October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 314-G
Washington, D.C. 20201

SUBJECT: CMS-1734-P; Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule, Federal Register (Vol. 85, No.159), August 17, 2020

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the calendar year (CY) 2021 physician fee schedule (PFS) proposed rule.

California’s hospitals — like hospitals across the nation — continue to respond to the unprecedented challenge of the COVID-19 public health emergency (PHE). This response has required hospitals to take advantage of the significant regulatory flexibilities provided by CMS and other federal agencies to quickly expand workforce and surge capacity to care for patients and address the spread of COVID-19. Though the full extent and duration of the pandemic are still unknown, hospitals expect to be operating in this challenged environment well into 2021. Hospitals across California — including those located in communities that have not emerged as hot spots — continue to dedicate significant resources to obtaining personal protective equipment, readying their facilities to surge patient capacity as needed, and ensuring that front-line health care workers are ready to meet the community’s needs. As such, we are pleased that in this proposed rule CMS has proposed to permanently extend a number of its interim regulatory flexibilities and have generally limited our comments to provisions related to those policies.
Telehealth and Other Communication Technology-Based Services

During the COVID-19 PHE, CMS extended a number of regulatory flexibilities that allowed hospitals and health systems to greatly expand the use of telehealth and other communication technology-based services. These flexibilities have been key to maintaining access to care for patients while preventing the spread of COVID-19. Beyond the use of telehealth as an infection control strategy during the pandemic, opening up these innovative modes of virtual care to new patient populations has demonstrated that telehealth will continue to be an important method to improve access to care and reduce barriers to entry for some of our most vulnerable populations. Given the regulatory flexibility – and corresponding reimbursement – hospitals and health systems have quickly learned how to utilize telehealth not as simply a replacement for in-person care, but as a new tool in the toolbox to improve care delivery. As CMS has reported, before the PHE only 14,000 Medicare fee-for-service beneficiaries received telehealth services in a week. During the PHE, that number skyrocketed to 10.1 million beneficiaries receiving a telehealth service between mid-March and early July. CHA believes that widespread adoption of telehealth is here to stay, and we are encouraged that CMS is proposing regulatory changes to permanently expand some of its COVID-19 PHE flexibilities.

While we are pleased to support many of CMS’ proposals, detailed below, we continue to urge the agency to work with Congress to remove statutory barriers to the greater adoption of telehealth. In particular, CHA supports the elimination of geographic and originating site restrictions that so often limit telehealth services to rural patients and do not recognize the patient’s home as a suitable location to receive these services. While telehealth has long been a key tool in expanding care access to rural, underserved communities, patients in urban and suburban areas can equally benefit. Expanded access to telehealth in these communities is particularly important for vulnerable patients without reliable access to transportation, for which a virtual follow-up visit could be key to managing a chronic condition. The COVID-19 PHE telehealth waivers have also significantly contributed to an expansion in access to critical behavioral health services – a segment of our health care system where patients in all geographic locations often experience provider shortages.

Furthermore, as technology has advanced, patients – including Medicare beneficiaries – have become much more comfortable utilizing virtual care options from the comfort of their home. One large California health system reports that it has also invested in in-home educational efforts to ensure its patients are properly connected and familiar with the telehealth format prior to these visits. These investments have been made with the increasing expectation that patients will continue to demand greater access to telehealth services, beyond the duration of the COVID-19 PHE, and that they will expect to receive that care in their home. CMS and Congress must work to ensure that patients who have come to rely on telehealth services can continue to do so long after the COVID-19 pandemic has passed.

Finally, we urge CMS to ensure telehealth services are adequately reimbursed at levels that recognize their important place in the care delivery system. Telehealth services require significant investments in
technology, as well as the time and expertise of clinicians providing the services. In addition, hospitals do not see telehealth as a replacement for in-person care and must always continue to maintain the infrastructure to provide that care. CMS should ensure that telehealth and other communication technology-based services provide reimbursement equitable to in-person care.

**Category 1 Medicare Telehealth Services**
Under the existing process to request the addition or deletion of services from the Medicare telehealth list, CMS assigns requests to one of two categories. Category 1 services are similar to services that are currently on the Medicare telehealth list, while Category 2 services are not similar to services on the list, and, as such, CMS requires supporting evidence of the clinical benefit of a service to add it to the list. In its COVID-19 interim final rules, CMS added many services to the list of Medicare telehealth services for the duration of the PHE. In this rule, CMS proposes to permanently retain some of those services on the list on a Category 1 basis, including group psychotherapy (90853), care planning for a patient with cognitive impairment (99483), and others. **CHA strongly supports the permanent addition of these services to the Medicare telehealth list.**

