UPMC
LIFE CHANGING MEDICINE

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Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via: http://www.regulations.gov

Attention: [CMS-1770-P] RIN 0938-AU81

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 Amounts

Dear Administrator Chiquita Brooks-LaSure:

On behalf of the University of Pittsburgh Medical Center (UPMC), we would like to express feedback on the proposed 2022 Revisions to Payment Policies under the Physician Fee Schedule.

UPMC is a world-renowned health care provider, insurer, and academic center of excellence. Our unique strategy of combining clinical and research excellence with business-like discipline translates into high-quality patient care for both western Pennsylvanians and the global community. We are dedicated to the advancement of quality, patient safety, and affordability of healthcare. UPMC operates more than 40 academic, community, and specialty hospitals, more than 800 doctors' offices and outpatient sites, employs more than 4,900 physicians, and offers an array of rehabilitation, retirement, and long-term care facilities.

Update to the Physician Fee Schedule Conversion Factor for 2023

In the proposed rule, CMS proposes the conversion factor would be $33.08, which is a 4.4% reduction from the 2022 conversion factor. This reflects the expiration of the 3% increase for services furnished in 2022 under provisions included in the Protecting Medicare and American Farmers from Sequester Act and a 1.4% reduction due to the budget neutrality adjustment. Additionally, physician practices are facing payment cuts from the expiration of the moratorium on the Medicare 2% sequester reduction and imposition of a 4% PAYGO sequester reduction that was triggered by the increase in spending under the

American Rescue Plan Act. Taken together, these three cuts would total a greater than 10% reduction in payment.

Comment: UPMC asks CMS to support stakeholder's efforts to urge Congress to provide funding to eliminate the collective 4.4% decrease in conversion factor and 4% PAYGO reduction for calendar year 2023. If Congress does not act on budget neutrality before January 1, 2023, we strongly urge HHS to use the public health emergency declaration as a basis to ensure access to care and mitigate financial impacts due to the COVID-19 pandemic by waiving budget neutrality adjustments. Compounding the public health emergency is the impact of inflation and an insufficient supply of labor. The expenses associated with labor, drugs, and supplies have escalated dramatically. According to the Bureau of Labor and Statistics June 2022 prices (CPI) increased by 9.1% versus June 2021. The combination of decreased payments, inflation, and staffing shortages will have a devastating impact on the ability to serve our patient population.

Changes to Payment for Medicare Telehealth Services

For CY 2023, CMS is proposing a number of policies related to Medicare telehealth services including making several services that are temporarily available as telehealth services for the PHE available through CY 2023 on a Category III basis, which will allow more time for collection of data that could support their eventual inclusion as permanent additions to the Medicare telehealth services list. CMS is proposing to extend the duration of time that services are temporarily included on the telehealth services list during the PHE, but are not included on a Category I, II, or III basis for a period of 151 days following the end of the PHE, in alignment with the Consolidated Appropriations Act, 2022 (CAA, 2022).

CMS is proposing to implement the telehealth provisions in the CAA, 2022 via program instruction or other sub regulatory guidance to ensure a smooth transition after the end of the PHE. These policies extend certain flexibilities in place during the PHE for 151 days after the PHE ends, such as allowing telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home, allowing certain services to be furnished via audio-only telecommunications systems, and allowing physical therapists, occupational therapists, speech-language pathologists, and audiologists to furnish telehealth services. The CAA, 2022 also delays the in-person visit requirements for mental health services furnished via telehealth until 152 days after the end of the PHE. We are proposing that telehealth claims will require the appropriate place of service (POS) indicator to be included on the claim, rather than modifier "95," after a period of 151 days following the end of the PHE and that modifier "93" will be available to indicate that a Medicare telehealth service was furnished via audio-only technology, where appropriate.

- ***Changes to the Medicare Telehealth Services List***

Comment: In general, CMS considers additions to the Medicare Telehealth Services List if such services fall within one of two categories. The criterion for adding services to "Category 1" is that the requested services are similar to professional consultations, office visits, and office psychiatry services currently on the Medicare Telehealth Services List. "Category 2" includes services that are not similar to those on the current Medicare Telehealth Services List, but nonetheless provide evidence of clinical benefit to patients when furnished via telehealth.

During the PHE, additional services were temporarily placed on the Medicare Telehealth Services List. Some of these services have since been added to the Medicare Telehealth Services List on a special "Category 3" basis, which covers services that likely pose a clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider adding permanently under Category 1 or 2. Services added under Category 3 are available on a temporary basis, through the end of CY 2023.

