September 13, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks-LaSure:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its *Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements* proposed rule (CY 2022 PFS proposed rule). NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services (LTC) and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings.[1] Together, our members represent a $76 billion healthcare marketplace, employ approximately 250,000 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.

Scope of practice

Community pharmacists are vital to healthcare quality and patient access, and NCPA appreciates CMS' continued recognition of the value of pharmacist-provided patient care services and the agency's clarification regarding pharmacists providing services incident to a physician, including medication therapy management (MTM) services under Part B, which CMS hopes would "encourage pharmacists to work with physicians and [non-physician practitioners] in new ways where

[1] National Community Pharmacists Association (2019). *2020 NCPA Digest.* Retrieved from https://ncpa.org/sites/default/files/2020-10/2020-Digest.pdf

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

pharmacists are working at the top of their training, licensure and scope of practice."[2,3] CMS has made similar statements in its COVID-19 regulatory flexibility rule, and while NCPA is pleased that the agency is making consistent statements regarding pharmacists' contributions, NCPA is disappointed that the agency continues to believe that pharmacists are not Medicare-eligible providers, with statute limiting reimbursement for incident-to E/M services provided by them to 99211.[4] Although NCPA continues to disagree with CMS' interpretation of the statute, ensuring that pharmacists' patient care services are reimbursed commensurate with their duration and complexity is critical to maintaining patient access to care, and NCPA recommends CMS reinforce its interpretation in the 2015 PFS rule, wherein CMS clarified the billing rules for pharmacist-provided evaluation and management (E/M) services, explicitly stating that physicians can bill the highest level of E/M codes for services provided by pharmacists if all incident-to requirements are met.[5] However, since 2015 some Medicare Administrative Contractors (MACs) have independently interpreted CMS requirements to allow physicians to bill only the lowest level E/M codes for pharmacist-provided incident-to services. These conflicting MAC interpretations make it difficult to implement innovative pharmacist care models. **In order to maintain patient access to pharmacist-provided care services, it is critical that CMS explicitly reinforce its 2015 interpretation and direct MACs to allow E/M billing accordingly.**

Vaccine provisions and reimbursement

The vital role of independent community pharmacies, especially in America's rural and urban underserved communities, has been highlighted by the ongoing COVID-19 pandemic, during which our members have been a true linchpin of our nation's public health response, contributing to efforts ranging from testing to immunization to administration and monitoring of monoclonal antibody treatments to reduce the spread of the virus. NCPA strongly supports CMS' goal that "every American has timely access to a COVID-19 vaccine without any out-of-pocket expenses, no matter their source of coverage, or whether they are covered at all" and 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.[6] NCPA also appreciates the additional $35 per dose

[2] Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84472 (December 28, 2020).

[3] Ibid.

[4] Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, 85 Fed. Reg. 27550 (May 8, 2020).

[5] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015, 79 Fed. Reg. 67547 (November 13, 2014).

[6] Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 71142 (November 6, 2020).

payment for vaccine administration at the homes of access-challenged and hard-to-reach individuals. 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.[7] Many of these individuals have complex care needs as a result of such factors as financial and social vulnerability, functional impairment, dementia, and multiple chronic conditions and could require complex care if they contracted COVID-19 and become hospitalized.[8] However, while the additional at-home vaccine administration payment helps account for some of the upfront costs associated with administering the vaccine safely and appropriately in a beneficiary's home and the clinical time needed to monitor a beneficiary after the vaccine is administered, **many of our members who administered vaccines between June 8, 2021 and August 23, 2021 found that the at-home add-on payment was inadequate to appropriately reimburse pharmacy staff for their time**. This is a particularly significant issue for NCPA because it was, and continues to be, primarily independent community pharmacists that visit beneficiaries in their homes to administer the COVID-19 vaccine. While NCPA appreciates CMS expanding the locations that qualify for the additional in-home payment to include communal spaces of a multi-unit or communal living arrangement and assisted living facilities (ALFs) participating in the CDC's Pharmacy Partnership for Long-Term Care Program effective August 24, 2021, **NCPA asks that CMS retroactively reimburse pharmacists and other providers who administered COVID-19 vaccines in these settings prior to August 24, 2021.** 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. Access to all preventive vaccines has been hampered by the ongoing COVID-19 pandemic, with three out of every four adults in the United States missing one or more of their recommended vaccines including influenza (flu).[9] This drop-off in vaccination rates is particularly troubling given the imminent arrival of flu season; the unprecedented co-circulation of flu and SARS-CoV-2 would not only strain an already overburdened health care system, but poses an even greater risk to adults with chronic conditions such as heart disease, lung disease, and diabetes—even when those conditions are well-managed. **NCPA strongly recommends add-on payments for at-home administration of influenza, pneumococcal, and hepatitis B virus vaccines.**

Telehealth services

NCPA continues to support the use of telehealth for delivering clinical health and person-centered care, particularly in rural health areas, and especially during times of national, state, and local emergencies such as the COVID-19 PHE. Pharmacists are an integral part of health care management teams providing Medicare services, including telehealth. Telehealth enables pharmacists to connect

[7] 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

[8] 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.

[9] Centers for Disease Control and Prevention. (2021). National Center for Health Statistics: Influenza. Retrieved from https://www.cdc.gov/nchs/fastats/flu.htm

with established health care management teams and patients, particularly when questions arise concerning medications prescribed or changes to medications, independent of geography. In many instances, especially in rural and underserved areas where telehealth would be invaluable, pharmacists are the first point of contact by patients and their caregivers.

