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September 11, 2023

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program (CMS-1784-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 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program* proposed rule (CY 2024 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 $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. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Diabetes self-management training (DSMT) (§ 410.72(d))

CMS is proposing to clarify that a registered dietician or nutrition professional must personally perform medical nutrition therapy services, but the enrolled registered dietician or nutrition professional, when acting as the DSMT certified provider, may bill for, or on behalf of, the entire DSMT entity, regardless of which professional personally delivers each aspect of the services. CMS has stated that if finalized, this proposal would build on recent policy changes designed to improve access to DSMT services. CMS provided a clarification to distinguish between when a RD or nutritional professional is personally providing MNT services, in accordance with the MNT

regulations, and when they are acting as or on behalf of an accredited DSMT entity and billing for DSMT services that may be provided by a group of other professionals working under an accredited DSMT entity, for example registered nurses (RNs), pharmacists, or RDs other than the sponsoring RD. CMS stated that under the National Standards for Diabetes Self Management Education Programs' quality standards, the RD, RN, or pharmacist is permitted to provide the educational DSMT services on a solo basis, that is without a multi-disciplinary team; however, only the RD or nutrition professional, when enrolled as a Medicare supplier, in these accredited DSMT entities is authorized by statute to bill Medicare on behalf of the entire DSMT entity as the DSMT certified provider.

CMS also stated that "…regulations and sub-regulatory policies for Medicare telehealth services do not address scenarios involving the furnishing of DSMT services via telehealth when the actual services are personally furnished by individuals who provide them, for example, RNs, pharmacists, or other multidisciplinary team members, who are not recognized as telehealth distant site practitioners under the statutory definition." [NCPA emphasis]

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**

[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.

request that CMS continue to clarify that pharmacists and pharmacies can provide DSMT services. We also ask CMS to 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 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 pharmacy accredited for DSMT by a National Accreditation Organization. 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 the National Accreditation Organization's requirements.[4] Moreover, to truly maintain the

[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-

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.

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)

Additionally, 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 pharmacists 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.**

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.

ICRs Regarding the Updates to the Medicare Diabetes Prevention Program

CMS is proposing to extend specific Medicare Diabetes Prevention Program (MDPP) flexibilities allowed during the PHE for COVID–19 1135 waiver events by 4 years. In addition, CMS is proposing to update the MDPP payment structure to pay for beneficiary attendance on a fee-for-service basis while retaining the diabetes risk reduction performance payments. Finally, CMS is proposing to remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition as well as remove most references to, and requirements of, the Ongoing Maintenance Sessions given that eligibility for these services will end on December 31, 2023. **NCPA supports these provisions.**

NCPA also recommends that CMS permanently allow in-person MDPP suppliers the flexibility to offer virtual sessions on an ongoing basis. Many MDPP supplier pharmacies have the capability to offer virtual sessions and have been doing so successfully since 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) (SSA § 1861(hhh)(2)(I)

CMS proposes to exercise its authority in section 1861(hhh)(2)(I) of the Social Security Act to add elements to the Annual Wellness Visit (AWV) by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. **NCPA supports this provision.**

NCPA additionally 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.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

NCPA supports CMS moving forward with its enforcement plan for the CMS EPCS Program.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

CMS proposes to allow periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the

end of CY 2024, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished, and all other applicable requirements are met. CMS believes this modification is needed because extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE, and evidence has shown that Medicare beneficiaries from historically underserved populations are more likely to be offered and use audio-only telemedicine services than audio-video services. **NCPA supports this policy, and encourages CMS to implement policy changes that leverage pharmacists to deliver clinical care services for patients with opioid use disorder (OUD).**

Caregiver Services

CMS is proposing to create CPT codes 96202 and 96203 (for caregiver behavior management) and 9X015, 9X016, and 9X017 (codes for caregiver training services), so that practitioners are appropriately paid for engaging with caregivers to support people with Medicare in carrying out their treatment plans. **NCPA requests that pharmacists be reimbursed for these services incident to the provider.**

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

CMS proposes to maintain the in-home additional payment for COVID–19 vaccine administration under the Part B preventive vaccine benefit. In addition, since CMS' statutory authority to regulate Part B preventive vaccine administration is identical for all four preventive vaccines, and since the payment has been shown to positively impact health equity and healthcare access, CMS proposes to extend the additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit—the pneumococcal, influenza, and hepatitis B vaccines. CMS proposes to provide the additional payment for pneumococcal, influenza, hepatitis B and COVID–19 vaccine administrations in the home, when the conditions described in section III.H.3.b of this proposed rule are met. CMS notes that several of the conditions we established for the in-home additional payment, discussed previously in this section of the proposed rule, refer specifically to COVID–19. If CMS finalizes the proposal to expand the in-home additional payment to the other preventive vaccines, CMS would broaden the conditions for the payment to reflect preventive vaccines for the other diseases. If finalized as proposed, the in-home additional payment for the administration of pneumococcal, influenza, and hepatitis B vaccines would be effective January 1, 2024, to join the current additional payment for the in-home administration of COVID– 19 vaccines that is now being extended.