In the CY 2023 proposed PFS, CMS considered several requests to add services to the Medicare Telehealth Services List on a Category 1, 2, or 3 basis. CMS also reassessed services that are currently temporarily available via telehealth pursuant to PHE waivers—based on both information provided by interested parties and its own internal review—to determine whether such services should be added to the Medicare Telehealth Services List on a Category 3 basis.

UPMC applauds CMS for continuing to add to the Medicare Telehealth Services List and expand payment opportunities for providers under Section 1834(m) of the Act. As stated in comments to prior CMS rulemaking, UPMC believes that population health management in the 21st Century requires a robust offering of telehealth services for our Medicare beneficiaries, especially for meeting the needs of our most vulnerable patients using care settings most responsive and demonstrating beneficial outcomes. Particularly during the PHE, providers and patients alike have come to rely on and frequently utilize telemedicine technologies for a variety of provider coordination and direct patient care needs. The result has been high-quality clinical care delivered both by telehealth and in-person to our beneficiaries. Accordingly, UPMC supports the widest possible expansion of telehealth coverage and reimbursement, including coverage for patients in every clinical setting – from the emergency room, the ICU, and all hospital and outpatient settings to the patient's home, regardless of geographic location.

As further discussed below, we urge CMS to continue to add services to the Medicare Telehealth Services List on a ***permanent*** basis.

- ***Requests to Add Services to the Medicare Telehealth Services List for CY 2023***

Comment: Other than HCPCS codes GXXX1, GXXX2, and GXXX3, discussed below, CMS rejected all requests to add specific services to the Medicare Telehealth Services List on a Category 1 or Category 2 basis. However, CMS did propose the addition of several services to the Medicare Telehealth Services List on Category 3 basis, making them available through at least to the end of 2023.

UPMC fully supports CMS's addition of the proposed services to the Medicare Telehealth List on a Category 3 basis, but urges CMS to consider making such services available on ***permanent***, Category 1 or 2 basis. UPMC further recommends that CMS continue to keep such services on the Medicare Telehealth Services List until a final determination regarding permanent adoption is made, extending the availability of such services beyond the end of CY 2023 if necessary, until sufficient data has been collected and considered. Such action, given current safe and effective delivery of these services utilizing telehealth, prevents an unnecessary abrupt and unexpected limitation on access to services for Medicare beneficiaries.

UPMC similarly urges CMS to reconsider its proposal ***not*** to add certain GI tract imaging and continuous glucose monitoring services (CPT codes 91110 and 95251) to the Medicare Telehealth Services List on a Category 3 basis.

Finally, UPMC strongly recommends that CMS continue to advocate to Congress to enact legislation to permanently remove outdated and illogical barriers to the provision of telehealth services, such as the geographic location, originating site setting, and eligible provider requirements set forth in Section 1834(m). Without the permanent removal of these barriers, the pool of Medicare beneficiaries who are eligible to receive telehealth services will be severely limited. For example, as CMS itself notes on page 45,890, some providers who furnish services that will be available on the Medicare Telehealth List on a Category 3 basis through the end of at least CY 2023 may no longer be able to provide such services at the end of the 151 day period following the end of the PHE, absent additional action from Congress.

- ***Other Services Proposed for Addition to the Medicare Telehealth Services List***

Comment: In addition to the services discussed above that CMS proposed for addition to the Medicare Telehealth Services List on a Category 3 basis in response to specific requests, CMS, based on its own review, also proposed to add a number of services to the list on a Category 3 basis that are currently included on the Medicare Telehealth Services List temporarily during the PHE. CMS also proposed to add newly created HCPCS Codes GXXX1, GXXX2, and GXXX3 to the Medicare Telehealth Services List on permanent, Category 1 basis (replacing similar codes currently available on the Medicare Telehealth Services List on a Category 1 basis).

UPMC applauds CMS's initiative in reviewing services currently on the Medicare Telehealth Services List temporarily during the PHE and proposing to make such services available on longer-term, Category 3 basis. Similar to prior points, however, UPMC urges CMS to consider making such Category 3 additions available on ***permanent***, Category 1 or 2 basis. UPMC further recommends that CMS continue to keep such services on the Medicare Telehealth Services List until a final determination regarding permanent adoption is made, extending the availability of such services beyond the end of CY 2023 if necessary, until sufficient data has been collected and considered.

UPMC similarly fully supports the addition of HCPCs codes GXXX1, GXXX2, and GXXX3 to the Medicare Telehealth Services List on permanent, Category 1 basis.

- ***Services Proposed for Removal From the Medicare Telehealth Services List After 151 Days Following the End of the PHE***

Comment: CMS proposed to continue to allow certain telehealth services that would otherwise not be available via telehealth after the expiration of the PHE (*i.e.*, all services "temporarily added" to the Medicare Telehealth Services List during the PHE but not on a Category 3 basis) to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE. CMS believes this will align the availability of such services with the flexibilities extended under the 2022 Budget Act.

UPMC fully supports CMS's decision to align the availability of certain services on the Medicare Telehealth Services List with other flexibilities that will remain in effect for 151 days after the expiration of the PHE. UPMC recommends that CMS continue to closely monitor Congressional action on telehealth and take swift action to mirror any extended flexibilities, whether on a temporary or permanent basis. For example, UPMC notes that current legislation – H.R. 4040 – would extend current telehealth

flexibilities related to geographic and originating site requirements, eligible telehealth practitioners, and audio-only telehealth services until December 31, 2024. If this or similar legislation is passed, UPMC urges CMS to commit to adopting similar flexibilities and to consider and implement structures allowing for immediately effective sub regulatory guidance aligned with any Congressional actions.

Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

- ***Expiration of PHE Flexibilities for Direct Supervision Requirements***

Comment: During the PHE, CMS changed the definition of "direct supervision" as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow a supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring physical presence with a supervisee. In the CY 2021 PFS final rule, CMS continued of this policy through the later of the end of the calendar year in which the PHE ends or December 31, 2021.

In the CY 2023 proposed PFS, CMS declined to further extend or make permanent this change. Under the currently proposed PFS, the "direct supervision" allowance will terminate after December 31 of the year in which the PHE expires. CMS stressed that at that point "the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply," and the temporary exception to allow immediate availability for direct supervision through virtual presence would no longer apply."

UPMC urges CMS to ***permanently*** allow the immediate availability requirement for direct supervision to be met through the use of real-time, audio/video technology. The ability to provide safe and effective supervision using remote technology has been well established. For example, even prior to the PHE, many states adopted practice standards governing supervision and collaboration relationships among physicians and physician assistants and nurse practitioners that allow for such supervision and/or collaboration to occur remotely. During the PHE, UPMC providers have safely and successfully provided direct supervision using technology in thousands of cases. The ability to do so has allowed UPMC to provide much-needed, high-quality care to a greater number of Medicare beneficiaries during a period of nationwide medical staffing shortages.

Further, separate CMS regulations on coverage of supervised services looks to the underlying state law of the beneficiary's state for setting when and how supervision is appropriate.[1] In fact, Medicare Benefit Policy Manual guidance incorporates a modality-neutral structure for physician supervision of a physician

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[1] Regarding physician assistants, Medicare covers services that are legally authorized to be performed by the state in which the services are performed, and many states allow for remote supervision of PAs by physicians. *See* 42 U.S.C. § 1395x(s)(K)(i); 42 C.F.R. § 410.74. See Medicare Claims Processing Manual, Chapter 12, Physicians/Nonphysician Practitioners, § 110; Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, § 190. Regarding advance practice nurses, CMS similarly looks to authority for supervision under state law, and in CMS's Medicare Benefit Policy Manual indicates the collaborating physician does not need to be present with the APNP when the services are furnished or to make an independent evaluation of each patient. *See* 42 U.S.C. § 1395x(s)(K)(ii); 42 C.F.R. § 410.75. See Medicare Claims Processing Manual, Chapter 12, Physicians/Nonphysician Practitioners; Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, § 200. Further, almost 20 states now authorize certain APNPs to treat patients independently, without any supervision or collaboration, demonstrating confidence and capable safe and effective care by mid-level providers.

assistant when no relevant state law exists.[2] UPMC urges CMS to coordinate these concepts for on-going telehealth-enabled care models supported by non-physician providers aligned with state authority.

- ***Flexibilities for Opioid Treatment Programs ("OTPs") to Use Telecommunications for Initiation of Treatment With Buprenorphine***

Comment: During the PHE, CMS authorized the expanded use of telehealth options for OTPs, including a temporary allowance for audio-only technologies to be used for certain telehealth services. Specifically, in 2020, CMS allowed, on an interim final basis, periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video communication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. Further, under the CY 2021 PFS final rule, CMS finalized that, on a permanent basis, periodic assessments (HCPCS code G2077) must be furnished during a face-to-face encounter, but may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met. Currently, the flexibility for OTPs to furnish periodic assessments via audio-only communication are limited to the duration of the PHE for COVID–19, and currently there are no flexibilities under Medicare for OTPs to furnish the intake add-on code via communication technology.

