September 13, 2021

[Submitted electronically to www.regulations.gov]
Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Docket CMS-1751-P for "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."

Dear Administrator Brooks-LaSure:

ASHP (American Society of Health-System Pharmacists) is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed changes to the Physician Fee Schedule (PFS) for calendar year 2022. ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization's nearly 58,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 79 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP thanks CMS for the opportunity to comment on the proposed rule. We hope that our feedback will assist CMS in refining the PFS to meet our shared patient care and quality goals.

A. Coding, Reimbursement, and Supervision

I. *Ensure Appropriate Coding of Evaluation & Management (E/M) Visits*

In response to repeated requests for clarification from ASHP and other pharmacy organizations regarding evaluation and management (E/M) coding for pharmacist-provided incident-to services, in its Physician Fee Schedule (PFS) Final Rule for CY 2021, CMS stated those services can be billed only at 99211, regardless of their duration or complexity. This clarification represented a wholesale policy shift from CMS's previous position, which was articulated in the 2016 PFS final rule. Per the 2016 final rule, pharmacist-provided incident-to services could be reimbursed without limitation provided requisite the incident-to and E/M service requirements were met.[1] The 2021 change disrupted established care models and left providers scrambling to ensure patient access to services. As we have in letters and meetings with the agency and Administration officials following the release of the PFS CY 2021 final rule, we strongly urge CMS to reverse this policy change and allow physicians and non-physician providers (NPPs) to bill pharmacist-provided incident-to services at the E/M level commensurate with their duration and complexity.

[1] CMS, Medicare program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to part B for CY2016. 80 Fed. Reg. 71066 (Nov. 16, 2015), *available at* https://www.federalregister.gov/d/2015-28005/p-1578.

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Limiting coding for incident-to services ignores the essential role pharmacists play in treating patients in the ambulatory care space and the value and expertise they provide to their healthcare teams. Pharmacists' expertise is critical to quality patient care. Medications are the first line of therapy to treat patients with chronic diseases and acute complex diseases such as cancer and heart disease. Nearly 70 percent of Medicare beneficiaries have one or more chronic conditions[2], and many of these beneficiaries take multiple medications. Lack of proper medication oversight and management can result in suboptimal therapeutic outcomes and patient harm. It also costs the healthcare system hundreds of billions of dollars annually.[3] Pharmacists are uniquely qualified to provide the type of medication and disease management (including behavioral health conditions) needed to not only stem the waste on adverse drug events and nonadherence, but also to enhance patient outcomes through improved medication use.

Pharmacists in hospitals and ambulatory clinics work with physicians, nurses, and other providers on interprofessional teams to manage patients' medications and ensure appropriate care transitions. These pharmacists often provide intensive patient care services including, but not limited to, comprehensive medication management, transition of care services, chronic disease management, anticoagulation services, and wellness visits. For instance, for medically complex new patients with multiple comorbidities and complicated medication regimens, pharmacists may take 45 – 60 minutes with the patient. Delegating such services to pharmacists reduces physician workload, ensures that pharmacist training and education is fully utilized, and increases care quality. Studies indicate that the inclusion of pharmacists on the patient care team demonstrates a significant return on investment in both patient outcomes and real dollars.[4] For every dollar invested in clinical pharmacy services in all types of practice settings (hospital, clinics, government, etc.), health systems realize an average savings of $4.[5] Thus, if the goal is to maximize the value of all clinical resources in our healthcare system while providing quality care, pharmacists should be integrated into healthcare teams across the full continuum of care.

Given the resource constraints of many providers, CMS should encourage and incentivize use of care delivery models that fully engage and utilize all clinicians on the healthcare team rather than instituting arbitrary limitations on E/M incident-to billing and coding that force providers to jettison highly efficient care models in favor of outdated models that add to physician and practitioner burden.

