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October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1734-P

Dear Administrator Verma:

The eHealth Initiative (eHI) appreciates the opportunity to comment on the Calendar Year 2021 Medicare Physician Fee Schedule and Quality Payment Program proposed rule.

eHI is a multi-stakeholder member organization dedicated to promoting innovation in health care to improve access and lower costs. Given the impact of COVID-19 and the multitude of temporary Medicare payment policies – many related to digital health - put in place since March, we commend the Centers for Medicare and Medicaid Services' (CMS) consideration of which and to what extent these temporary policies can and should be made permanent.

General Comments

eHI has long been a supporter of technology-enabled health care delivery solutions, including telehealth. Unfortunately, since 2001, statutory restrictions have kept telehealth utilization low in the Medicare program. Save for a few exceptions, CMS can only reimburse for telehealth services if a beneficiary is located in a medical facility in a federally defined rural area. While CMS has made great progress in expanding access to digital health services over the past few years – including communications technology- based services and remote physiological monitoring (RPM) – the agency was hamstrung by the law when it came to telehealth services. The tide shifted drastically when COVID-19 struck the United States and Congress passed legislation to give Health & Human Services Secretary Alex Azar the authority to reimburse for any and all telehealth services – free from statutory restrictions – for the remainder of the COVID-19 public health emergency (PHE) period, which CMS exercised through rulemaking.

CMS also acted quickly to remove previous regulatory restrictions on the use of RPM services and the Medicare Diabetes Prevention Program (MDPP). For RPM

services, CMS has allowed for the reimbursement of services for both new and established patients and acute and chronic conditions. Previously, CMS had only allowed for RPM services for established patients with one or more chronic conditions. For the MDPP, CMS allowed for reimbursement of virtual sessions for the first time – previously, CMS had only allowed for virtual make-up sessions.

In this proposed rule, CMS is seeking to make permanent a number of these temporary changes to the extent possible under current law; however, eHI urges CMS to go further in proposed changes to RPM services and the MDPP. The utility and necessity of the temporary changes clearly will not abruptly end with the end of the COVID-19 PHE and CMS has the regulatory authority to ensure that all beneficiaries have continued access to these services.

Specific Comments

Telehealth Services

eHI appreciates CMS' proposals that will help – to the extent possible under current law – providers and patients avoid a "telehealth cliff" at the end of the COVID-19 PHE. By proposing a Category 3 Basis for Adding or Deleting Services from the Medicare Telehealth Services List, CMS allows for flexibility for providers once the COVID-19 PHE ends and allows for on-going reimbursement as data are collected and analyzed to determine whether they should be permanently added to the Medicare telehealth services list. ***eHI supports the establishment of a Category 3 Basis for Adding or Deleting Services from the Medicare Telehealth Service List*. *We urge CMS to provide on-going support of provider data collection and analysis of the codes on the Category 3 list, including regular communication on what data and how CMS would like them reported.***

During the COVID-19 PHE, audio-only telehealth services has been a lifeline for many Medicare beneficiaries. CMS' regulatory actions to allow for reimbursement of audio-only telehealth services at the same rate as an in-office visit was crucial in areas that lack access to high-speed broadband required for audio-visual technology and for beneficiaries who lack access to necessary devices. According to your own data, nearly one-third of Medicare beneficiaries who utilized telehealth from mid-March through mid-June did so using audio-only technology. Moreover, even where audio-visual capabilities are usually available for providers and patients, for any specific encounter, there may be technical and practical circumstances that prevent use of the audio-visual capability (e.g., temporary internet interruptions, temporary lack of access to a smartphone or tablet, etc.).

Despite the value of these services to rural and underserved Medicare beneficiaries, and in the expected but occasional circumstances cited above, CMS is not proposing to continue to recognize these codes for payment after the end of the COVID-19 PHE as CMS does not believe it has the statutory authority to do so. We note, however, the statutory definition of telehealth services in Section 1834m of the Social Security Act states that they are services "furnished via a telecommunications system." In fact, nowhere in Section 1834(m) of the Social Security Act is there mention of audio-visual technology. It was CMS, not Congress, in the 2001 Physician Fee Schedule Final Rule that promulgated a definition for interactive "telecommunications system"

that stated "[w]e are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and physician or practitioner at the distant site." Therefore, there is no statutory requirement that would prohibit CMS from reimbursing for audio-only telehealth services. ***eHI urges CMS to use its existing statutory authority to extend reimbursement of audio-only telehealth services after the end of the COVID-19 PHE, as necessary and clinically appropriate***. If CMS does not move forward with allowing reimbursement of audio-only telehealth services, we do support establishing separate payment for telephone-only services, similar to the virtual check-in codes; however, these codes must be able to be billed for both new and established patients and reimbursement must accurately reflect the time and intensity of the service.