In the CY 2023 proposed PFS, CMS proposed allowing the use of two-way audio-video communications technology to ***initiate*** treatment with buprenorphine at OTPs under the intake add-on code, to the extent authorized by the Drug Enforcement Agency and Substance Abuse and Mental Health Services Administration. CMS also proposed allowing the use of audio-only communication technology to ***initiate*** treatment with buprenorphine when live video is not available to the beneficiary. CMS noted that it interprets audio/video technology unavailability to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction.

UPMC agrees with CMS's proposal to allow the use of two-way audio-video communications technology to ***initiate*** treatment with buprenorphine at OTPs under the intake add-on code and to allow the use of audio-only communication technology for such services when live video is not available to the beneficiary. UPMC also urges CMS to allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for patients who are receiving treatment via buprenorphine, as well as to patients receiving methadone or naltrexone.

The need for OTP services is greater than ever. The opioid crisis is an ongoing nationwide public health emergency, and opioid overdose deaths have increased during the COVID-19 PHE. UPMC fully supports allowing OTPs greater flexibility to provide lifesaving services to patients, including via audio-only communications.

- ***Public Reporting on the Compare Tools Hosted by HHS – (1) Telehealth Indicator***

Comment: CMS has proposed adding a search feature to the Physician Compare Finder function of the Medicare website that would allow Medicare beneficiaries to search whether a provider uses telehealth

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[2] *See* Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, § 190.

to deliver services, as identified based upon the provider's use of POS 02 on paid physician and ancillary service claims, or modifier 95 appended on paid claims.

UPMC supports CMS's proposal to add a telehealth indicator to the Physician Compare Finder. In light of other changes proposed by CMS in the CY 2023 proposed PFS, UPMC recommends that CMS also identify providers that use POS 10, as well as POS 02 and modifier 95, as providers furnishing telehealth services. In addition, UPMC recommends that CMS consider establishing a process by which providers can request an update or correction to their provider profile regarding their ability to furnish telehealth services.

Other General Comments: UPMC urges CMS to consider streamlining the enrollment process for provider groups with telehealth practitioners located across multiple jurisdictions. Nationwide provider shortages have been exacerbated during the PHE, necessitating health care organizations to hire providers located across the United States. This has resulted in health care organizations that typically enroll with and bill for services through one Medicare Administrative Contractor ("***MAC***") to enroll with and bill services to multiple MACs across the country, even when the Medicare beneficiaries who receive such services are located within a single MAC jurisdiction. UPMC urges CMS to evaluate appropriate methods for eliminating these unnecessary administrative burdens.

Further, UPMC urges CMS to continue expanding opportunities for providers to use and be reimbursed for services provided to Medicare beneficiaries using audio-only technologies, consistent with CMS's recognition of other digital health tools, such as for communication technology-based services. Many services can be provided safely and effectively without the use of real-time video technology, and enabling the provision of such services using audio-only technology would allow UPMC and other providers to furnish necessary services to more Medicare beneficiaries in a manner that increases beneficiary engagement and satisfaction.

Payment for Split/Shared Evaluation and Management Visits

A "split" or "shared" E/M visit is one that is performed by both a physician and a non-physician practitioner (NPP) in the same group. Physicians in a facility setting may bill for an E/M visit when both the billing physician and an NPP in the same group each perform portions of the visit, but only if the physician performs a "substantive" portion of the visit. If the physician does not perform a substantive part of the split visit and the NPP bills for it, Medicare will pay only 85% of the fee schedule rate.

In last year's rulemaking, CMS finalized a policy under which, for 2022, the "substantive portion" of non-critical care split (or shared) visits was defined as the performance of either one of the three key components of a visit (history, physical exam or medical decision-making) or more than half of the total time performing the visit. For 2023 and beyond, the agency would define the substantive portion of the visit only as more than half of the total time spent. However, CMS now proposes delaying implementation of this policy for one year, until Jan. 1, 2024. Thus, for 2023, the substantive portion would continue to be defined as either one of the three key components of a visit, or more than half of the total time.

Comment: UPMC supports the proposed delay until at least January 2024. Additionally, we ask CMS to evaluate at least one other non-time- based option to determine the substantive portion of the

visit. Allowing for Medical Decision Making or time as the criteria for determining the substantive portion will allow for clarity in the documentation to be provided based on the provider leading the care provided to the patient. Allowing providers to focus their efforts on addressing the patient's clinical needs vs monitoring the time they spent caring for the patient will allow for quality patient care while achieving the intent of the policy.