Community pharmacists are fully capable of providing telehealth benefits, especially during the periods of national, state, and local emergencies such as the COVID-19 PHE when the need for telehealth is heightened, and the technology for exchanging COVID-19 information from a telehealth visit in a standardized, electronic care plan is available at over 3,500 clinically integrated community pharmacies. Such services include, but are not limited to, MTM, chronic care management (CCM), transitional care management (TCM), pharmacogenomics, interpretation of diagnostic tests and providing test results, consultations with patients and health care providers, and ambulatory care services. Under the current Medicare Telehealth Benefit, however, pharmacists are not recognized as practitioners. **NCPA urges CMS to recognize and ensure payments to pharmacists when billing for telehealth services**. In the CY 2021 PFS final rule, CMS extended virtual supervision until the end of the calendar year in which the COVID-19 PHE ends or December 31, 2021, whichever is later. While NCPA is supportive of the extension, **NCPA recommends that CMS make virtual supervision a permanent option for services reimbursed under the CY 2022 PFS proposed rule.**

CMS has waived the "originating site" requirement on Medicare telehealth services to allow delivery of these services to all areas and locations within the country, including patients' homes, for the duration of the PHE.[10] Under normal conditions, a beneficiary must travel to an actual site of care—the originating site—to receive telehealth services, but the waiver authority allows beneficiaries to receive services wherever they are. **NCPA recommends that CMS: 1) avoid imposing an in-person requirement for telehealth, either before or after the first telehealth visit**—services have been successfully furnished to patients via audiovisual or audio-only technology during the PHE, and reimposing the in-person visit is not only burdensome for current patients, but will discourage new patients from utilizing telehealth services; and 2) **collaborate with NCPA and other stakeholders to designate pharmacies as originating sites to receive telehealth services for beneficiaries who may not be able to access telehealth services in their homes.**

Electronic Prescribing of Controlled Substances

While NCPA understands CMS' rationale to extend the effective date for EPCS compliance one year to January 1, 2023 and to January 1, 2025 for Medicare Part D prescriptions in LTC facilities, NCPA members are ready for the implementation of ECPS on the original deadline of January 1, 2022 as established in the CY 2021 PFS. However, **NCPA opposes the determination that the exception for certain patients in LTC facilities (LTCFs) is inappropriate**. Patients in LTCFs are typically older, take more prescriptions, including opioids, and suffer from chronic pain at a higher rate than peers in their respective age group. Additionally, there is a unique care setting in LTCF which creates a distinctive challenge for prescribers which CMS acknowledges as "due to the necessary three-way

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

communication involving the prescriber, the facility, and the pharmacy."[11] This setting, and the inability and unlikelihood of prescribers to access the IT health systems of LTCFs, could result in delays for the dispensing of appropriate and urgent opioid medication for LTC patients. However, in crafting the statute, Congress recognized the difficulty this situation presents in providing effective opioid medication by providing two applicable exceptions for EPCS for LTC patients.[12] The statute provides exceptions for "a situation where a practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition" or for facilities in which frequently abused drugs are dispensed to residents through a contract with a single pharmacy, which encompasses the inability for a multiparty system to quickly treat the chronic pain needs of LTC patients. **NCPA recommends that CMS preserve the LTC resident exception by being cognizant of the unique setting and circumstances and honor the plain language of the statute and the intention of Congress**. Furthermore, while the National Council for Prescription Drug Programs (NCPDP) does have SCRIPT Standard changes in process to address the e-Prescribing three-way communication needs of the LTC community, these changes will be included in a future version of SCRIPT. This change request was approved by NCPDP Work Group 11 (ePrescribing and Related Transaction) during its May 2021 meeting and is currently being balloted by NCPDP. Ballot comments will be adjudicated during NCPDP's November 2021 work group meeting, and if approved, these changes will be included in the January 2022 version of the SCRIPT Standard (v2022011). Therefore, it is ill-advised for CMS to mandate an EPCS implementation on LTC prescribers, facilities, and pharmacies using v2017071 of the SCRIPT Standard, that is based on last minute, yet to be determined, guidance from NCPDP. While there are suggestions that prescribers connect to an LTCF's electronic health record (EHR) system via a web portal to electronically prescribe controlled substances, such a solution would be very disruptive to a prescriber's practice, particularly those seeing residents in multiple LTCFs. In addition, a web portal does not meet the 21st Century Cures Act definition of interoperability which states that the exchange of health information occurs "without special effort on the part of the user."[13] Therefore, given that NCPDP is currently incorporating changes in the SCRIPT Standard that will address the LTC three-way communication needs and that these changes will necessitate a new version of the Standard, **NCPA recommends that CMS coordinate the timing of its LTC EPCS compliance deadline with its implementation of a new named version of the SCRIPT Standard in 42 C.F.R. 423.160 (b).**

Medicare Diabetes Prevention Program

NCPA appreciates the provisions proposed by CMS in the CY 2022 PFS proposed 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

[11] Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI), 85 Fed. Reg. 47151 (August 4, 2020).

[12] 42 U.S.C. 1395w-104(e)(7)(B)(iv)

[13] 21st Century Cures Act, Pub. L. No. 114-255, 1033 Stat. 130 (2016).

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 by five percent. 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.**[14]

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 greatly appreciates the opportunity to share with CMS our comments and suggestions on the CY 2022 PFS proposed rule. Should you have any questions or concerns, please feel free to contact me at ronna.hauser@ncpa.org.

Sincerely,

Ronna B. Hauser, PharmD
Senior Vice President, Policy & Pharmacy Affairs
National Community Pharmacists Association

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