875 N. Michigan Avenue
Suite 3100
Chicago, IL 60611
www.lugpa.org

October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CY 2021 Medicare Physician Fee Schedule Rule [CMS-1734-P]

On behalf of the Large Urology Group Practice Association (LUGPA), we thank you for the opportunity to comment on the Calendar Year 2021 Medicare Physician Fee Schedule ("MPFS") Proposed Rule (the "Proposed Rule").[1] Our comments focus on supporting the Center for Medicare Services ("CMS") proposals regarding restructuring of E/M coding, expansion of telehealth services, and expansion of scope of practice to include supervision of diagnostic tests by non-physician practitioners.

LUGPA believes these proposed changes fulfill CMS's goal of creating a "healthcare system that results in better accessibility, quality, affordability, empowerment, and innovation."[2]

I. LUGPA

In 2008, when physician leaders of large urology group practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was initially established with the purpose of enhancing communication between large urology groups, allowing for benchmarking of operations, promoting quality clinical outcomes, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 154 urology group practices in the United States, with approximately 2,200 physicians who, collectively, provide nearly 40% of the nation's urology services.[3]

Integrated urology practices are able to monitor health care outcomes and seek out medical "best practice" in an era increasingly focused on medical quality and the cost-effective delivery of medical services. Additionally, these practice models can better overcome the economic and administrative obstacles to successful, value-based care. LUGPA practices often include advanced practice providers and other specialists, such as pathologists and radiation oncologists, who work as teams with urologists to coordinate and deliver care with added patient convenience. LUGPA's mission is to provide urological surgeons committed to providing integrated, comprehensive care the

[1] 85 Fed. Reg. 50074 (Aug. 17, 2020).
[2] Centers for Medicare and Medicaid Services, *Physician Fee Schedule: CY 2021 Physician Fee Schedule Proposed Rule with Comment Period*, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched.
[3] Centers for Medicare and Medicaid Services, *Medicare Provider Utilization and Payment Data: Physician and Other Supplier*, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-andReports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html.

means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system, including prostate, kidney, and bladder cancer, in an efficient, cost effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, regulatory agencies, and legislative bodies

II. LUGPA Supports CMS's Proposed Restructuring of the E/M Visit Code Set

In the CY 2020 MPFS Final Rule[4] CMS made several changes to the office/outpatient E/M visit code set (CPT codes 99201 through 99215). Specifically, CMS finalized a policy to generally adopt the new coding, prefatory language, and interpretive guidance framework that had been issued by the American Medical Association's ("AMA") CPT Editorial Panel. These changes will be effective January 1, 2021. Under this new CPT coding framework, history and exam will no longer be a required component in order to calculate the level of code for office/outpatient E/M visits. Instead, an office/outpatient E/M visit shall include only documentation of whatever medically appropriate history and physical exam is performed, if any, at that visit.

The specific changes will include deletion of CPT code 99201(Level 1 office/outpatient visit, new patient), which the CPT Editorial Panel decided to eliminate because CPT codes 99201 and 99202 are both straightforward medical decision-making ("MDM") and are currently largely differentiated by history and exam elements. Thus, new patient office/outpatient visit services will be reported with CPT codes 99202-99205. Selection of the code level to report will be based on either the level of MDM, as redefined in the new AMA/CPT guidance framework, or the total time personally spent by the reporting practitioner on the day of the visit.

Furthermore, in the CY 2020 MPFS Final Rule CMS finalized separate payment for a new prolonged visit add-on CPT code (CPT code 99XXX), and discontinued the use of CPT codes 99358 and 99359. CMS also finalized separate payment for HCPCS code GPC1X, to provide payment for visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

In the CY 2020 MPFS Final Rule, CMS also finalized new values for CPT codes 99202 through 99215, and assigned RVUs to the new office/outpatient E/M prolonged visit CPT code 99XXX, as well as the new HCPCS code GPC1X. These valuations were finalized with an effective date of January 1, 2021.