Reimbursement amount. In addition, like the current in-home additional payment for COVID–19 vaccine administration, the proposed in-home additional payment for the administration of Part B preventive vaccines that would be effective beginning for CY 2024, if finalized, would be geographically adjusted based on the PFS GAF, and annually updated by the CY 2024 MEI percentage increase. For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through fourth quarter 2022. Therefore, CMS would multiply the CY 2023 in-home additional payment amount for Part B preventive vaccine administration of $36.85 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent, which would result in a proposed CY 2024 in-home additional payment for Part B preventive vaccine administration of

$38.51 ($36.85 x 1.045 = $38.51). CMS is also proposing that if more recent data are subsequently available (for example, a more recent estimate of the MEI percentage increase), CMS would use such data, if appropriate, to determine the CY 2024 MEI percentage increase in the CY 2024 PFS final rule; we would apply that new MEI percentage increase to update last year's $36.85 CY 2023 in-home additional payment amount for Part B preventive vaccine administration.

NCPA supports this policy, and strongly recommends add-on payments for at-home administration of all vaccines recommended by the CDC Advisory Committee on Immunization Practices (ACIP).

Further, since expanding this policy could mean that multiple vaccines are administered during the same visit to the home, CMS proposes to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit. CMS emphasizes that every vaccine dose that is furnished would still receive its own unique vaccine administration payment. CMS intends to continue to monitor utilization of the M0201 billing code for the in-home additional payment, and CMS plans to revisit the policy should CMS observe inappropriate use or abuse of the code. **NCPA advocates that each vaccine administered in the home get a separate payment, both for product and administration, given the additional time pharmacists need to administer each vaccination.**

CMS is proposing to amend the Part B payment for preventive vaccine administration regulations at § 410.152(h) to reflect the following:

- Effective January 1, 2022, the Medicare Part B additional payment amount paid to providers and suppliers administering a COVID–19 vaccine in the home, under certain circumstances, is $35.50. For COVID–19 vaccines administered in the home January 1, 2022 through December 31, 2022, the additional payment amount under Medicare Part B is adjusted to reflect geographic cost variations using the PFS GPCIs.
- Effective January 1, 2023, the additional payment amount for the administration of a COVID–19 vaccine in the home is annually updated based upon the percentage change in the MEI. For COVID–19 vaccines administered in the home January 1, 2023 through December 31, 2023, the payment amount is adjusted to reflect geographic cost variations using the PFS GAF.
- Effective January 1, 2024, the payment policy allowing for additional payment for the administration of a COVID–19 vaccine in the home would be extended to include the other three preventive vaccines included in the Part B preventive vaccine benefit, and the payment amount for all four vaccines would be identical. That is, beginning January 1, 2024, the Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID–19 vaccine in the home, under certain circumstances. This additional payment amount would be annually updated using the percentage increase in the MEI and adjusted to reflect geographic cost variations using the PFS GAF.

Clarification on Policies for COVID– 19 Vaccine

In the Proposed Rule, CMS stated that, regarding COVID-19 vaccine payment policies:

> Under section 1861(s)(10) of the Act, Medicare Part B currently covers both the vaccine and vaccine administration for the specified preventive vaccines— the pneumococcal, influenza, hepatitis B and COVID–19 vaccines. Section 1861(s)(10)(B) of the Act specifies that the hepatitis B vaccine and its administration is only covered for those who are at high or intermediate risk of contracting hepatitis B, as defined at § 410.63. Under sections 1833(a)(1)(B) and (b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccines or the services to administer them. Per section 1842(o)(1)(A)(iv) of the Act, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for the vaccine product, except where furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or Federally qualified health center (FQHC).

And additionally:

> Effective January 1 of the year following the year in which the EUA declaration ends, the COVID–19 vaccine administration payment would be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines, that is, $30 per dose. As mentioned above, we also finalized that, beginning January 1, 2023, we would annually update the payment amount for the administration of all Part B preventive vaccines based upon the percentage increase in the MEI, and that we would use the PFS GAF to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the vaccine is administered. The current payment rates for the CPT codes that describe the service to administer COVID–19 vaccines, as finalized in the CY 2023 PFS final rule, can be found on the CMS COVID–19 Vaccines and Monoclonal Antibodies website.230 The payment rates for these services with the annual update applied for CY 2024, will be made available at the time of publication of the CY 2024 PFS final rule.

NCPA requests CMS provide information on 2024 payment for COVID-19 vaccines (both for the product and for administration), preferably in a chart as was in the previous finalized fee schedule.

NCPA appreciates the opportunity to share with CMS our comments and suggestions on the CY 2024 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