E/M Component Emergency Department, Nursing Facilities, Domiciliary, Rest Home, Custodial Care Services, Home or Residence, and Consultation

CMS proposes to adopt most of the changes made by the AMA CPT Editorial Panel in coding and documentation for other evaluation and management services. These changes will include E/M visits across various settings from acute care inpatient and outpatient, nursing facility, home or residence services, and cognitive impairment assessment) effective January 1, 2023. These changes include new descriptor times, revised interpretive guidelines for levels of medical decision making, selection of level of E/M code level based on time or medical decision-making, and elimination of use of history and exam to determine code level. CMS proposes to maintain the current billing policies that apply to the E/M codes and to consider changes in the future.

Comment: UPMC fully supports CMS' adoption of the proposed changes related to the above E & M visits, which are designed to simplify documentation requirements and reduce excessive administrative burden for providers regarding Evaluation & Management (E/M) services. This change will allow physicians and other eligible providers to spend more time with patients and less on paperwork.

We appreciate and support CMS' efforts to streamline and simplify documentation required for E & M services by proposing to:

- Eliminate the history and physical exam component unless it is relative to the specific visit.
- Modify the Medical Decision Management (MDM) criteria and move away from simply adding up tasks (such as number of diagnoses or management options, amount and or complexity of data reviewed, risk of complications and or morbidity or mortality).
- Allow physicians and other practitioners to choose whether the visit code is based on MDM or total time and adopt the actual total time the reporting provider spent on the day of the visit, including face-to-face and non-face-to-face time.
- Delete CPT codes 99241 and 99251 to support the MDM as the basis of code selection.

We support the proposal to use medical decision as the criteria for level of service selection for emergency room visits. Time-based coding is fundamentally too hard to track as the ED providers are always involved in multiple patients at any given time and as such time is rarely if ever devoted to one patient.

We support CMS' proposals as noted above in order to foster improved quality of time that providers can spend with patients, and most likely result in improved physician/practitioner relationships with their patients. We particularly applaud CMS for selecting the actual total time methodology for E/M visits rather than the RUC-recommend "Total Time."

Additionally, UPMC fully supports CMS' adoption of merging the In-Patient and Observation E & M services into the three level of services with using the same codes for either a patient with a status of admission under In-patient or Observation. Additionally these codes are changing to align with MDM is used for the selection of the level of service or time; which are designed to simplify documentation requirements and reduce excessive administrative burdens for providers regarding Evaluation & Management (E/M) services. This change will allow physicians and other eligible providers to spend more time with patients and less on paperwork.

Critical Care

CMS Clarifies that if critical care is provided by multiple practitioners in the same group and the same specialty to the same patient, CPT code 99291 is reportable for the first 30-74 minutes of critical care services furnished to a patient on a given date. CPT code 99292 is reportable for additional complete 30-minute time increments furnished to the same patient (74 +30 =104 minutes). Clarifies that the policy is the same for critical care whether the patient is receiving care from one physician, multiple practitioners in the same group and specialty who are providing concurrent care, or physicians and NPPs who are billing critical care as a split (or shared) visit.

Comment: UPMC seeks clarity on how services represented by add on CPT code 99292 (critical care each additional 15 minutes) would be paid if performed by a different provider than the original critical care service. A typical scenario could be as follows: Dr. Cass sees and performs critical care services for 70 minutes. Later that same day Dr. Well is called to the bedside and performs an additional 55 minutes of critical care for the same patient. When billing 99292 alone with the provider being Dr. Well, our concern is this will be denied as 99292 being add on code that would require coding the primary CPT of 99291. It is also unlikely the billing of CPT 99292 alone by Dr. Well will pass internal claims scrubbing edits.

Behavioral Health

To address the shortage of behavioral health providers, CMS proposed that different mental health practitioners, including licensed professional counselors, marriage and family therapists, and others, be integrated behavioral health services as part of patients' primary care teams. Additionally, CMS proposes to amend the direct supervision requirement to allow behavioral health services to be furnished under the general supervision of a physician or NPP when the services are provided by auxiliary personnel incident to the services of a physician or NPP. In addition, CMS proposes to establish a new code as part of the existing set of codes describing services furnished using the Psychiatric Collaborative Care Model. This code would account for monthly care integration where the mental health services furnished by a clinical psychologist or clinical social worker (as opposed to a physician) serve as the "focal point" of care integration and would be allowed under general supervision.

Comment: UPMC applauds the efforts of CMS to ensure their beneficiaries have access to high quality behavioral health services furnished in a timely manner. Allowing Licensed Professional Counselors (LPC) to enroll as Medicare providers would greatly enhance access to quality care for older adults. Private Licensed Clinical Social Workers LCSW) and PhD level providers frequently choose not to enroll as

Medicare providers, thereby limiting access. Currently at UPMC, we have a greater than 70 day wait for a new patient visit. Enhancing the provider eligibility will ensure more timely care.

The term "geriatrics" encompasses a large group of potential patients (ages 65 to 121 years old) who present with a variety of diagnoses and needs. Many older patients, especially those who are otherwise aging well, benefit from 'standard' therapy interventions such as cognitive behavioral therapy and dialectical behavior therapy. LPC are as qualified as LCSW to utilize these modalities in working with a geriatric patient as with an adult patient.

Similarly, many older adults face issues related to their marital relationships (and to other family relationships) in the context of all the changes that go along with aging. Hence, both LPC and marriage and family therapists have the training to help an older adult process and heal marital/family relationships. This is especially important as many older adults become dependent (physically) on their spouse or older family members as they age.

There is a 'special' group within geriatrics, namely those with cognitive impairment, for whom modified therapeutic interventions are needed to accommodate and compensate for the cognitive impairment. In this instance, training in most LCSW programs do not prepare the therapist to work with this group. Yet, Medicare will cover their services. Indeed, individuals self-select themselves to work with this subpopulation and seek out formal and informal training and supervision so that they can competently work with this special group. A person's internal motivation to work with cognitively impaired older adults should not be limited by their initial training and certification.

Opioid Treatment Programs (OTPs)

Due to the unreliable nature of voluntary reporting of average sales price (ASP) data for various forms of methadone, CMS believes that the ASP data cannot provide an appropriate reflection of methadone costs for OTPs, and thus proposes a different method of updating the payment rate for the drug component of the methadone weekly bundle and add-on code for take-home supplies of methadone. Under this proposal, CMS would use the payment amount used in CY 2021 (rather than more recent pricing data, which would result in a decrease in payments) and update the amount annually to account for inflation.

CMS also proposes changes to the rate for individual therapy of the bundled payment. This rate is currently based on a crosswalk to a code that describes 30 minutes of psychotherapy, but stakeholder feedback leads CMS to believe that the severity of needs of the patient population diagnosed with OUD and receiving services in the OTP setting is generally greater than that of patients receiving 30-minute psychotherapy services paid under the PFS. Thus, the agency proposes to instead crosswalk to a code (CPT code 90834) describing 45 minutes of psychotherapy.

Finally, CMS proposes to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology for the initiation of treatment with buprenorphine under certain circumstances. The agency seeks comment on whether it should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE.

Comment: UPMC agrees with CMS's proposal to factor in inflation rates when rate setting for the drug component of OTPs. This is critical to ensure beneficiaries have access to these treatment programs. Additionally, we support the update of the base rate for individual therapy to 45 minutes, with the applicable increase in payment. We also support the continued use of the 30 minute add on code G0280.

Additionally, UPMC supports the proposal to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology for the initiation of treatment with buprenorphine under certain circumstances. The agency seeks comment on whether it should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE.

Audiology Services

CMS is proposing to allow beneficiaries to have direct access, when appropriate, to an audiologist without a physician referral by creating a new HCPCS code (GAUDX) for audiologists to use when billing for audiology services they already provide that are defined by other code(s). The service(s) encompassed by the new HCPCS code would be personally furnished by the audiologist and would allow beneficiaries to receive care for non-acute hearing or assessments unrelated to disequilibrium, hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids. CMS is proposing to permit audiologists to bill for this direct access (without a referral) once every 12 months.

Comment: UPMC applauds the efforts of CMS to ensure their beneficiaries face no barriers to receiving crucial audiology services. Allowing direct access to diagnostic hearing and balance testing breaks down those barriers. We welcome the opportunity to provide feedback on certain provisions of this proposal which we believe will align more closely with the intent of CMS to allow the Medicare Beneficiary direct access to these services. These suggestions will also relieve some of the administrative burden in operationalizing these changes.

Please see UPMC suggestions on certain proposals:

- ***Direct Access to Diagnostic Testing***

Currently, a physician's order is required for a patient to see an audiologist for diagnostic hearing and balance testing. CMS is proposing to allow beneficiaries to have direct access, when appropriate, to an audiologist without a physician referral. We fully support this concept. Audiologists are masters or doctoral level prepared. They are qualified to identify, diagnose, manage, and treat disorders of hearing and balance. Allowing direct access to an audiologist will not change their current scope of practice or diminish the important role played by physicians and other primary care providers. Audiologists are trained to recognize conditions needing medical treatment and appropriately refer patients that require medical services. Direct access will save Medicare dollars by reducing unnecessary physician visits while ensuring timely patient care. More importantly, timely care mitigates the consequences of untreated hearing loss such as falls, social isolation, and accelerated cognitive decline.

- ***Administrative Burden***

In this rule, CMS is proposing a time-limited benefit of coverage for direct access diagnostic services performed by an audiologist. If this rule is finalized, CMS will need to ensure there is a real time

verification tool so providers can validate if the patient is eligible for services. Such tools could be as portals that are used to assess other aspects of Medicare eligibility.

- ***Acute vs. non-acute Hearing Loss***

In this rule, CMS qualifies direct access to audiology services will only be for non-acute hearing loss. We ask that CMS allow direct access for both acute and non-acute hearing loss. Restricting beneficiary direct access to the services of an audiologist based on the definition of acute vs non-acute creates a barrier for seeking timely audiology services. With an acute hearing loss, the diagnostic tests performed by the audiologist are needed before the physician or NPP can make decisions for treatment. Requiring the patient to see the physician first, then be referred to the audiologist and then return to the physician post testing, delays the diagnosis and care for the patient. This will also reduce Medicare spend.

- ***GUADX HCPCS Coding***

Currently, there are 36 CPT codes which represent audiology services. CMS is proposing a new HCPCS code, GAUDX, for audiology service(s) furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to disequilibrium, or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids once in a period of 12 months. UPMC does not support the use of the one umbrella HCPCS code. We contend this single GAUDX code will not provide CMS the clarity of actual services rendered. This is contrary to the goal of CMS seeking a better understanding the situations and services for which beneficiaries would seek direct access to audiology services.

CMS proposes a work RVU of 0.8 and practice expense inputs using the combined values of CPT codes 92557 Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined). This appears to be outside of the normal AMA RUC process. UPMC is concerned this methodology does not accurately reflect the relative clinical work. If the one GAUDX code is finalized, we ask CMS to value this code appropriately, reflecting relative clinical work and practice expense inputs.

We ask CMS to consider the use of a modifier which could be used when services are furnished via the direct access pathway. Services can then be reported with the existing CPT codes. This would address the issue of incorrect RVU validation, ease provider burden with using two sets of codes, while providing CMD the clarity of direct access services.

In summary, UPMC is supportive of efforts to ensure direct access to these vital services, but the beneficiary should have direct access to the spectrum of audiology services and not be limited to a yearly test and not limited to specific tests. We ask the agency work with relevant stakeholders such as the American Academy of Audiology (AAA), the American Hospital Association (AHA) and others to simplify processes and decease administrative burden. This collaboration will ensure the Medicare Beneficiary receives the care needed in a timely manner.

Skin Substitutes

CMS is proposing several changes to their policies for skin substitute products to streamline the coding, billing, and payment rules and to establish consistency in how they code and pay for these products across various settings. Specifically, CMS is proposing to change the terminology of skin substitutes to

'wound care management products' in order to accurately reflect how clinicians use these products, to provide a more consistent and transparent approach to coding for these products, and to treat and pay for these products as incident to supplies under the PFS beginning on January 1, 2024.

CMS is soliciting feedback on our key objectives related to skin substitute policies, which include (1) ensuring a consistent coding and payment approach for skin substitute products across the physician office and hospital outpatient department setting; (2) ensuring that all skin substitute products are assigned an appropriate HCPCS Level II code, including proposal regarding what documentation is necessary to provide CMS for currently marketed and future products; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of material, so they can incorporate payment methodologies that are more consistent; and 4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures.

Comment: UPMC supports changing the name of skin substitutes to 'wound care management products. We agree that this change more accurately reflects how these products are used. We support the effort to standardize coding across payment systems. Standardization will ensure we have the data to understand the clinical outcomes as well as the financial implications of different courses of treatment. This would be essential to improving patient health and reducing cost burden to providers, patients, families, payers, and the healthcare system overall.

We do ask that CMS ensure the payment rate for the wound management products be sufficient to cover costs per each individual product and not across the products in total. With the coverage policies in place that provide coverage of certain products per clinical indication, there cannot be a barrier to care on an individual covered product due to cost not being covered.

Colorectal Cancer Screening

For CY 2023, CMS is proposing two updates to expand Medicare coverage policies for colorectal cancer screening in order to align with recent United States Preventive Services Task Force and professional society recommendations. CMS is proposing to expand Medicare coverage for certain colorectal cancer screening tests by reducing the minimum age payment limitation to 45 years. Additionally, CMS is proposing to expand the regulatory definition of colorectal cancer screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result.

Comment: UPMC fully support the proposal to expand Medicare coverage policies in order to align them with recent United States Preventative Services Task Force and professional society recommendations. This would expand Medicare coverage for certain colorectal screening tests by reducing the minimum age of coverage to 45 years of age.

Additionally, we support the proposal to expand the regulatory definition of colorectal screening tests to include a follow-up screening colonoscopy after a Medicare covered non-invasive stool based colorectal cancer screening test returns a positive result. As this follow up screening colonoscopy would be considered a preventative service, there will be no cost sharing due from the beneficiary. This is critical to ensure these follow up services are completed.

Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Section 90004 of the Infrastructure Investment and Jobs Act require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10% of total allowed charges for the drug in a given calendar quarter. The proposals to implement section 90004 of the Infrastructure Act include: how discarded amounts of drugs are determined; a definition of which drugs are subject to refunds (and exclusions); when and how often CMS will notify manufacturers of refunds; when and how often payment of refunds from manufacturers to CMS is required; refund calculation methodology (including applicable percentages); a dispute resolution process; and enforcement provisions.

Comment: CMS proposes to continue the use of the JW modifier to identify discarded amounts of single-dose container or single-use package drugs that are separately payable under the OPPS and ASC payment systems. CMS also proposes the use of a separate modifier, JZ, when a single dose/single use drug was utilized without any wasted amount. UPMC finds the proposal to use the JZ modifier to be duplicative and administratively burdensome.

Hospitals are already using the JW modifier successfully and accurately to report the amount of wasted single use/dose drugs. They have spent time and resources to reconfigure internal systems to identify the amount of drug wasted and assigning JW to the line item reporting the specific amount wasted. The absence of modifier JW on a claim indicates there is no drug wastage for that specific drug.

CMS' proposal puts additional operational burden on providers to attest to something that is already attested to on the claim. The NDC number reported on the claim provides the information regarding a specific item being provided in a single use vial and the medical record documentation supports the number of units administered and the number of units wasted if any.

We ask that CMS consider identifying all "single use vials" that may be subject to a manufacturer refund. These drugs can be assigned a unique status indicator. The unique status indicator plus claims data with/without modifier JW will provide the information that CMS needs in order to recoup the rebate/refund.

Preventive Vaccine Administration Services

CMS is proposing refinements to the payment amount for preventive vaccine administration under the Medicare Part B vaccine benefit. The agency is proposing to annually update the payment amount based upon the increase in the MEI and to adjust for the geographic locality, based upon the PFS locality where the preventive vaccine is administered using the geographic adjustment factor (GAF). CMIS is also proposing to continue the additional payment for at-home COVID-19 vaccinations for CY 2023.

Additionally, CMS proposes to clarify their 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.

Comment: UPMC supports the use of geographical locality to determine payment for preventative vaccines. We appreciate the continued payment for COVID-19 vaccines and monoclonal antibody products until the emergency use declaration for drugs and biological products ends.

RHC and FQHC Chronic Pain Management and Behavioral Health Services

CMS is proposing to add the new chronic pain management and behavioral health integration services to the RHC and FQHC specific general care management HCPCS code, G0511, to align with the proposed changes made under the PFS for CY 2023. Since the requirements for the new chronic pain management and behavioral health integration services are similar to the requirements for the general care management services furnished by RHCs and FQHCs, the payment rate for HCPCS code G0511 would continue to be the average of the national non-facility PFS payment rates for the RHC and FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491) and PCM codes (CPT codes 99424 and 99425) and would be updated annually based on the PFS amounts for these codes.

Comment: As a placeholder, HCPCS code GYYY1 (*Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, and community based care, as appropriate)* appears to meet the definition of an RHC encounter and therefore we believe should be billed as an RHC visit and reimbursed at the RHC's All-Inclusive Rate (AIR).

Specified Provider-Based RHC Payment Limit Per-Visit

CMS is proposing to clarify that a 12-consecutive month cost report should be used to establish a specified provider-based RHC's payment limit per visit. The agency believes 12-consecutive months of cost report data accurately reflects the costs of providing RHC services and will establish a more accurate base from which the payment limits will be updated going forward.

Comment: UPMC supports this proposal.

In closing, we appreciate the opportunity to submit these comments on the 2023 Medicare Professional Fee Schedule Proposed Rule. If you have any questions, please contact Kathy Noorbakhsh at (412) 864-0547 or email noorkj@upmc.edu.

Sincerely,

Kathy Noorbakhsh

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