LUGPA largely supported these changes in its public comments on the CY 2020 MPFS Proposed Rule. We agreed with CMS that these changes would "reduce administrative burden, improve payment accuracy, and update this code set to better reflect the current practice of medicine."[5] We continue to share CMS's belief that these changes will reduce a substantial amount of administrative burden and result in appropriate specialty-level redistributive impacts.[6]

A. Time values for levels 2-5 office/outpatient E/M visit codes

In the CY 2020 MPFS Final Rule, CMS finalized adoption of the AMA RUC-recommended time valuation method, but stated that it would continue to consider whether this issue had implications for the MPFS

[4] 84 Fed. Reg. 62568, 62844 – 62860 (Nov. 15, 2019).
[5] 84 Fed. Reg. 40482, 40672 (Aug. 14, 2019).
[6] *Id*.

broadly. Subsequently, CMS found that the approach recommended by the AMA RUC sometimes resulted in two conflicting sets of times. Thus, in the Proposed Rule, CMS proposes to adopt an approach of actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.[7]

LUGPA supports CMS's proposal to simply coding for office and outpatient E/M visits.

B. Comment solicitation on the definition of HCPCS Code GPC1X

In the CY 2020 MPFS Final Rule, CMS finalized HCPCS add-on code GPC1X because it believed that "the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits."[8] HCPCS add-on code GPC1X describes the ''visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition.''[9]

However, according to CMS, since the publication of the CY 2020 MPFS Final Rule, some specialty societies have stated that its definition of this service, as articulated in the code descriptor and the associated preamble discussion, is unclear. Therefore, CMS is now soliciting public comments providing additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how CMS might address those concerns, and how CMS might refine its utilization assumptions for the code.

CMS provides several reasons for why its current formulation of HCPCS add-on code GPC1X is appropriate. First, it "appropriately recognizes the resources involved when practitioners furnish services that are best-suited to patients' ongoing care needs and potentially evolving illness."[10] Furthermore, it "reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time."[11]

LUGPA is aware that there has been concern regarding the implementation of this code, but believes that it is essential that CMS recognize the additional cognitive effort that is required to manage chronic conditions. As such, LUGPA largely agrees with CMS's analysis of HCPCS add-on code GPC1X, and does not believe that CMS's definition is confusing. We believe that the definition is appropriate and that ultimately it will benefit our patients, as it allows for a more holistic approach to addressing patients' ongoing care needs and potentially evolving illnesses.

C. Prolonged office/outpatient E/M visits (CPT Code 99XXX)

In the CY 2020 MPFS Final Rule, CMS finalized CPT code 99XXX to report prolonged office/outpatient E/M visits. CPT code 99XXX is only reported when time is used to select the visit level, and only time of the physician or qualified healthcare professional is counted. In the CY 2020 Final Rule, CMS stated that

[7] 85 Fed. Reg. at 50124.
[8] 85 Fed. Reg. at 50138.
[9] *Id*.
[10] *Id*.
[11] *Id*.

its interpretation of revised CPT prefatory language and reporting instructions would mean that CPT code 99XXX could be reported when the physician's (or NPP's) time is used for code level selection and the time for a level 5 office/outpatient E/M visit (the floor of the level 5 time range) is exceeded by 15 minutes *or more* on the date of service.[12] However, having reviewed this policy, in the Proposed Rule CMS now states that it "believe[s] that allowing reporting of CPT code 99XXX after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time."[13]

CMS is now proposing that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99XXX could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. Thus, CPT code 99XXX would add 15 minutes above the stipulated maximum time for the respective code, but preclude the reporting of fragments of 15 minutes. LUGPA recognizes the need for accommodations in instances in which extended services are provided beyond what is can be captured in the existing E&M code set and as such supports this proposal.

III. LUGPA Supports CMS's Proposal to Expand Access to Telehealth Services

Prior to the COVID-19 pandemic, telehealth in the Medicare program was generally only available for patients living in rural areas and only for a limited number of services. However, the COVID-19 pandemic has forced all stakeholders in the health care community to re-evaluate the role of telehealth in ensuring adequate access to care for vulnerable populations. Reflecting this realization, CMS has proposed several changes to how the Medicare program covers telehealth services.

