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BY ELECTRONIC SUBMISSON

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program (CMS–1784–P)

As North America's largest technology trade association, the Consumer Technology Association (CTA®) is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most influential tech event in the world. CTA is the trade association representing the more than 1000 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA's Health Division strives to advance the use of consumer-based technology enabled health solutions to deliver better health outcomes and reduce overall healthcare costs. The Division, which includes some of the most well-respected thought leaders in the healthcare and technology sectors, provides policy advocacy, healthcare market research, and standards initiatives that advance the appropriate use of consumer technologies in the healthcare context. Many of our members are leaders in the digital health economy and can provide HHS a unique perspective.

Unlike most trade associations, CTA is accredited by the American National Standards Institute (ANSI) as a Standards Development Organization (SDO), and we have a long history of voluntary national standards development. Among the wide range of topics addressed by our standards program are mobile health, digital therapeutics, cardiovascular technology solutions and artificial intelligence.

CTA appreciates the opportunity to share our comments on the proposed rule for CY 2024 Payment Policies under the Medicare Physician Fee Schedule and Other Changes to Part B Payment Policies.

General Comments

CTA appreciates CMS' continued work to ensure Medicare beneficiaries have access to innovative technologies. Digital health tools can help address barriers to accessing care such as distance, affordability, and provider shortages. It is critical for CMS to continue work to ensure a regulatory structure in which providers can utilize all available tools to deliver high-quality care to their patients.

While we appreciate CMS continues to support telehealth after the end of the COVID-19 public health emergency (PHE) on May 11, 2023, we urge further action to support virtual care by allowing virtual Diabetes Prevention Program (DPP) providers to enroll as Medicare Diabetes Prevention Program (MDPP) suppliers.

Additionally, CTA supports CMS' work to define other non-face-to-face services involving communications technologies such as the various clarifications for Remote Monitoring Services. The proposed 2024 Medicare Physician Fee Schedule includes proposals to help increase patient access to remote monitoring services. However, the proposed clarifications may unduly increase the burden on providers in an already complicated area of practice. We urge CMS to make important modifications to the proposed clarifications to help encourage providers to pursue this new area of medicine--critical to the health and wellbeing of Medicare beneficiaries and to reducing costly hospitalizations and other procedures through remote monitoring.

Our topline recommendations:

- The agency should continue to work with stakeholders to ensure continued access to care via telehealth, free from arbitrary restrictions like in-person visit requirements.

- Allow virtual DPP providers to enroll as MDPP suppliers.

- Allow Community Health Integration (CHI) services to be delivered virtually or in-person.

- Providers should be allowed to furnish Remote Physiological Monitoring (RPM) services to new and established patients and CMS should clarify that this policy also applies to Remote Therapeutic Monitoring (RTM) services.

- The 16 days of data collection requirement should apply only to RPM PE-Only codes 99453 and 99454, as well as to RTM PE-Only codes 98975, 98976, 98977, and 98978; the 16 days of data collection requirement ***should not*** apply to the RPM Professional Work codes 99457 and 99458, and RTM Professional Work codes 98980 and 98981.

- Due to technical inconsistencies, CMS should reconsider the limitation that only one provider may report RPM/RTM, per patient, per 30-day period, regardless of device, when 16 days of data collection are accomplished.

- CMS should clarify that RTM used with physical therapy (when related to a diagnosis under the global period) is allowed, since physical therapy is not included under the global period.

- We support the agency's proposal to allow RPM and RTM services to be furnished in rural health clinics (RHCs) and federally qualified health centers (FQHCs) and to allow physical therapists (PTs) and occupational therapists (OTs) the "General Supervision" of physical therapy assistants (PTAs) and occupational therapy assistants (OTAs) during outpatient RTM physical therapy services in private practice.

- CTA also commends the agency for requesting input on how digital therapeutics could be covered under existing benefit categories and urges CMS to take swift action to allow for reimbursement using existing pathways.

