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September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: RIN 0938-AU42

Dear Administrator Brooks-LaSure:

The eHealth Initiative (eHI) appreciates the opportunity to comment on the Calendar Year 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies proposed rule.

eHI is a multi-stakeholder member organization dedicated to promoting innovation in health care to improve access and lower costs. We appreciate CMS' commitment to extending important flexibilities to allow continued patient access to care via technology, as well ensuring patient access to data and health data interoperability.

General Comments

eHI is a strong supporter of CMS' on-going work to recognize the promise of and reimburse for innovative health technologies and digital health tools. We appreciate the attention CMS is paying to updating processes for determining provider reimbursement for use of innovative technologies, as well as proposed reimbursement for new Remote Therapeutic Management codes.

While we also support CMS' proposals around continuing, on a temporary basis, reimbursement for certain telehealth services past the end of the COVID-19 public health emergency, we believe there is more CMS can do using existing regulatory authority to ensure all Medicare beneficiaries can continue to access high-quality health care via telehealth.

Specific Comments

Telehealth Services

Category 3 Services

Last year, given the uncertainty of when or if the COVID-19 public health emergency declaration would end, CMS proposed a new category of telehealth services, Category 3, which would be covered on a temporary basis through the end of CY 2021. eHI supported this proposal, which was finalized by CMS. This year, CMS is proposing to extend Category 3 services through the end of CY 2023, which eHI also supports. While we support the continuation of Category 3 services, we also encourage CMS to make permanent the Category 3 process. Without reimbursement, it can be very difficult to meet the data requirements of Category 1 and/or 2 as providers are unlikely to furnish services which will not be reimbursed. Making permanent a Category 3 process will allow temporary coverage of services while CMS and providers collect data to support permanent reimbursement through the Category 1 or 2 process. **eHI supports CMS' proposal to continue the existing Category 3 services through the end of CY 2023 and urges establishing a permanent Category 3 process to support continued coverage of telehealth services.**

Although eHI supports the continuation of Category 3 services through CY 2023, we do not support the removal of virtual outpatient cardiac rehabilitation and intensive cardiac rehabilitation (CPT 93797, 93798, G0422, G0423) from the Category 3 list. We are especially concerned given the impact removal of these services could have on health equity. Cardiac rehabilitation consists of 36 visits over 12 weeks, which can be difficult for many vulnerable and underserved populations who may not be able to take time away from work or may not have reliable transportation. In fact, prior to Medicare reimbursement of virtual cardiac rehabilitation:

- Only one quarter (24.4%) of Medicare fee-for-service beneficiaries eligible for outpatient cardiac rehabilitation participated, and among those who participated, only 24.3% initiated within 21 days and 26.9% completed a full course of 36 or more sessions[1]
- Participation was lower among women (18.9%) compared with men (28.6%) and was lower among Hispanics (13.2%) and non-Hispanic blacks (13.6%) compared with non-Hispanic whites (25.8%)[2]

Virtual cardiac rehabilitation offers a safe and effective option for many patients and has been shown to increase adherence. A study from the Veterans Health Administration found that patients offered both virtual and center-based rehabilitation were four-times as likely to participate than a center-based option alone.[3] [4] We understand CMS must balance the benefits of virtual cardiac rehabilitation with the potential for adverse outcomes; however, the risk of adverse events in cardiac rehabilitation is very low. Well-established research has found few

[1] https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.054378
[2] https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.054378
[3] Beatty AL, Truong M, Schopfer DW, Shen H, Bachmann JM, Whooley MA. Geographic variation in cardiac rehabilitation participation in Medicare and Veterans Affairs populations: opportunity for improvement.Circulation. 2018;
[4] Schopfer DW, Krishnamurthi N, Shen H, Duvernoy CS, Forman DE, Whooley MA. Association of Veterans Health Administration home-based programs with access to and participation in cardiac rehabilitation.JAMA Intern Med. 2018;

instances of cardiac arrest during cardiac rehabilitation.[5] [6] Further, virtual cardiac rehabilitation is effective. A recent study from the American College of Cardiology found "available data suggest that HBCR [home-based (or virtual) cardiac rehabilitation] is equivalent to CBCR [center-based cardiac rehabilitation]."[7] **Given the available data on virtual cardiac rehabilitation and the risk of exacerbating health inequities, eHI urges CMS to continue CPT 93797, 93798, G0422, G0423 as Category 3 services through the end of CY 2023.**

Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

CMS is proposing a number of policies to implement provisions of the CAA allowing for permanent reimbursement of telemental health services. In keeping with the statutory requirements, CMS is proposing to allow for reimbursement for such services outside of rural areas and in patients' homes, as long as an in-person visit has occurred within the past six months of the telehealth visit, and subsequently at least every six months.

eHI does not support provisions of the law that require in-person visits in order to furnish telemental health services to patients' homes. There is no evidence to support a clinical necessity for in-person visits prior to furnishing telehealth services and these arbitrary barriers to care only harm patients. Further, according to the American Medical Association, all states allow a physician to establish a relationship with a patient via telehealth.[8] eHI has endorsed legislation, the Telemental Health Care Access Act of 2021 (S. 2061/H.R. 4058), to remove this arbitrary barrier to care and we hope CMS will support as well. While we understand CMS is statutorily bound to implement provisions of the CAA, the law does provide the Secretary discretion to establish a time-frame for subsequent in-person visits in order to continue furnishing telemental health services. **eHI urges CMS to establish a long time frame for subsequent in-person visits and therefore support CMS' alternate proposal to adopt a requirement for an in-person visit within three years from the physician or physician group**

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology

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 the Kaiser Family Foundation, a majority of Medicare beneficiaries reported receiving telehealth services by telephone only.[9] Given this, KFF states

[5] Van Camp SP, Peterson RA. Cardiovascular complications of outpatient cardiac rehabilitation programs. JAMA. 1986

[6] Pavy B, Iliou MC, Meurin P, Tabet JY, Corone S; Functional Evaluation and Cardiac Rehabilitation Working Group of the French Society of Cardiology. Safety of exercise training for cardiac patients: results of the French registry of complications during cardiac rehabilitation. Arch Intern Med. 2006

[7] https://www.acc.org/Latest-in-Cardiology/Articles/2021/01/04/14/03/Cardiac-Rehabilitation-and-Implications-During-the-COVID-19-Era

[8] https://www.ama-assn.org/system/files/2018-10/ama-chart-telemedicine-patient-physician-relationship.pdf

[9] https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/

that policies requiring use of audio/visual technologies could pose a barrier to care for subgroups of Medicare beneficiaries.[10]

In previous physician fee schedules, CMS stated that there is not statutory authority to reimburse for audio-only telehealth services given the parameters of the Social Security Act. eHI previously provided public comment that 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.

CMS seemingly acknowledges this interpretation in this proposed rule and proposes to continue to reimburse for audio-only communications for telemental health services if a provider has the capability to also offer audio/visual communications and an in-person visit is conducted every six months. While eHI generally supports this proposal, we do not support requiring in-person visits as it poses an additional barrier to accessing care, as discussed above. We also note that there are many other services CMS must consider continuing reimbursement if delivered using audio-only communication technology. CMS must balance concerns around improper overutilization with current barriers to utilizing audio/visual technologies for many subgroups of Medicare beneficiaries. **We urge CMS to finalize reimbursement of telemental health services using audio-only technology without an in-person visit requirement and to subsequently evaluate all telehealth services to determine additional appropriate audio-only services. While evaluating, CMS should add audio-only services as Category 3 services to ensure they are reimbursed post-PHE while CMS is evaluating.**

Comment Request on Resource Costs for Services Involving the Use of Innovative Technologies

eHI appreciates CMS' comment request regarding the use of innovative technologies. We recognize that as the use of innovative technologies, such as artificial intelligence (AI), grows in healthcare, CMS must reexamine traditional ways of calculating reimbursement rates. eHI believes technology, powered by robust and accurate data, can reduce provider burden and improve the quality of care provided to patients; however, we recognize that as it reduces burden on providers, that may affect the current PE process. **eHI supports CMS' work to modernize the PE process given the impact of innovative technologies such as software algorithms and/or AI and we urge CMS to issue a more robust, stand-alone request for information to inform this work.**

Generally, eHI believes CMS should recognize that there will be differences in practice expenses between technologies. Not all software is created equal; however, given CMS' questions, we

[10] Ibid

assume CMS is referring to what the International Medical Device Regulators Forum (IMDRF) defines as software as a medical device (SaMD), or "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."[11] In terms of PE costs, there is not variation between hardware and software that both perform the same function as both are, by definition, medical devices.