**Category 3 Medicare Telehealth Services**
During the PHE, CMS adopted a subregulatory process to add services to the Medicare telehealth list. However, at the expiration of the PHE, CMS will return to annual rulemaking for adding or deleting services. CMS notes that the end of the PHE may not align with the annual rulemaking cycle. To prevent a sudden disruption to clinical practice and patient access to services should that occur, CMS proposes to create a third category of criteria for adding services to the Medicare telehealth list on a temporary basis. Specifically, the proposed Category 3 would be for services added during the PHE for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the services as permanent additions under Category 1 or Category 2 criteria. Category 3 services would remain on the Medicare telehealth services list through the calendar year in which the PHE ends. To be added on a permanent basis, these services would need to meet Category 1 or 2 criteria. **CHA supports the proposed addition of Category 3 criteria as a step to ensure certain telehealth services are not abruptly disrupted at the expiration of the PHE. However, we remain concerned that without Congressional action, advances in telehealth care will be halted when the PHE ends.**

In addition, CHA urges CMS to reconsider certain services for inclusion on the telehealth list. CMS proposes to include emergency department visits, levels 1-3 (CPT codes 99281-99283) on a Category 3 basis. However, CMS does not propose to include emergency department visits, levels 4-5 (CPT 99284-99285). When an emergency department visit is initiated, the level of service cannot always be immediately determined. We urge CMS to include emergency department visits, levels 4-5 on a Category 3 basis. We also urge CMS to include initial nursing facility visits, all levels (low, moderate, and high complexity) (CPT 99304-99306) – which have been critical to providing care to those most vulnerable to COVID-19 – on a Category 3 basis.
Remote Physiologic Monitoring Services
Remote physiologic monitoring (RPM) services involve the collection and analysis of patient physiologic data that is used to develop and manage a treatment plan for a chronic and/or acute illness or condition. In recent years, innovative technologies in health care, including RPM tools, have been increasingly used to expand access to care and improve outcomes for patients. During the PHE, remote monitoring has been a critical tool allowing hospitals and health systems to conserve critical personal protective equipment and limit health worker exposure while collecting valuable data to inform care decisions. In this proposed rule, CMS provides clarifications about the descriptors and instructions for some of the RPM CPT codes, and proposes to make permanent certain RPM-related policies adopted for the duration of the COVID-19 PHE.

Proposal on Interactive Communication
For CPT Codes 99457 and 99458, CMS proposes that the minimum 20 minutes of interactive time with a patient in a billing period be “face-to-face time with the patient or patient’s caregiver/medical decision-maker” and for services not typically furnished in person with the patient, it will interpret time to mean “the time spent in direct, real-time interactive communication with the patient.” CHA urges CMS to reconsider this proposal because it does not account for clinician and clinical staff time spent reviewing physiologic data and other care management functions.

RPM Codes 99453 and 99454
CMS proposes that, in scenarios where a single patient is using multiple medical devices, the CPT codes 99453 and 99454 may be billed only once per patient each 30-day period. The proposed clarification only allows for billing the codes once per month per patient – even if a patient has multiple providers who use different (or even the same) devices to track multiple chronic conditions (for example their cardiologist uses RPM to track heart disease/failure while their pulmonologist uses RPM to track chronic obstructive pulmonary disease). CHA urges CMS to clarify that the limitation is on the number of times a provider can bill for these codes within a 30-day period rather than the number of providers who can bill during that period.

COVID-19 PHE RPM Policies
CMS proposes to make permanent two RPM-related policies it adopted during the COVID-19 pandemic. First, CMS proposes to allow consent for RPM services to be obtained at the time the services are furnished. Second, for CPT codes 99453 (remote monitoring of physiologic parameter, initial) and 99454 (remote monitoring of physiologic parameter, each 30 days), CMS proposes allowing auxiliary staff to furnish RPM services under the general supervision of the billing physician or practitioner. CHA supports these proposals. However, CHA urges CMS to reconsider its proposal to reinstate the requirement that RPM services be furnished only to established patients at the conclusion of the PHE. The use of RPM for acute conditions has underscored the value of these services for patients without an established relationship and this flexibility should be made permanent.
Teaching Physician and Resident Moonlighting Policies

For the duration of the PHE, CMS finalized several flexibilities intended to enable health care professionals to practice at the top of their licenses and professional training and expand workforce capacity. In this proposed rule, CMS is considering making several of these flexibilities permanent, including policies related to teaching physicians and residents moonlighting. In general, CHA supports policies that allow health care professionals to practice to the top of their licenses as allowed by state law.

In particular, CHA supports policies to increase flexibilities for teaching physicians and residents. During the PHE, CMS permitted teaching physicians to use audio/video real-time communications technology to interact with and supervise residents. Specifically, CHA supports the permanent extension of the following flexibilities currently allowed for the duration of the PHE:

- The requirement for the teaching physician to be present during the key portion of a service furnished involving a resident may be met using audio/visual real-time communications technology. The teaching physician must be observing real time and may not use audio-only technology.
- Teaching physicians may remotely direct primary care furnished by residents, and remotely review resident-provided services during or after the visit, using audio/visual real-time communications technology.
- The requirement for the teaching physician to be present during the interpretation of diagnostic radiology by a resident may be met using audio/visual real-time communications technology.
- The requirement for the teaching physician to be present during a psychiatric service involving a resident may be met by the teaching physician’s direct supervision using audio/visual real-time communications technology.
- Audio/visual real-time communications may be used to establish a teaching physician’s presence when a resident furnishes telehealth services.

CHA believes these policies strike the appropriate balance between increasing flexibility for teaching physicians and residents and ensuring residents are adequately supervised in providing high-quality care to patients.

Under certain conditions, when a resident furnishes services that are unrelated to their graduate medical education (GME) training program in an outpatient or emergency department of the hospital – also known as moonlighting – those services are separately billable and payable under the PFS. During the PHE, CMS extended this policy to services furnished to inpatients if the services are identifiable physicians’ services, can be separately identified from services that are required as part of the resident’s GME training program, and meet relevant conditions for payment and state licensure. In many cases, this provision would apply to residents who are in fellowship programs and thus have completed a residency program and are fully licensed. CHA supports extending this policy permanently.
Direct Supervision by Interactive Telecommunications Technology
Under current requirements, direct supervision requires a physician or non-physician practitioner (NPP) to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. During the COVID-19 PHE, CMS allowed physicians and NPPs to provide direct supervision virtually, using interactive audio/video real-time communications technology. In this rule, CMS proposes to extend this policy through the calendar year in which the PHE ends or December 31, 2021, whichever is later. The policy, which is subject to the clinical judgment of the supervising physician and NPP, has been proven a safe and effective option for the provision of direct supervision for the duration of the PHE. CHA urges CMS to extend this policy permanently.

Clinical Laboratory Fee Schedule Revised Data Reporting Period and Phase-in of Payment Reductions
As required by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, CMS proposes to delay by an additional year the requirement that certain “applicable laboratories,” including hospital outreach laboratories, report their private payer data to establish payment rates for the clinical laboratory fee schedule (CLFS). Therefore, the next CLFS data reporting period will be delayed until January 1, 2022, and run through March 31, 2022. The private payer laboratory data to be reported will still be based on the original data collection period of January 1, 2019, through June 30, 2019. In addition, CMS extends the phase-in of payment cuts for CLFS services through CY 2024. As a result, there is a 0% reduction for CY 2021, and payment may not be reduced by more than 15% for CYs 2022 through 2024. CHA strongly supports the delay in clinical laboratory reporting requirements until 2022 and the extended phase-in of payment cuts. Hospital laboratories remain focused on expanding testing capacity in response to the COVID-19 PHE, and the burden of collecting and reporting private payer payment rate information is significant.

Furthermore, we continue to be concerned that requirements for hospital outreach laboratories to report non-patient private payer information are overly burdensome. As acknowledged by agency statements both in the CY 2019 PFS final rule and a May 2019 letter to the Senate Finance Committee, additional reporting by hospital outreach laboratories is unlikely to impact payment rates. We urge CMS to reconsider its requirement that hospital outreach laboratories be required to determine applicable laboratory status based on Medicare 14x type of bill revenue and revoke the policy in future rulemaking.

Valuation of Evaluation & Management and Related Services and Payment for Evaluation & Management Services
In recent years, CMS has undertaken a significant redesign of its coding, documentation, and payment policies for office/outpatient evaluation & management (E/M) visits. In the CY 2019 PFS final rule, CMS finalized a blended payment rate for Levels 2 through 4 E/M visits. However, in response to significant
concerns from CHA and other stakeholders that the policy would be detrimental to providers who care for the most complex patients, CMS adopted an alternative framework developed by the Joint AMA Current Procedural Terminology Workgroup on E/M in its CY 2020 PFS final rule. In light of the significant changes adopted, the AMA RVS Update Committee resurveyed and revalued the revised office/outpatient E/M visit code set, and CMS finalized new values last year. These valuations were finalized with an effective date of January 1, 2021.

In the proposed rule, and in conjunction with the revaluations for the office/outpatient E/M visit code set, CMS proposes to revalue several services that are closely tied to office/outpatient E/M visits. The proposed revalued office/outpatient E/M visit and related codes have a differential impact across practice specialties, depending on the volume of E/M visits billed. In addition, to maintain budget neutrality under the PFS, CMS proposes to offset these and other payment changes with a significant decrease of almost 11% to the conversion factor.

While CHA is generally supportive of CMS’ efforts to better value office/outpatient E/M visits, we are concerned that the significant redistributive impact could threaten access to care. In California – where hospitals generally cannot employ physicians – hospitals often utilize contracting strategies, such as Relative Value Unit (RVU)-based compensation models, that are intended to shield clinicians from unfavorable payer-mixes and expand their ability to recruit and retain primary care and specialists in vulnerable communities. These contracts are often negotiated every two or three years, and the impact of increasing RVUs for certain specialties – without additional reimbursement – will impact the bottom line for hospitals financially challenged by the COVID-19 pandemic. In addition, many of the most negatively impacted specialties provide their services in hospitals. We urge CMS to consider policy alternatives that would delay or phase-in the significant redistributive impacts of its proposal.

CHA appreciates the opportunity to share our comments on the CY 2021 PFS proposed rule. If you have any questions, please contact me at (202) 488-3742 or mhoward@calhospital.org.

Sincerely,

/s/
Megan Howard
Vice President, Federal Policy