Medicare Telehealth Services

As CMS noted, the *Consolidated Appropriations Act, 2023* extended current Medicare telehealth flexibilities through December 2024. CTA supports this extension and we look forward to continuing to work toward establishing permanent policy for Medicare telehealth reimbursement without arbitrary barriers to accessing care such as in-person visit requirements.

Medicare Diabetes Prevention Program

While CMS has allowed for MDPP suppliers to continue to deliver services virtually, there is not yet an established policy to allow for virtual MDPP suppliers. Currently, millions of Americans across the country are participating in the CDC-recognized DPP. In fact, in 2021, the American Diabetes Association (ADA) announced a partnership with a virtual service platform to increase access.[1] We urge CMS to follow the lead of the organizations who developed the program, including the CDC and ADA, and recognize virtual MDPP suppliers.

Community Health Integration (CHI) Services

CMS has proposed two new G-codes that would enable practitioners to better furnish community health integration services to beneficiaries with the assistance of local community health workers. We applaud these efforts to further expand access to care and convenience for Medicare beneficiaries. Additionally, we strongly urge CMS to align with its recent approach to Medicare telehealth services and ensure these services are modality neutral and allow providers and beneficiaries to choose the most appropriate modality, whether virtual or in-person. For example, a practitioner may determine during an initiating CHI visit (virtual or in-person) that a beneficiary

[1] https://diabetes.org/newsroom/press-releases/2021/ada-yumlish-make-virtual-DPP-program-available-to-88M-americans-with-prediabetes

may be experiencing food insecurity. The practitioner could connect the beneficiary to a community health worker, whether contracted or otherwise, familiar with local programs able to help. Connecting to these local programs can be just as easily accomplished via virtual means and studies have shown that community health workers are as effective at addressing gaps in care when working remotely.[2]

Remote Monitoring Services

Providers Should be Allowed to Furnish RPM Services to New and Established Patients; and CMS Should Clarify That This Policy Applies to RTM Services

At the end of the PHE, CMS reinstated the requirement that RPM services be furnished only to an established patient. However, in the Calendar Year (CY) 2021 Medicare Physician Fee Schedule (MPFS) final rule, CMS clarified that although it initially described RPM services in the CY 2019 MPFS final rule as "services furnished to patients with chronic conditions," that practitioners may furnish these remote physiologic services to patients with acute conditions, as well as to patients with chronic conditions on a permanent basis. Given the agency has definitively clarified that acute care patients may benefit from RPM services, CMS should allow RPM services for new patients who present with a sudden acute illness, much like established patients who may have an ongoing chronic disease.

While it is helpful for a practitioner to have an established relationship with a patient, it is not always practical when new patients present with acute symptoms. Whether RPM is reasonable and necessary for new patients presenting with acute symptoms should be decided by the practitioner based on his or her clinical judgment and experience, and the circumstances of the patient's situation. New patients may present with a range of symptoms, from acute flu-like symptoms to heart failure. Depending on the severity of the situation, practitioners should be allowed to service those patients using the means that best suits the patient at the time. Requiring an established relationship for acute care may actually unnecessarily increase costs to the Medicare program because providers will require a visit to establish that relationship followed up by a remote monitoring visit once the relationship is "established"—resulting in increased visits which drive up costs.

Moreover, CMS remains silent on whether the new or established patient policy will be applicable to RTM services. Since RTM services were modeled after RPM (including a crosswalk of payments), CMS should clarify (once finalized) the new and established patient policy is applicable to both RPM and RTM.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8274676/

The 16 Days of Data Collection Requirement Should Apply Only to Certain Codes

CMS attempts to clarify that as of the end of the PHE, the 16 days of data collection monitoring requirement was reinstated as it applies to RPM and RTM. CMS is "proposing to clarify" that the data collection minimums apply to "existing RPM and RTM code families for CY 2024." The agency goes on to state that remote monitoring codes "currently depend on collection of no fewer than 16 days of data in a 30-day period, as defined and specified in the code descriptions" and references "CPT codes 98976, 98977, 98978, 98980, and 98981." CMS further claims they "reiterate" their analysis:

> [D]escribed in the CY 2021 PFS final rule, in which we explained that CPT code descriptor language suggests that, even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected (85 FR 84545). We refer readers to our CY 2021 PFS final rule (85 FR 84545) for additional background.