A. Addition of services to the Medicare telehealth services list for CY 2021

Normally, Medicare will only make payment for telehealth services that are on the telehealth services list.[14] To develop this list, CMS established a process of internal review that also provides the public "an ongoing opportunity to submit requests for adding services."[15] Under this process, CMS assigns any submitted request to one of the following two categories: Category 1, which includes services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list; and Category 2, which includes services that are not similar to those on the current Medicare telehealth services list. Both categories carry with them their own criteria for inclusion.

In response to the PHE for the COVID–19 pandemic, CMS undertook emergency rulemaking to add a number of services to the Medicare telehealth services list on an interim basis.[16] In developing the Proposed Rule, CMS considered which of the services that were added to the Medicare telehealth services list on an interim basis should remain on the list permanently, or alternatively, on an interim basis after the end of the PHE. CMS identified the following services as being sufficiently similar to services currently on the Medicare telehealth services list to be added on a Category 1 basis: GPC1X, 90853, 96121, 99XXX, 99483; 99334; 99335; 99347; and 99348.

LUGPA supports CMS's decision to add HCPCS codes 99483, 99334, 99335; 99347, and 99348 to the telehealth services list. LUGPA agrees with CMS that these codes are similar to services currently on the Medicare telehealth list. Furthermore, the services described by these HCPCS codes expand access to much

[12] 84 Fed. Reg. at 62848 – 62849. (emphasis added).
[13] 85 Fed. Reg. at 50139.
[14] Section 1834(m)(4)(F)(ii) of the Social Security Act.
[15] *See* CY 2003 PFS final rule with comment period, 67 Fed. Reg. 79988 (Dec. 31, 2002).
[16] *See* Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 Fed. Reg. 19230, 19234- 19241 (March 31, 2020).

needed care for a vulnerable population. Allowing for varying levels of evaluation and management (E/M) services to be provided at home via telehealth will remove barriers to access to care, strengthen the physician-patient relationship, and improve continuity of care. Facilitating access to care is vital during the PHE, but will remain an issue for many beneficiaries as the country recovers from the pandemic and thereafter.

B. Temporary addition of a Category 3 basis for adding to or deleting services from the Medicare telehealth services list

The congressional response to the COVID-19 pandemic provided the Secretary of HHS with new authority to modify Medicare telehealth payment requirements during the PHE for the COVID-19 pandemic.[17] CMS has used this and other authority to remove the geographic and site of service originating site restrictions,[18] as well as restrictions on the types of practitioners who may furnish telehealth services,[19] for the duration of the PHE for the COVID–19 pandemic. Furthermore, CMS has used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. As mentioned above, CMS has also added several HCPCS codes to the Medicare telehealth services list on an interim basis.

However, many of the changes made are set to expire at the end of the PHE. Thus, before eliminating the full range of these services from the Medicare telehealth services list and potentially jeopardizing beneficiary access to those services that have been clinically beneficial, CMS believes it would be prudent to collect information from the public regarding which, where and how various telehealth services have been in use in various communities during the COVID–19 response. Thus, CMS is proposing to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis (Category 3). This new category would describe services that would be included on the Medicare telehealth services list on a temporary basis. CMS would include in this category the services that were added during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria.

LUGPA supports CMS's decision to create a Category 3 basis for adding services to the Medicare telehealth services list. The COVID-19 pandemic has in a way expedited the evolution and adoption of telehealth services. However, "the extent to which service delivery via telehealth demonstrates clinical benefit outside the conditions of the PHE is not known at this time."[20] Providers will need additional time to collect data and CMS time to adequately assess the data provided by health care providers. Allowing for certain telehealth services to remain on the Medicare telehealth services list on a temporary basis under a new Category 3 that does not end with the expiration of the PHE will "give the public the opportunity to gather data and generate requests to add certain services to the Medicare telehealth services list permanently."[21]

[17] Section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020), subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116– 136, March 27, 2020).
[18] Section 1834(m)(4)(C) of the Social Security Act.
[19] Section 1834(m)(4)(E) of the Social Security Act.
[20] 85 Fed. Reg. at 50100.
[21] *Id*.