Barring a full reversal of the policy to allow pharmacists' services to be billed using existing E/M codes, ASHP urges CMS to adopt coding changes that will allow physicians to bill for pharmacists' more complex E/M services. Ideally, to reduce potential confusion and inconsistency across payors and to ease implementation, the agency should create a pharmacist modifier that would be appended to the existing E/M codes, including 99212 – 99215. If a pharmacist modifier is not an acceptable solution for CMS, ASHP and its partner organizations worked with our members to develop a full code set that delineates pharmacist patient care services that correspond to higher-level E/M codes. As with existing E/M codes, these pharmacist-specific codes would be billable only incident-to a physician or NPP's services. ASHP has previously shared the proposed code set below with CMS. We look forward to working with the agency to find a workable solution that ensures continued patient access to pharmacists' critical patient care services.

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[2] *See* Centers for Medicare & Medicaid Services. *Chronic Conditions Among Medicare Beneficiaries Chartbook* (2012), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf.

[3] *See* New England Healthcare Institute**,** *Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease* (2009), *available at* https://www.nehi.net/publications/17-thinking-outside-the-pillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view.

[4] C.A. Bond and C.L. Raehl, *Clinical Pharmacy Services, Pharmacy Staffing, and Hospital Mortality Rates,* 27 Pharmacotherapy 482-93 (2007).

[5] G.T. Schumock *et al*., *Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996–2000,* 23 Pharmacotherapy 113–32 (2003).

Table 1: Codes for Pharmacist Patient Care Services

Code	Complexity of Services/ or Time Spent	Elements of Complexity and Work		
		Number and Complexity of Medication related issues	Amount and complexity of information to be reviewed, assessed, and actions implemented	Risk of complication and/or morbidity and mortality
G9202 G9212	**Straightforward** 15-29 minutes (NP) 10-19 minutes (EP)	**Minimal** 1 self-limited or minor medication related issue	**Minimal** Any combination of 2 of the following 1. Review of 1 other provider note 2. Evaluation of 1 medication related test result 3. 1 medication optimized	Minimal risk of morbidity from issue or action to resolve the issue.
G9203 G9213	**Low** 30-44 minutes (NP) 20-29 minutes (EP)	**Low** 2-4 medication related issues causing minor risk of illness or injury due to the medication. *or* 1-2 chronic disease management	**Limited** Any combination of 2 of the following: • Review of 2 other provider notes • Evaluation of 2 medication related test results • 2 medications optimized with patient/team education • Coordination of care and discussion with one other provider	Low or minor risk of morbidity from medication issues
G9204 G9214	**Moderate** 45 to 59 minutes (NP) 30-39 minutes (EP)	**Moderate** 5-9 medication related issues with at least one causing moderate risk of illness or injury due to the medication *or* 1 acute medication related problem or new medication that poses a high risk of medication induced illness or bodily harm, requiring immediate management and of moderate medical risk. *or* 3-4 chronic disease management *or* an acute exacerbation of 1 chronic disease	**Moderate** Any combination of 3 of the following: • Review of 3 other provider notes • Evaluation of 3 medication related test results • 3 medications optimized • One acute moderate risk medication optimized • Coordination of care and discussion with two other providers	Moderate risk of morbidity from medication issues
G9205 G9215	**High** ≥ 60 min (NP) ≥ 46 min (EP)	**High** 10 or more medication related issues with at least one causing serious risk of illness or injury due to the medication *or* 2 or more acute medication related problems or 2 or more medications that poses a high risk of medication induced illness or bodily harm, requiring immediate management and of serious medical risk. *or* 5 or more chronic disease management *or* an acute exacerbation of 2 or more chronic diseases	**High** Any combination of 3 of the following: • Review of 4 or more other provider notes • Evaluation of 4 or more medication related test results • 4 or more medications optimized • 2 acute moderate risk medications optimized • Coordination of care and discussion with three or more other providers	High risk of morbidity from medication issues.