This reference appears to be an error. The 2021 MPFS final rule does not contain language that refers to, or discusses, the 16 days data requirement applying to any codes beyond CPT codes 99453 and 99454. In fact, RTM codes 98976, 98977, 98980, and 98981 did not exist in 2021 and first appeared in the 2022 MPFS proposed rule under "(37) Remote Therapeutic Monitoring (CPT Codes 989X1, 989X2, 989X3, 989X4, and 989X5)."

Both the 2021 MPFS proposed and final rules do contain several references on the 16 days of data requirement for codes 99453 and 99454, but do not have any references to RTM codes. We provide some examples from the 2021 MPFS proposed and final rules:

- 2021 MPFS proposed rule, 85 FR 50074: "*Additionally, and in keeping with the CPT prefatory language for CPT codes 99453 and 99454, when the PHE for the COVID-19 pandemic ends,* ***we will once again require that 16 days of data be collected within 30 days to meet the requirements to bill CPT codes 99453 and 99454***."

- 2021 MPFS final rule, 85 FR 84472: "*Review of CPT prefatory language (CPT® 2021 Professional Codebook (hereafter, CPT Codebook), pp. 52-53) provides additional information about the two PE-only codes. For example, the* ***CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period in order for CPT codes 99453 and 99454 to be billed****. Additionally, these two codes are not to be reported for a patient more than once during a 30-day period. This language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected. We also noted that CPT code 99453 can be billed only once per episode of care where an episode of care is defined as "beginning when the remote physiologic monitoring service is initiated and ends with attainment of targeted treatment goals" (CPT Codebook, p. 52).*"

- 2021 MPFS final rule, 85 FR 84472: "*For example, **the CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period in order for CPT codes 99453 and 99454 to be billed**. Additionally, these two codes are not to be reported for a patient more than once during a 30-day period. This language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected.*"

- 2021 MPFS final rule, 85 FR 84472: "*After considering public comments, **we are not extending the interim policy to permit billing for CPT codes 99453 and 99454 for fewer than 16 days in a 30-day period beyond the end of the PHE for COVID-19**. At the conclusion of the PHE for COVID-19, **we will require, in accordance with the code descriptors for CPT codes 99453 and 99454, that 16 days of data each 30 days must be collected and transmitted to meet the requirements to bill CPT codes 99453 and 99454**.*"

In subsequent MPFS rules (2022 and 2023), CMS never finalized proposals to require the 16 days of data on codes beyond 99453 and 99454. The agency clarifies that the 16 days of data collection requirement applies only to CPT codes 99453 and 99454. CMS' proposal in the CY 2024 MPFS that the 16 days of data collection requirement now applies to "existing RPM and RTM code families for CY 2024" is an unwarranted and confusing, and a seemingly erroneous expansion of the agency's existing policy.

CMS Should Consider CPT's Requirements Regarding 16 Days of Data Collection

In the 2023 CPT Professional Edition codebook, the 16 days of data collection requirement applies to RPM (99453 and 99454) and RTM (98975, 98976, 98978, 98978). In both RPM and RTM families, the 16 days of data only applies to the technical component codes that mostly consist of Practice Expense and Liability Relative Value Units (RVUs):

- **RPM**
  Guideline:
  - "Codes 99453, 99454 are not reported if monitoring is less than 16 days."

  Parentheticals:
  - (Do not report 99453 for monitoring of less than 16 days)
  - (Do not report 99454 for monitoring of less than 16 days)

- **RTM**:
  Guideline:
    - "Codes 98975, 98976, 98977, 98978 are not reported if monitoring is less than 16 days."

  Parentheticals:
    - (Do not report 98975 for monitoring of less than 16 days)
    - (Do not report 98976 for monitoring of less than 16 days)
    - (Do not report 98977 for monitoring of less than 16 days)
    - (Do not report 98978 for monitoring of less than 16 days)

CPT does not impose the 16 days of data collection Guidelines or Parentheticals on remote physiologic or therapeutic monitoring professional work "Treatment Management Services" codes (i.e., RPM 99457 and 99458; or RTM 98980 and 98981).