C. Comment solicitation on continuation of payment for audio-only visits

In the March 31st IFC, CMS established separate payment for audio-only telephone evaluation and management (E/M) services.[22] CMS noted that, "although these services were previously considered non-covered under the PFS, in the context of the PHE and with the goal of reducing exposure risks associated with the COVID–19 pandemic … [the agency] believes there are circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit."[23]

In the Proposed Rule, CMS says it is not proposing to continue to recognize these codes for payment under the MPFS after conclusion of the PHE for the COVID–19 pandemic because, outside of the circumstances of the PHE, it does not have the authority to do so. However, CMS recognizes that the need for audio-only interaction could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office. In this circumstance, a longer phone conversation may be needed to determine if an in-person visit is necessary than what is described by a virtual check-in.

Thus, CMS is seeking comment/input on three issues relating to audio only services. First, CMS is seeking comment on whether the agency should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. Second, CMS is seeking input from the public on the appropriate duration interval for such services and the resources that would be associated with furnishing them. Last, CMS is seeking comment on whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE, or if it should become permanent MPFS payment policy.

LUGPA supports the three issues on which CMS is seeking comment. Developing coding and payment for a service similar to the virtual check-in but for a longer unit of time will encourage the use of audio-only services. During the course of the pandemic, telehealth services generally have allowed providers to continue treating patients with chronic conditions and take on new patients during a time when many patients are uncomfortable presenting for an in-person visit. Audio-only services specifically are vital for Medicare beneficiaries, as research shows 80 percent of seniors have cell phones but only 42 percent have smartphones with access to video conferencing technology.[24] Thus, audio-only visits are incredibly important to facilitate the use of telehealth in the Medicare population. For the same reasons, LUGPA believes that payment for audio-only services should be a permanent MPFS payment policy. Even after the end of the PHE, many seniors will feel uncomfortable presenting at the doctor's office. Furthermore, there are several different types of services, such as certain E/M visits, that can be performed effectively over the phone. Thus, allowing for audio-only services would significantly contribute to expanding access to care for the Medicare population.

D. Direct supervision by interactive telecommunications technology

As currently defined, direct supervision means that the physician or non-physician practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of a procedure.[25] Normally, direct supervision does not require the physician or NPP to be present in the room when the service or procedure is performed. However, to mitigate COVID-19 exposure,

---

[22] 85 Fed. Red. at 19264 – 19266.
[23] 85 Fed. Reg. at 50113.
[24] M. Anderson & A. Perrin, *Tech Adoption Climbs Among Older Adults*, Pew Research Center (May 17, 2017), https://www.pewresearch.org/internet/2017/05/17/technology-use-among-seniors/.
[25] 42 C.F.R. §§ 410.26 and 410.32(b)(3)(ii),

in an interim final rule CMS adopted for the duration of COVID-19 PHE a policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology.[26] CMS is now proposing to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021. Specifically, CMS is proposing to revise 42 § 410.32(b)(3)(ii) to allow direct supervision to be provided using real time, interactive audio and video technology through the later of the end of the calendar year in which the PHE ends or December 31, 2021. CMS is also seeking "information from commenters as to whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use."[27]

LUGPA supports this proposal. LUGPA agrees that this would be beneficial to "recognize the different and unique circumstances faced by individual communities that may continue after the PHE ends, and provide time to solicit public input on circumstances where the flexibility to use interactive audio/video real-time communications technology to provide virtual direct supervision could still be needed and appropriate."[28]

E. Supervision of residents in teaching settings through audio/video real-time communications technology

At the beginning of the COVID-19 PHE, CMS adopted a policy on an interim basis that provides that the requirement for the presence of a teaching physician during the key portion of the service furnished with the involvement of a resident can be met using audio/video real-time communications technology.[29] Furthermore, CMS also adopted a policy on an interim basis to allow Medicare to make payment under the MPFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology.