RPM Services

Much like telehealth services, RPM services have been critical tools during the COVID-19 pandemic – and it is similarly clear we cannot go back to restrictions that were in place pre-COVID. Fortunately, CMS has the statutory authority to make permanent the temporary RPM changes and eHI supports CMS' proposals in these areas. Unfortunately, CMS fell short in proposing to roll back one crucial policy after the end of the COVID-19 PHE.

eHI fully supports CMS' proposals to allow consent to be obtained at the time the service is furnished and to allow auxiliary personnel to furnish services described in CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

eHI does not support CMS' proposal to only allow for RPM services for established patients after the COVID-19 PHE ends. This is an arbitrary restriction on services, particularly for those with acute conditions. If providers are meeting standards of care and providing necessary services to patients, eHI supports reimbursement of RPM services for both new and existing patients.

With respect to specific RPM CPT code proposals, eHI has the following comments:

<u>CPT Codes 99457 & 99458</u>

1. Definition of interactive communication

In the explanatory language for CPT codes 99457 & 99458, there is language "requiring interactive communication with the patient/caregiver during the month." Since CMS began reimbursing for codes 99457 & 99458, many stakeholders have requested that CMS clarify what satisfies "interactive communication." In the proposed rule, CMS proposes to define "interactive communication" to mean "at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission." We believe CMS is misinterpreting the intent of the codes in using the term "interactive communication." By requiring real-time audio (with capability of video), it limits the intraservice work of CPT codes 99457 & 99458 to real-time audio interactions, thereby relegating them to a telehealth consult. The proposed clarification does not include clinician and clinical staff time spent reviewing

physiologic data, care management functions, educating the patient, and other aspects included in the description of procedures for 99457, which we believe should be included as substantive elements of "interactive communication" with the patient/caregiver. Further, we believe many of these aspects can be effectively delivered using a mix of both synchronous and asynchronous modalities, as opposed to strictly real-time, two-way audio interaction. ***We urge CMS to amend the proposed clarification of interactive communication to include the full array of intraservice work and asynchronous modalities.***

CPT Codes 99453 & 99454

1. Minimum of 16 days of data reporting in a 30-day period

In the current CPT code explanatory language for CPT Codes 99453 & 99454 there is a requirement that, in order to bill these codes, the patient must have monitoring devices, in use for at least 16 days of data in a 30-day period. CMS temporarily waived this requirement for those with a COVID 19 or suspected COVID 19 exposure. While this requirement is likely valid for the tracking and treatment of many chronic conditions, COVID-19 has highlighted the benefit of using RPM for acute conditions as well. In the proposed rule, CMS asks for input on removing the 16-day requirement despite the inclusion in the CPT code explanatory language. eHI believes that ultimately there should be distinct codes for RPM services for acute conditions and RPM services for chronic conditions; however, in the meantime, ***we urge CMS to continue the flexibility it created in CMS-5531-IFC on allowing RPM monitoring services to be reported for no less than 2 days for patients with acute conditions.***

2. Once-per-month limitation

(per episode of care) and 99454 (each 30 days) be allowed to be reported only once per month per patient – even if a patient has multiple providers who use different devices to track a specific chronic condition. **We urge CMS to allow for more than one provider to report either code in a 30-day period, if necessary and clinically appropriate.**

CPT Code 99091

1. Requirements for billing

In the proposed rule, CMS lays out a "process" for billing RPM codes. The process CMS lays out begins with a provider first billing CPT code 99091 *then* billing CPT codes 99457 and 99458. CMS also states that CPT code 99091 includes a total of 30 minutes of professional time and CPT codes 99457 and 99458 includes 20 minutes and any additional 20 minutes, respectively, resulting in a total of at least 50 minutes of professional time required to be reported in a 30-day period. In laying out this process, CMS has misinterpreted how the CPT codes are intended to be reported. In fact, CPT Code guidance to clinicians is that CPT code 99091 may not be used within the same month or in conjunction with CPT code 99457. ***eHI urges CMS to clarify and correct this misinterpretation in the final rule.***

Medicare Diabetes Prevention Program

The rate of type 2 diabetes among Americans 65 and older is growing at an alarming rate, costing lives and billions of dollars as it rises. To combat this trend, in 2018, CMS began reimbursing a structured intervention model known as the Medicare Diabetes Prevention Program (MDPP). However, prior to the COVID-19 PHE, CMS had yet to reimburse for virtual MDPP. When COVID-19 struck, as in other areas, CMS acted quickly to allow for MDPP to be delivered virtually, but as indicated in the proposed rule, CMS does not intend to extend this policy beyond the COVID-19 PHE (or future during future PHEs).

eHI urges CMS to continue to allow for virtual MDPP after the COVID-19 PHE. Studies have shown that virtual DPP has higher participation and similar results as in-person DPP.[1] Knowing that even not during a global pandemic, many populations at greatest risk of type 2 diabetes face challenges to accessing in-person care, CMS should recognize virtual, as well as in-person, MDPP providers and reimburse accordingly.

Interoperability Measures for the Merit-based Incentive Payment System (MIPS)

Prescription Drug Monitoring Program

CMS proposes to retain the Query of Prescription Drug Monitoring Program (PDMP) measure as an optional measure for CY 2021 and to make it worth 10 bonus points, up from 5 points in CY 2020. ***We support this proposal for the reasons stated by CMS. Despite slower than desired progress, integration of PDMPs with EHRs, including the ability to query PDMPs, is very valuable and we believe that CMS strikes the right balance.***

Health Information Exchange (HIE) Objective

1. CMS proposes to reword the "Support Electronic Referral Loops by Receiving and Incorporating Health Information" measure, previously created by combining "Request/Accept Summary of Care" and "Clinical Information Reconciliation"). CMS proposes to change "Incorporating" to "Reconciling" to better reflect actions under the measure. ***We support this proposed change change for the reasons cited by CMS and emphasize the importance of this measure for advancing interoperability.***

2. Health Information Exchange (HIE) Bi-Directional Exchange

   In the proposed rule, CMS proposes a new optional measure, "Health Information Exchange (HIE) Bi-Directional Exchange," two existing measures: "Support Electronic Referral Loops by Sending Health Information" measure and "Support Electronic Referral Loops by Receiving and Incorporating Health Information."

   We support this proposed optional measure, the proposed value, and reporting by

[1] Moin T, Damschroder LJ, AuYoung M, Maciejewski ML, Havens K, Ertl K, Vasti E, Weinreb JE, Steinle NI, Billington CJ, Hughes M, Makki F, Youles B, Holleman RG, Kim HM, Kinsinger LS, Richardson CR. Results From a Trial of an Online Diabetes Prevention Program Intervention. Am J Prev Med. 2018 Nov;55(5):583-591. doi: 10.1016/j.amepre.2018.06.028. Epub 2018 Sep 24. PMID: 30262149; PMCID: PMC6699502.

attestation rather than needing to track numerators and denominators. As outlined below, we do, have suggestions for refining the proposed attestations to better reflect the current and anticipated state of bi-directional interoperability.

CMS proposes that clinicians would attest:

- *I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period.*

  CMS uses "HIE" as a noun but does not define the term. Elsewhere in the preamble in discussing on this proposed measure, CMS uses HIE as a verb as well. We are concerned that a focus on HIEs as a noun, but with the term undefined, could exclude models that might not be formally identified as HIEs but that would meet the measure's intent, especially for national-level exchange. In addition, participation in just one HIE might not meet the need of the measure to support HIE for "every patient encounter, transition or referral." ***We suggest that the measure should be expanded to "HIEs, exchange frameworks, or other organizations focused on bi-directional health information exchange." We also suggest that CMS consider cross-referencing the definition of HIEs and HINs established by the Office of the National Coordinator for Health IT in 45 CFR § 171.102.***

- *The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners.*

  CMS states that ". . . we would exclude exchange networks that only support information exchange between affiliated entities, such as health care providers that are part of a single health system, or networks that only facilitate sharing between health care providers that use the same EHR vendor." ***We ask CMS to clarify that, if such a provider or vendor-specific network connects with a regional or national exchange framework that enables connection across "a broad network of unaffiliated exchange partners," this connection would enable the attestation. We also believe providers should not be held responsible for attesting to the actions of the HIE in which they participate and ask CMS to add language to the attestation to read "…and does not, to the best of my knowledge, engage in exclusionary behavior when determining exchange partners."***

- *I use the functions of CEHRT for this measure, which may include technology certified to criteria at 45 CFR 170.315(b)(1), (b)(2), (g)(8), or (g)(10).*

  CMS notes that there are "numerous certified health IT capabilities which can support bi-directional exchange with a qualifying HIE" (e.g., C-CDA, APIs, USCDI, etc.)." ***We agree that the applicable CEHRT functions should be used for this measure but also ask that CMS acknowledge that capabilities used may go beyond what is certified, including technologies that are not subject to certification.***

Conclusion

eHI appreciates the opportunity to comment on the Calendar Year 2021 Medicare Physician Fee Schedule and Quality Payment Program proposed rule and we look forward to continuing to work with CMS to advance and support technology-enabled health care delivery and innovation.

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer