ConnectedHealthInitiative

August 28, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, District of Columbia 20201

RE: *Connected Health Initiative Comments on the Center for Medicare and Medicaid Services'* Medicare Program; Transitional Coverage for Emerging Technologies *(88 Fed Reg 41633; CMS-3421-NC)*

Dear Administrator Verma:

The Connected Health Initiative (CHI) appreciates the opportunity to provide input and suggestions to the Centers for Medicare and Medicaid Services (CMS) on the process for providing transitional coverage for emerging technologies (TCET) through the national coverage determination (NCD) process under the Social Security Act and on the proposed TCET pathway.[1]

I. Introduction & Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to connected health technologies that improve health outcomes and reduce costs. We seek to advance responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery. CHI is an active advocate before Congress, numerous U.S. federal agencies, and states, where we seek to advance responsible digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in collecting and leveraging patient-generated health data (PGHD). For more information, see www.connectedhi.com.

[1] 88 Fed Reg 41633.

CHI is a long-time advocate for the increased use of telehealth and remote monitoring across the Department of Health and Human Services (HHS) as well as before other agencies such as the Federal Communications Commission, as well as the U.S. Congress. CHI is also a current appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group, an initiative bringing together a diverse cross-section of 15 nationally recognized experts that identifies barriers to digital medicine adoption and proposes comprehensive solutions revolving around coding, payment, coverage, and more.[2]

II. Connected Health's Integral Role in the Future of Medicare

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today—whether called "telehealth," "mHealth," "store and forward," "remote patient monitoring," "remote physiologic monitoring," "communication technology-based services," or other similar terms—improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. Connected health tools, including wireless health products, mobile medical devices, software as a medical device (SaMD), mobile medical apps, and cloud-based portals and dashboards, are able to fundamentally improve and transform American healthcare.[3] Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and CMS regulatory-level policy decisions, among other constraints, inhibit the use of these solutions. As a result, there was low utilization of digital health innovations prior to the COVID-19 public health emergency, despite the ability to drastically improve beneficiary outcomes as well as to generate immense cost savings.

Further, CMS should seek to enable the use of health data and PGHD through AI, including through improved pathways for coverage of efficacious technologies. There are varied applications of AI systems in healthcare such as research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value. Payment policies must incentivize a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.

The need for rapid modernization of Medicare's approach to coverage of and payment for innovative technologies is more imperative considering the experiences gained during the COVID-19 crisis in the United States. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient.

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[2] https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group

[3] This CHI resource is publicly accessible at https://bit.ly/2MblRou.

With the congressionally mandated shift from fee-for-service to value-based care in Medicare approaching, CMS' continued efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

CHI notes that CMS has begun to taking important steps to provide incentives for the adoption of innovative technology around the proposed TCET pathway, which CMS should build on. For example, coverage of asynchronous remote monitoring began in CY2018, when Current Procedural Terminology (CPT®) Code 99091 was unbundled. In the calendar year 2019 and 2020 Physician Fee Schedules (PFS), CMS then took significant steps forward in activating and paying for four remote *physiologic* monitoring codes, with subsequent steps taken in CY2022 to support a new family of remote *therapeutic* monitoring use cases. CMS has also ensured utilization of remote monitoring in existing alternative payment models such as Medicare Advantage, where it has been eligible for inclusion as a basic benefit. CMS has also provided support in the PFS for the use of AI, e.g., providing unbundled payment for the use of AI in the imaging of a retina for detection or monitoring of disease.

While the progress described above represents responsible digital health policy changes, the pace of uptake for digital health innovations in the Medicare system continues to lag when compared to the well-established benefits and efficiencies this cutting-edge technology offers. Notably, CMS' NCD process takes, on average, nearly 6 years,[4] and does not keep pace with innovation cycles in digital health. As a result, Medicare beneficiaries do not experience the well-demonstrated benefits of new digital health tools that could be covered. As we discuss below, CMS should take the opportunity to improve its TCET proposal; however, past its TCET pathway, CMS must take much broader steps at the policy level to enable responsible support for digital health products. Under its existing authority, CMS can and should exercise flexibility when determining whether a potential device or diagnostic falls within a Medicare benefit category by considering how such a solution may already be eligible for inclusion in an existing benefit category even if not explicitly outlined in statute.