II. *Ensure Telehealth Services Remain Accessible to Patients*

a. Allow Permanent Virtual Supervision of Telehealth Services

ASHP appreciates CMS's efforts to quickly expand access to telehealth during COVID-19, through the availability of virtual supervision and the agency's regular updates to the list of telehealth-eligible codes. We strongly urge CMS to make virtual supervision of telehealth services permanent. During the pandemic, allowing physicians and pharmacists (as auxiliary personnel) to provide services from two separate locations has helped support the expansion of telehealth services and has protected frontline workers by allowing appropriate social distancing. Further, we encourage the agency to adopt virtual supervision permanently for non-telehealth services reimbursed under the PFS to the greatest degree possible, as this flexibility helps ensure care access, particularly in rural and underserved communities.

Many providers are currently evaluating further financial and operational investments in telehealth, and virtual supervision has allowed creative care delivery models to flourish without sacrificing any clinical oversight. Removing virtual supervision will unnecessarily limit clinician flexibility and undercut care innovation, making it less likely for providers to offer these services and more difficult to maintain and build on the telehealth expansion after the public health emergency ends.

b. Allow Permanent Use of Audio-Only Codes

ASHP supports CMS's proposal to allow mental health services, including certain opioid use disorder treatment services, to be provided using audio only, rather than requiring both audio and video for reimbursement. However, we urge CMS to reconsider its proposed discontinuation of reimbursement for audio-only E/M telehealth services when the public health emergency ends. Audio-only services have proven to be particularly beneficial for patients who do not have consistent access to a device and/or network that supports a video component or who are uncomfortable with, or otherwise struggle with, audio-visual technology. If audio-only codes can be used safely for mental health services, there is no reason that they cannot also be used for other services in order to ensure continued patient access to care.

III. *Make COVID-19 Diagnostic Flexibilities Permanent and Maintain Vaccine Payment Rates*

ASHP urges CMS to make the reimbursement for specimen collection permanent for COVID-19. Scientists have suggested that, much like influenza, COVID-19 may become a seasonal ailment. Until we have a better grasp of whether the virus will become endemic, it is short-sighted to limit reimbursement in a way that might de-incentivize the provision of testing, particularly for those providers who invested in creating new testing models during the pandemic.

In a similar vein, CMS should also make permanent the flexibility that allows pharmacists to order and administer COVID-19 tests, as well as influenza and respiratory syncytial virus (RSV) diagnostic tests because those viruses can present the same way as COVID-19. These new diagnostic testing models removed needless regulatory hurdles to greatly increase patient access. Logically, these mechanisms should be maintained to ensure that a similar quick response can be mounted in response to any viral threat, rather than forcing providers to recreate the wheel during the next outbreak. Recognizing that some state scope-of-practice laws would have to change to accommodate this authority after the public health emergency ends, ASHP would work

with members to ameliorate any state barriers to pharmacist ordering and administration of these diagnostic tests.

Additionally, to maintain access to vaccines, CMS should retain the current reimbursement rate for COVID-19 vaccines, and consider whether the payment rates for other vaccines should be raised to match it. Our members indicate that prior to the COVID-19 public health emergency, the vaccine administration rates had declined to unsustainable levels. With the enhanced rate for the COVID-19 vaccine, providers were able to shift staff to vaccine administration, thereby increasing access to those services. Given the decline in routine vaccination rates during the pandemic, CMS should consider increasing the reimbursement rates for other vaccines to match the current COVID-19 vaccine administration rate.

B. Electronic Prescribing of Controlled Substances (CIIs) in Medicare Part D

ASHP's appreciates CMS's clear timeline for implementing the CII e-prescribing mandate in Part D, as well its explanations of the various mandate exemptions. Although CMS indicates that it will not enforce the mandate until January 1, 2023, given the ongoing public health emergency, even that deadline may be a stretch for under-resourced providers. Given the current Delta surge, and the potential convergence of COVID-19 and flu season this fall, we encourage CMS to revisit its timeline should the public health emergency extend longer than is currently anticipated.

ASHP appreciates the opportunity to offer our input and suggestions on the proposed rule. Please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.

Sincerely,

Jillanne Schulte Wall, J.D.
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