Remote Therapeutic Monitoring

CMS is proposing, beginning in CY 2022, to reimburse for Remote Therapeutic Monitoring (RTM) codes CPT codes 989X1, 989X2, 989X3, 989X4, and 989X5) created by the CPT Editorial Panel in October 2020 and valued by the RUC at its January 2021 meeting. **eHI supports CMS' proposal to reimburse for these codes.**

CMS is further soliciting feedback on how to allow additional practitioners to furnish RTM codes given their interpretation that the codes are written as evaluation and management (E/M) codes, which can only be furnished by physicians or qualified healthcare professionals (QHPs). While the codes were created by the CPT Editorial Panel, CMS has the authority to adopt the family of codes as E/M and place them under care management services so that practitioners can bill these codes incident to. CMS also has the authority to create temporary HCPCS codes that are identical to how CPT intended the codes to be used (as General Medicine) that would allow non-physician providers to be reimbursed for these services. **eHI urges CMS to take either action to allow for E/M under Care Management Services, in addition to General Medicine; thereby allowing all providers the ability to furnish RTM services. CMS should also consider creating temporary HCPCS G-Codes for General Medicine that parallel RPM (99457 and 99458) to allow non-physician providers to report RPM "assessment" services.**

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.[12] Knowing that even not during a global pandemic, many populations at greatest risk of type 2

[11] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf
[12] 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.

diabetes face challenges to accessing in-person care, CMS should recognize virtual, as well as in-person, MDPP providers and reimburse accordingly.

Promoting Interoperability Program

Query of PDMP Measure

CMS proposes to retain the Query of Prescription Drug Monitoring Program (PDMP) measure as an optional measure for CY 2022 and to make it worth 10 bonus points, up from 5 points in CY 2021. 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. Moving forward, eHI supports CMS' considering use of HL7 FHIR to facilitate PDMP/EHR data exchange.

Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT Attestation

CMS is proposing to remove two of the three attestation statements related to prevention of information blocking. Beginning in CY 2022, eligible clinicians will only have to attest to the following:

- *Statement 1: Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.*

eHI supports this change for the reasons outlined by CMS.

Proposed New SAFER Guides Measure

CMS is proposing that an eligible clinician attest to having conducted an annual self-assessment of all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs, with one "yes/no" attestation statement accounting for a complete self-assessment using all nine guides.

eHI does not support the addition of this measure. As CMS notes, the SAFER Guides have not been updated since 2016 and are not widely used in the marketplace today. While we support measures to address health IT safety, we believe ONC should revisit and update the SAFER Guides, as appropriate, or consider other tools more widely used, accepted, and implemented in hospitals.

Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information (RFI)

eHI strongly supports CMS' actions to further health equity in the Medicare program. Ensuring accurate patient demographic data, as well as data on language preference, tribal membership, and disability status, is captured is an important first step. eHI supports the recently finalized

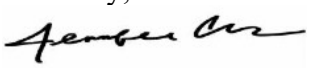
United States Core Data for Interoperability (USCDI) v2, which, for the first time, includes data elements related to sexual orientation, gender identity, and social determinants of health.

In recognition of the impact social determinants can have on an individual's health care outcomes and the importance of data collection in addressing these social determinants, in 2016, CMS made available a set of "Z Codes" for providers to document their patients' social risk factors. Unfortunately, utilization of these codes in Medicare fee-for-service (FFS) is low. A CMS report that looked at use of these Z Codes in 2017 found that only 1.4% of FFS claims included Z Codes. The use of these codes is optional and not heavily incentivized by CMS, though they, along with implementation of USCDI v2, could help better target and leverage federal funding to address social determinants of health.

Health Equity Measures in MVPs - Request for Information

While eHI supports the long-term goal of developing health equity measures, we agree with a March 2020 report from HHS that states "a prerequisite to measuring and reporting quality for beneficiaries with social risk factors is knowing beneficiaries' social needs."[13] Critical to developing quality measures will be collection of standardized, interoperable data. While USCDI v2, which includes data related to social determinants of health, was recently released, it has no set date of when it will be required for certified electronic health record technology (CEHRT). USCDI v1 is currently required beginning in 2022.

Sincerely,



Jennifer Covich Bordenick
Chief Executive Officer

[13] https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf