and aim to make such services more accessible to patients. In many cases, the pharmacist is the most accessible health care provider in a community and may be the sole instructor for DSMT. Furthermore, when pharmacists inquire about DSMT billing problems to CMS or MACs, staff are not often aware of pharmacists' and pharmacies' roles in DSMT. This was not clarified in the CY 2017 final PFS rule or subsequent rules. **Accordingly, we request that CMS clarify that pharmacists and pharmacies can provide DSMT services. We also ask CMS provide education and training materials for staff and information for patients and other stakeholders about the program and its benefits.** This acknowledgement and awareness will address concerns expressed in the CY 2017 PFS proposed rule, that "claims have been rejected or denied because of confusion about the credentials of the individuals who furnish DSMT services," and will help address the "issues that may contribute to the low utilization of these services." **We also ask CMS to clarify that a DSMT accredited pharmacy can bill for services without sign-off from a Part B DSMT accredited provider—a position reinforced by the fact that CMS and national accreditation organizations ("NAOs") allow pharmacists to be DSMT certified instructors.**

One of NCPA's members is currently in discussions with the CDC who, after seeing the impact pharmacists made with covid vaccine administration, are asking community pharmacies accredited for DSMT to be extenders of local county health departments across the nation. However, pharmacies are hesitant to partner because of all the billing difficulties they currently face.

Billing barriers include requiring multiple NPIs and multiple PTANs that undoubtedly get crossed over in the background when trying to bill, resulting in incorrectly denied claims. Furthermore, the DSMT identifier is a sub-qualifier that is added on to a PTAN behind the scenes, so

---

[1] CMS. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017. 82 FR 33950. July 15, 2016, available at: https://www.federalregister.gov/documents/2016/07/15/2016-16097/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

[2] See §1848(k)(3)(B) and 1842(b)(18)(C). Available at: https://www.ssa.gov/OP_Home/ssact/title18/1848.htm.

pharmacists are unable to track their status with their PECOS accounts nor can they easily track and reconcile DSMT claims that were billed with pharmacy designated PTANs that may be billing for other services as well. **That being said, CMS could ease barriers to DSMT access by allowing pharmacists working within an accredited program to be able to bill as a provider with their own NPI number.** NCPA believes that it is essential for pharmacies to maintain their accreditations, and we support pharmacists maintaining their accreditations even if CMS were to allow pharmacists to bill as a provider with their own NPIs.

Community pharmacists have been able to vaccinate against COVID-19 at such a high rate because they were able to bill with personal NPIs and were able to prescribe the vaccine. A similar comparison could be made to pharmacists working in an accredited pharmacy. According to major billers working with our member in his CDC project mentioned above, if pharmacists were given provider status, they could bill everything under one "clinic" NPI and payment would instantly be easier resulting in less layers of people at the MAC level having to work inappropriately denied claims.

We also strongly recommend that CMS clarify in the Medicare Benefit Policy Manual, Chapter 15, Section 300[3] that DSMT services are already permitted at pharmacies that meet CMS' and NAOs' requirements.[4] Moreover, to truly maintain the viability of DSMT programs, we urge CMS to update the outdated terminology and design of the benefit. Our organizations also recommend CMS adopt the updated terminology defined in the 2022 Standards of Medical Care in Diabetes, "diabetes self-management education and support" or "DSMES." This terminology reflects the continuous support that diabetes patients need in managing their chronic condition as patients may require intensified re-education and self-management planning and support that often go beyond the current DSMT benefit. In addition, CMS should also consider allowing additional hours of DSMT for beneficiaries, similar to the Medical Nutrition Therapy ("MNT") benefit, during the four critical times[5] identified in the Joint Position Statement of the American Association of Diabetes Educators ("AADE"), the American Diabetes Association ("ADA") and the Academy of Nutrition and Dietetics ("AND").[6] Investing in a more robust service for certain high-risk diabetes patients can help improve their quality of life and health outcomes, and prevent high-cost services and procedures.

---

[3] See CMS. Medicare Policy Benefit Manual. Chapter 15, Section 300. May 22, 2022, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf.

[4] In accordance with § 410.144, a CMS-approved NAO may accredit an individual, physician or entity to meet one of three sets of DSMT quality standards: CMS quality standards; the National Standards for Diabetes Self-Management Education Programs (National Standards); or the standards of an NAO that represents individuals with diabetes that meet or exceed our quality standards. Currently, CMS recognizes the American Diabetes Association and the American Association of Diabetes Educators as approved NAOs, both of whom follow National Standards. Medicare payment for outpatient DSMT services is made in accordance with §414.63.

[5] The Joint Statement identified for critical times for allowing additional hours of DSMT: 1. New diagnosis of type 2 diabetes; 2. Annually for health maintenance and prevention of complications; 3. When new complicating factors influence self-management; and 4. When transitions in care occur.

[6] Powers, Margaret. Et. al. A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Self-management Education and Support in Type 2 Diabetes. 2015, available at: https://www.diabeteseducator.org/docs/default-source/practice/practice-resources/position-statements/dsme_joint_position_statement_2015.pdf?sfvrsn=0.

Additionally, NCPA suggests that CMS should allow pharmacists to order labs like a provider. This would allow pharmacists to track and affect DSMT outcomes more effectively. Having to request the physician to share A1C and lipids is often a barrier to care.

Continuous glucose monitoring (CGM)

The proposed rule mentions that for CY 2022, based on requests from interested parties for CMS to allow beneficiaries critical access to a newly approved 180-day continuous glucose monitoring system, CMS established two new HCPCS codes to describe the new 180-day monitoring service. Specifically, CMS established HCPCS code G0308 (Creation of subcutaneous pocket with insertion of 180-day implantable interstitial glucose sensor, including system activation and patient training) and G0309 (removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180-day implantable sensor, including system activation).

Diabetes management is a necessary and growing service provided by community pharmacists, which is made possible by continuous glucose monitoring (CGM). CGM devices allow patients and providers to monitor glucose levels in real time and optimize medication usage and wellness practices. Diabetes management is a necessary and growing service provided by community pharmacy as pharmacy is the true gateway to care in the community. Patient access to CGM allows pharmacist to better coach and counsel their patients with diabetes. It illuminates patient adherence to their medications and allows for high personalization of recommendations.

It is important that CMS set a precedent for allowing pharmacists to bill for the device unit and the corresponding counseling of continuous glucose monitoring (CGM) in Medicare. We are aware of a number of private plans that cover the CGM device unit under the prescription benefit, while others cover it under the medical benefit. We are not aware of private plans that cover and reimburse for the counseling component. **NCPA urges CMS to expand access to needed diabetes services, specifically by covering CGM that is delivered by pharmacists and other qualified practitioners under direct or general (preferable) supervision.**

Medicare Diabetes Prevention Program

NCPA appreciates the provisions in the CY 2022 PFS final rule to: 1) use Center for Medicare & Medicaid Innovation (CMMI) waiver authority to waive the enrolment fee beyond the COVID-19 PHE period for suppliers enrolling after January 1, 2022; 2) address supplier feedback that the current structure of the program is overly cumbersome and for beneficiaries starting MDPP on or after January 1, 2022, that services will only be a single year with no Ongoing Maintenance phase (months 13 through 24); and 3) incentivize supplier participation by increasing performance payments and beneficiary attendance payments for Core and Core Maintenance sessions. Furthermore, while NCPA appreciates the temporary provisions made by CMS in its COVID-19 interim final rule to permit certain beneficiaries to obtain the set of MDPP services more than once per lifetime, waive the five percent weight loss eligibility requirements, and allow certain MDPP suppliers to either pause the delivery of services or deliver virtual MDPP sessions on a temporary basis, **NCPA recommends CMS establish an Emergency Policy that applies more broadly and would improve the current flexibilities for the COVID-19 PHE and provide MDPP**

suppliers and MDPP beneficiaries with flexibilities to address future applicable 1135 waiver events.[7]

NCPA also recommends that CMS allow in-person MDPP suppliers the flexibility to offer virtual sessions on an ongoing basis following the conclusion of the COVID-19 PHE. Many MDPP supplier pharmacies have the capability to offer virtual sessions and have been doing so successfully during the COVID-19 PHE. CMS should offer pharmacies the flexibility to determine how to best deliver MDPP services, whether in-person, virtual, or in a hybrid manner to increase access for MDPP beneficiaries who may be unable to attend in-person classes due to geographical isolation or for reasons related to health and safety, particularly to avoid the transmission of contagious diseases, not limited to COVID-19.

NCPA also recommends that CMS consider adding virtual and hybrid models to their MDPP Supplier requirements. Currently, only programs that achieved preliminary or full recognition with in-person classes via the CDC's Diabetes Prevention Recognition Program can move forward with the MDPP Supplier application. Those that receive recognition for virtual or hybrid models are currently not eligible to become MDPP Suppliers.

Annual Wellness Visit (AWV)

NCPA recommends that CMS allow AWVs to be delivered under general supervision. MA plans have been interested in partnering with community pharmacists to bridge their metrics gaps. As AWVs are currently only delivered in the office under direct supervision, general supervision would increase community pharmacist participation.

Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services

CMS is proposing for CY 2023 to create four new HCPCS G codes with one pair of codes aimed at increasing patient access to remote therapeutic monitoring services and the second pair aimed at reducing physician and NPP supervisory burden. **NCPA supports this proposal and asks that CMS ensure that pharmacists can engage in remote therapeutic monitoring and other telehealth services.** For codes GRTM1 and GRTM2, pharmacists would be able to participate as auxiliary personnel working under general supervision.

In-Home Additional Payment for Administration of COVID–19 Vaccines

NCPA appreciates the additional $35.50 per dose payment for vaccine administration at the homes of access-challenged and hard-to-reach individuals, and for continuing this through CY 2023. Approximately 1.6 million adults 65 years of age and over in the United States have trouble accessing the COVID-19 vaccine because they are homebound, over half of whom face at least one additional barrier to vaccine access.[8] Many of these individuals have complex care needs as a result of such factors as financial and social vulnerability, functional impairment, dementia, and

---

[7] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 19264 (April 6, 2020).

[8] Assistant Secretary for Planning and Evaluation. (2021). Characteristics of Homebound Older Adults: Potential Barriers to Accessing the COVID-19 Vaccine. Retrieved from https://aspe.hhs.gov/sites/default/files/private/aspe-files/265346/homeboundvaccovid.pdf.

multiple chronic conditions and could require complex care if they contracted COVID-19 and become hospitalized.[9]

NCPA also strongly believes that the same barriers that have prevented beneficiaries from accessing COVID-19 vaccines impede their access to other vaccines and that CMS should offer a similar add-on payment in those circumstances. **NCPA strongly recommends add-on payments for at-home administration of influenza, pneumococcal, hepatitis B virus, and all vaccines recommended by the CDC Advisory Committee on Immunization Practices (ACIP).**

CMS also proposes that beginning January 1, 2023, it would adjust the payment amount for the administration of preventive vaccines for geographic cost variations using the geographic adjustment factor (GAF) described in § 414.26. **NCPA supports this adjustment, so long as it does not result in a reduction in reimbursement from how these vaccines are currently reimbursed.**

Clarification on Policies for COVID– 19 Vaccine and Monoclonal Antibody Products

CMS is proposing to clarify its policies finalized in the CY 2022 PFS final rule regarding the administration of COVID-19 vaccine and monoclonal antibody products to reflect that those policies will continue until the EUA declaration for drugs and biological products is terminated. **NCPA supports the continuation of these policies permanently.**

NCPA is generally pleased with CMS' Medicare payment rates for COVID-19 vaccine administration, set at approximately $40 for single-dose vaccines and $40 for vaccines requiring multiple doses, including any additional doses for vaccines administered on or after March 15, 2021. **NCPA does not support the reduction to $30 following the end of the calendar year in which the PHE expires and asks CMS to maintain $40 payment following the PHE's expiration.** NCPA strongly urges CMS to reconsider this proposal as the operational costs associated with administration of the COVID-19 vaccine remain higher than for other Part B preventive vaccines and this will not change immediately following the end of the PHE.

NCPA appreciates the opportunity to share with CMS our comments and suggestions on the CY 2023 PFS proposed rule. Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association

---

[9] Ornstein, K., Garrido, M., Bollens-Lund, E., Husain, M., Ferreira, K., Kelley, A., and Siu, A. (2020). Estimation of the Incident Homebound Population in the US Among Older Medicare Beneficiaries 2012 to 2018. *JAMA Internal Medicine, 180(7)*, 1022-1025.