Codes 99457, 99458, 98980, and 98981 are composed of Professional Work, PE, and Liability RVU's which are valued and calculated according to the intra-service time and intensity performed by the billing/reporting provider and clinical staff. The time measurements for those codes are accounted for in 20-minute increments over the course of a calendar month—not 16 days of data collection over a 30-day period. The distinction is that all RPM and RTM codes require the use of a "medical device as defined by the FDA," but CPT only specifies/requires the 16 days of data collection for the PE only codes. The treatment management service codes do not require the 16 days of data collection.

Given that CMS clarified in 2021 that RPM codes 99453 and 99454 (and no other codes) are subject to the 16 days of data collection, CPT guidelines, and other factor discussed, CMS should clarify that the 16 days of data collection requirement applies only to the RPM and RTM technical component codes 99453, 99454, 98975, 98976, 98977, 98978; and not to the RPM and RTM professional work treatment management service codes 99457, 99458, 98980, and 98981.

Due to Technical Inconsistencies, CMS Should Reconsider the Limitation That Only One Provider May Report RPM/RTM

CMS must restate its position "that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary" to reflect that such a policy should only apply to the PE technical component codes 99453, 99454, 98976, 98977, and 98978.[3]

The RPM and RTM professional work codes (99457, 99458, 98980, and 98981) are not—and should not—be subject to provider limitations. To do so would be akin to limiting Medicare beneficiaries to a single physician for all medical services. RPM and RTM professional work via treatment

[3] Please note we omit code 98975; because although it is a PE only code, CPT excludes 98975 from its Guidelines as follows "*Codes 98976, 98977, 98978 are used to report remote therapeutic monitoring services during a 30-day period*"—thus, according to CPT, code 98975 is not measured on a 30-day basis.

management services should be allowed to be performed and billed/reported by any practitioner or specialist who is working with a single patient, per 30-day period, and not contingent by the 16 days of data collection requirement since that policy was not defined by CMS on codes 99457, 99458, 98980, and 98981 (as described above).

CPT has not set stipulations on the number of physicians and non-physician practitioners (NPP) that may concurrently bill 99453 and 99454. It is possible that more than one provider may be involved in remote physiologic monitoring of the same patient, under separate treatment plans, for separate conditions.

CMS should not suggest that only one provider may bill remote monitoring codes, per patient, per 30-day period. There should be no implicit priority between medical specialties. Doing so creates provider confusion, and additional burdens to practitioners who may become reluctant to conduct remote monitoring services.

CMS Should Clarify That RTM Used with Physical Therapy is Permitted When Related to a Diagnosis Under the Global Period

Regarding the use of remote monitoring during global periods for surgery, CMS clarifies the circumstances when an individual beneficiary receives a procedure or surgery along with remote monitoring services that are unrelated to the diagnosis for which the global procedure was performed. So long as the purpose of the remote monitoring addresses an episode of care "that is separate and distinct from the episode of care for the global procedure" (*i.e.*, when the remote monitoring service addresses an underlying condition that is not linked to the global procedure or service). This is issue for RTM services that are related to the diagnosis for which the global procedure was performed but associated to services that are typically not included under the global period such as PT. It is current Medicare policy to exclude PT from CMS global periods because those services are not included in what the surgeon is responsible for. PT is separately billable even though it is related to the Global Procedure.

CMS should clarify that in those instances (such as with RTM associated to physical therapy which technically are related to the global procedure but are not actually covered/included under the global procedure), the RTM will be covered when furnished to the beneficiary. In those circumstances the practitioner should receive payment for the RTM provided, separate from the global service payment. For an individual beneficiary who is currently receiving services during a global period, a practitioner may furnish RPM or RTM services (but not both RPM or RTM services) to the individual beneficiary, and the practitioner will receive separate payment.