CMS is now considering whether these changes that were implemented on an interim basis during the PHE should be extended on a temporary basis or made permanent.[30] For many of the same reasons outlined above, LUGPA is generally supportive of these changes, and believes CMS should extend this policy on a temporary basis until the end of the calendar year in which the PHE ends. However, LUGPA believes that, as many independent physicians participate in resident education, this provision should be extended to all sites of service, and not be restricted to the teaching hospital setting. This will be particularly beneficial in communities where COVID-19 continues to persist or that experience a resurgence after the expiration of the PHE.

IV. LUGPA Supports the Expansion of Scope of Practice to Include Supervision of Diagnostic Tests by Non-Physician Practitioners

Prior to COVID-19, non-physician practitioners (NPPs) were already authorized under Medicare regulations to order and furnish diagnostic tests.[31] However, generally only physicians were authorized to supervise the performance of diagnostic tests.[32] As part of the COVID-19 PHE declaration, CMS allowed non-physician practitioners to also supervise the performance of diagnostic tests.[33] CMS is now proposing

[26] 85 Fed. Reg. at 19245.
[27] 85 Fed. Reg. at 50116.
[28] *Id*. at 50115.
[29] *See* 85 Fed. Reg. at 19258 – 19261; *see also* 85 Fed. Reg. at 27550 – 27629.
[30] 85 Fed. Reg. at 50140.
[31] 42 C.F.R § 410.32(a)(2).
[32] 42 C.F.R. § 410(b)(1).
[33] 85 Fed. Reg. at 27550 – 27629.

to make the changes permanent.[34] Specifically, CMS is proposing to allow certified nurse midwives, clinical nurse specialists (CNSs), nurse practitioners (NPs) and physician assistants (PAs) to supervise the administration of diagnostic tests, as long as these NPPs comply with their state scope of practice and applicable state laws, and maintain required relationships with collaborating or supervising physicians.

LUGPA generally supports this proposal, but emphasizes the need for continued physician integration in this area. LUGPA supports agency efforts to reduce administrative burdens throughout the Medicare program, and recognizes the value of nonphysician providers. However, we believe continued physician integration is necessary to ensure the standard of care for Medicare patients.

V. LUGPA Supports Policies that Facilitate Expansion of Patient Choice in Site of Care

In the Proposed Rule, CMS proposes changes that may have the potential of compromising patient choice. For example, for ablation of malignant prostate tissue with high intensity focused ultrasound (CPT Codes 558XX), CMS is proposing a work RVU of 17.73 based on a crosswalk to CPT code 69930 (Cochlear device implantation, with or without mastoidectomy) which CMS states has similar total time and identical intraservice time values and is more consistent with other codes of similar time. In doing so, CMS is proposing to reject the RUC recommendation to use the survey median work RVU of 20.00 to value this service.

Discussion of clinical appropriateness of various forms of treatment for prostate cancer are beyond the scope of this comment letter. That said, LUGPA firmly believes that given equivalent patient experience and outcomes, economic barriers should not be created that would bar patients from accessing the most convenient and cost effective site of service. As such, LUGPA urges CMS to reconsider its valuation of CPT 558XX and consult further with stakeholders prior to finalizing this proposal.

VI. Request for Action

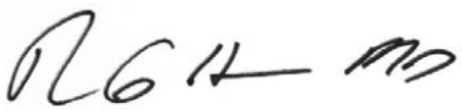
As a brief summary, our principal recommendations are that the Agency,

- LUGPA supports CMS's proposed restructuring of E/M visit codes sets.
- LUGPA supports CMS's proposal to expand access to telehealth services.
- LUGPA generally supports scope of practice, but emphasizes the need for continued physician integration.
- LUGPA supports policies that facilitate expansion of patient choice in site of care; as such, LUGPA asks CMS to revisit its valuation of CPT 558XX

[34] 85 Fed. Reg. at 50146.

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Proposed Rule. Please feel free to contact Dr. Kapoor at (516) 342-8170 or dkapoor@impplc.com if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



Richard G. Harris, MD
President

Deepak A. Kapoor, M.D.
Chairman, Health Policy