CMS Should Properly Categorize and Account for Software as a Medical Device (SaMD)

Medical devices are not an "other expense" akin to "administrative labor" or "office expenses." Neither is SaMD an "other expense" because SaMD is, by U.S. law, a medical device.[4] SaMD has

[4] https://www.fda.gov/training-and-continuing-education/cdrh-learn/overview-regulatory-requirements-medical-devices-transcript#:~:text=FDA%20was%20given,Parts%20800%2D1299

been included within the definition of a medical device under the Federal Food, Drug, and Cosmetic Act since the term "medical device" was defined in the Medical Device Amendments Act of May 28, 1976. SaMD is subject to the same regulatory oversight by the Food and Drug Administration (FDA) as hardware medical devices. The legal, regulatory, and financial burdens for a SaMD manufacturer/developer are no less stringent than those of hardware medical device manufacturers. Under the law, SaMD is a medical device no different than hardware, thus, it is not logical to consider SaMD as an "other expense" and not a "medical equipment" direct practice expense.

SaMD, by its technological nature evolves, improves, updates, and continually defends against risks and vulnerabilities. Thus, SaMD should not only qualify as "medical equipment" direct PE costs, but its updates, and upgrades (required to help mitigate against cyber security threats, vulnerabilities, and improvements based on continual real-world evidence and real-world data), are analogous to "medical supplies" and should also be considered direct PE. CMS has stated in past PFS rulemaking (83 FR 59557), that they have considered most "computer software" and "associated analysis and licensing fees" to be *indirect costs tied to costs for associated hardware that is considered to be medical equipment*. As CMS reports "*these costs are not well accounted for in the PE methodology*"—however, they can be properly accounted for, and should be. Doing so is well within CMS's regulatory authority.

Similarly, we have entered an age where medical provider professional work is either being assisted, augmented, or replaced (i.e., autonomous software output) by artificial intelligence. As a result, the American Medical Association (AMA) has recognized the importance of this area and created "Appendix S: AI taxonomy for medical services & procedures" that establishes an "Appendix that will improve the terminology and understanding of AI as it relates to the CPT code set." The taxonomy provides guidance for classifying artificial intelligence/augmented intelligence (AI) applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of three categories: assistive, augmentative, or autonomous. Thus, as professional work evolves and is replaced at some levels by autonomous "work performed by machines," CMS will need to properly cover and reimburse the changing nature of medicine. As AI sophistication increases, it won't simply replace the human element of work but it is also introducing new mechanisms of action that are unlike chemical drugs or provider interventions.

Given the importance of issues regarding emerging health technology, CTA recommends CMS issue a specific Request for Information soliciting information and input from a wide array of stakeholders, followed by a series of public meetings featuring national experts on AI and other innovative technologies. CMS should cast the widest net possible to capture the most relevant information, insights, and data from the most diverse group of stakeholders possible.

CTA Applauds the Proposal to Allow RPM and RTM Services to be Furnished in RHCs and FQHCs

For years, a broad array of stakeholders has actively petitioned CMS to allow RPM and RTM services as stand-alone billable visits in RHCs and FQHCs. Presently, when these services are furnished, payment is included in the RHC's AIR subject to a payment-limit or the per visit payment under the FQHC PPS. We have advocated that CMS payment for care management and coordination services as described by the general care management code (HCPCS G0511), should include RPM and RTM services because these services are inherently non-face-to-face.

CTA supports the agency's proposal to include the suite of services that comprise RPM and RTM into G0511 for when these services are furnished by RHCs and FQHCs. We strongly urge the provisions be finalized as proposed. We defer to other RHC and FQHC stakeholders on whether the proposed revision of payment amount for HCPCS code G0511 is appropriate as proposed.

CTA Supports the Proposal to Allow PTs and OTs the "General Supervision" of PTAs and OTAs During Outpatient RTM Physical Therapy Services in Private Practice

Current regulations at 42 C.F.R §§410.59(a)(3)(ii) and 410.60(a)(3)(ii) specify that all occupational and physical therapy services are performed by, or under the direct supervision of, the occupational or physical therapist, in private practice. These regulations make it difficult for physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs) to bill for the RTM services performed by the physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) they are supervising, since the PTPP or OTPP must remain immediately available when providing direct supervision of PTAs and OTAs.

CMS proposes to establish an RTM-specific general supervision policy at §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow OTPPs and PTPPs to provide general supervision only for RTM services furnished by their OTAs and PTAs. Medicare requires each therapist in private practice to meet the requirements specified in our current regulations at §§ 410.59(c) and 410.60(c) to qualify under Medicare as a supplier of outpatient occupational therapy or physical therapy services.

We support the agency's new approach and agree that it will increase access to remotely provided services performed by PTAs and OTAs under the general supervision furnished by PTPPs and OTPPs. This proposal aligns well with the RTM general supervision policy that CMS finalized in the CY 2023 PFS Final Rule and should be finalized as proposed.

Request for Information on Digital Therapies

CTA commends CMS' continued consideration of how new technologies, such as therapies (also referred to as "digital therapeutics"), should be covered and reimbursed through the Medicare program. We urge CMS to move swiftly to provide coverage and reimbursement of digital

therapeutics as we believe they can be covered under existing benefit categories, which we outline below.

Background

As noted previously, CTA is an ANSI-accredited SDO. We believe that voluntary, consensus-based standards are critical in assuring trust and reliability in consumer health technology. CTA's Health Fitness & Wellness Committee develops standards, recommended practices, and related documentation for consumer health and fitness technology, including fixed, portable and wearable health and fitness devices. As part of this Committee, the Digital Therapeutics Workgroup developed ANSI/CTA-2098, which defines a digital therapeutic (DTx) as an evidence-based, standalone or combination software products intended for management, maintenance, prevention or treatment of a disease, disorder or condition acting directly as a medical intervention or guiding the delivery of a medical intervention. [5] Because digital therapeutics are intended for management, maintenance, prevention or treatment of a disease, disorder or condition as a medical intervention, they generally meet the definition of a medical device under the Federal Food, Drug & Cosmetics Act, as CMS notes in the proposed rule.

Overall, CTA believes digital therapeutics can be important tools for providers and patients. Nearly half of Americans live in a mental health workforce shortage area.[6] Given these growing provider shortages, many patients face insurmountable barriers to accessing needed mental health care. According to a report from Mental Health America, 55 percent of adults with mental illness receive no treatment and 93.5 percent of adults who had a substance use disorder in the last year received no treatment.[7] There is evidence that delays in treatment of mental health conditions can lead to increased morbidity and mortality.[8] While these statistics paint a dire picture, CTA believes digital health tools, such as digital therapeutics, are critical in meeting unmet need. Digital therapeutics encompass the gold standard for psychotherapy treatment, cognitive behavioral therapy, and allow patients to, through guidance of their providers, receive these treatments outside of a healthcare setting.

Specific Responses

- What standards have interested parties developed or consulted to ensure the physical safety and privacy of beneficiaries utilizing digital cognitive behavioral therapy (CBT) and/or other digital therapeutics for behavioral health?

As previously noted, digital therapeutics meet the definition of a medical device under the Federal Food, Drug & Cosmetics Act; therefore, the safety of these products is determined by the Food & Drug Administration (FDA), which reviews every medical device for safety and effectiveness. Many

[5] https://shop.cta.tech/products/definitions-characteristics-of-digital-therapeutics-ansi-cta-2098
[6] https://www.kff.org/medicaid/issue-brief/a-look-at-strategies-to-address-behavioral-health-workforce-shortages-findings-from-a-survey-of-state-medicaid-programs/
[7] https://mhanational.org/sites/default/files/2023-State-of-Mental-Health-in-America-Report.pdf
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361004/#:~:text=As%20noted%20by%20these%20authors,licit%20and%20illicit%20substance%20abuse).

of these products are regulated as Class 2 medical devices by the FDA and they are required to undergo premarket review. For most digital therapeutics, FDA premarket review will require clinical data in the form of randomized controlled trial evidence demonstrating the safety and effectiveness of the device (de novo pathway) or demonstrating substantial equivalence in terms of safety and effectiveness to a predicate product (510(k) pathway).

Similarly, digital therapeutics companies must follow all applicable state and federal data privacy laws, including the *Health Insurance Portability and Accountability Act* (HIPAA) when there are Business Associate agreements in place.

For best practices in addition to what is established in statute and regulation, industry consensus-based standards play an important role. CTA's Digital Therapeutics workgroup continues to consider the needs of the industry in relation to privacy and security and future standards development.

- Do interested parties believe digital CBT could be billed using the existing remote therapeutic monitoring codes described by CPT codes 98975, 98980, and 98981? What impediments may exist to using these codes for digital CBT?

CTA believes digital therapeutics can fit under existing Medicare benefit categories, including devices furnished incident-to a physician's service (e.g., digital therapeutics furnished by providers as part of their treatment of patients) or as durable medical equipment (e.g., digital therapeutics housed in virtual reality hardware systems that meet Medicare's durability requirements for use at home).

Under the incident-to pathway, Medicare is already paying for similar "software as a medical device" produces in diagnostic (e.g., IDXDR) and monitoring services. For the remote therapeutic monitoring (RTM) code set as identified in CMS' question, these codes as currently established account for monitoring devices and surrounding services that are designed to collect data from the patient and transmit that data back to the QHP. These codes include initial set-up and patient education (CPT 98975), treatment management services (CPT 98980, 98981), and the monitoring devices themselves (CPT 98976, 98977, 98978). They do not account for the underlying therapy or therapeutic devices that are described in this letter, meaning that as currently written they cannot be used for digital therapeutics, which have intended therapeutic effects.

There are new coding proposals on the Public Agenda for the September 2023 CPT Editorial Panel meeting to allow for reporting of digital cognitive behavioral therapy, remote therapeutic treatment, and other digital therapeutics as incident-to services. Assuming such coding is adopted, this would provide an appropriate mechanism to facilitate coverage when furnished incident-to a healthcare practitioner's service. If such coding is not adopted, we encourage CMS to adopt such coding under the HCPCS system where CMS would establish a separate set of dedicated G-codes to account for when digital therapeutic devices are acquired by a Medicare enrolled practitioner, and that practitioner then furnishes that device to a patient and manages their treatment.

Regardless of the format or code series under which these would fall, we strongly recommend a coding solution under the incident-to service benefit category that adheres to the following requirements:

- Professional services, including but not limited to initial patient education and on-boarding to the device, and ongoing treatment management services, should be accounted for.

- Code(s) that account for furnishing the device should include devices that are intended to have a therapeutic effect, not just a diagnostic or monitoring role as addressed by existing diabetic retinopathy or remote physiologic (RPM) and remote therapeutic monitoring (RTM) codes. As new digital therapeutics come to market, additional supply codes may be needed to accommodate products and services that are not described by existing codes.

- CMS' physician fee schedule practice expense methodology accounts for both direct practice expenses (e.g., supplies and equipment) and indirect expenses (e.g., rent and electronic health records that support many or all of the services furnished by the QHP). Digital therapeutic devices furnished incident to are used by QHPs consistent with other direct practice expenses and specifically how CMS treats supplies under the direct practice expense methodology. That is, the digital therapeutic license is acquired by the QHP and represents a practice expense of the QHP in furnishing the digital therapeutic to the patient. These expenses are incurred uniquely for a specific patient's treatment (rather than as an underlying expense for running the practice), and the use of the digital therapeutic is consumed by a single patient and cannot be used by another patient.

The financial structure of digital therapeutics, which may include subscription models or other models that do not comprehend purchase of a tangible device per se, may require CMS's adaptation of the practice expense methodology. CMS has already adopted certain processes to allow for appropriate payment of software-based services in both the office setting (e.g., digital device services under the MPFS) and hospital outpatient setting (software as a service under OPPS), and we encourage CMS to continue to be flexible in fitting these new financial structures into the practice expense methodology.

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CTA appreciates this opportunity to comment and thanks CMS for expanding beneficiary and clinician access to healthcare technology. We would be pleased to discuss our comments in greater detail at any time. If you have any questions, please feel free to contact René Quashie at rquashie@cta.tech.

Respectfully submitted,

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