[4] *JAMA Health Forum*. 2023;4(8):e232260. doi:10.1001/jamahealthforum.2023.2260.

III. CHI Comments on CMS' Proposed Transitional Coverage of Emerging Technology Pathway

From a coverage standpoint, CHI agrees with CMS' assessment in its proposed rule that illustrates the disjointed and complex pathways to device coverage in today's regulatory environment. CHI is supportive of CMS' goal to realize innovation and value in Medicare, which can and should be accomplished through regulatory changes that will appropriately encourage the responsible deployment and utilization of connected health technology that will add value in Medicare. As explained below, while CHI finds alignment with CMS' goals, we request a resolution of the issues and ambiguities in the proposal before issuing a finalized TCET pathway.

CHI supports the Breakthrough Devices Program, which provides patients and health care providers with timely access to some medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and de novo marketing authorization, consistent with the Food and Drug Administration's mission to protect and promote public health. As discussed above, most cutting-edge medical technology today is (or includes) digital and connected health solutions. All these digital health solutions that meet the definition of a medical device under the Food, Drug, and Cosmetic Act face FDA regulation. Today, digital medical devices do not fall within a benefit category that would enable coverage by Medicare, which in practice represents a large barrier to the uptake of those products by Medicare clinicians, precluding countless Medicare beneficiaries from realizing the improved outcomes and reduced costs they bring.

CHI generally supports the TCET concept, and its voluntary opt-in approach. The TCET pathway should, using NCD and coverage with evidence development (CED) processes, expedite Medicare coverage. We agree that companies and patients will benefit from pre-market evaluations of potential harms and benefits of technologies as well as the identification of evidence gaps through "fit for purpose" studies. CHI also agrees that TCET should help coordinate benefit category determination, coding, and payment reviews.

However, CHI notes that, as proposed, the TCET pathway would benefit only a small subset of digital health technologies (those that are medical devices under FDA jurisdiction and which have attained market authorization along with designation as a breakthrough medical device), and would appear to entirely exclude SaMD, including Clinical Decision Support, Artificial Intelligence, and mobile medical applications that meet the legal definition of a medical device under the Food, Drug, and Cosmetic Act, yet do not fall within an existing benefit category and accordingly would be excluded from the TCET pathway, precluding countless Medicare beneficiaries from realizing the improved outcomes and reduced costs they bring. We urge CMS to make updates to its proposal that will equitably improve access and efficiency. We urge CMS to update its TCET pathway proposal consistent with the following:

- Again, CHI supports CMS' proposed opt-in/voluntary approach to the TCET pathway.
- CMS should make the TCET pathway more accessible by expanding eligibility to more than seven new devices per year. CMS' capping coverage to a maximum of seven devices, citing resource constraints, would inevitably exclude technology ideal for the TCET pathway. Further, such a cap would punish technology developers, and the patients that will benefit from their innovations, for developing a product "out of cycle" with the TCET annual application period/cutoff. Instead, CMS should create a TCET pathway without a set cap on eligibility with objective eligibility criteria to ensure that the technologies envisioned for support by CMS will not be subjectively excluded.
- CMS should provide equitable access to the new TCET pathway through ensuring that both devices and diagnostics are considered equitably for inclusion in TCET. Emerging digital healthcare technologies are under development in both areas, and both are subject to the same criteria and evaluation in the FDA's Breakthrough Device Program.
- As proposed, TCET would limit eligibility to devices approved by the FDA with an official breakthrough designation. While we support this eligibility criterion, CMS should also include further medical devices, including those already authorized for marketing by the FDA or currently undergoing FDA review, that demonstrate clinically meaningful improvement in medical care for Medicare patients but that did not request an FDA breakthrough designation. CMS should also expand its TCET eligibility to medical devices that do meet CMS' reasonable and necessary standard but have not yet demonstrated needed context for the Medicare population (such devices are required to address coverage through Medicare Administrative Contractors [MACs], which often vary in their approaches); participation in the TCET pathway would accelerate the generation of needed context for such reasonable and necessary devices.
- CHI is supportive of CMS' proposal to prioritize TCET nominations that benefit the greatest number of Medicare beneficiaries. This prioritization should be determined via clear and straightforward criteria that are objectively applied to all applicants equally, and such criteria should include (1) making significant improvements to patients' lives, including within the context of a particular population that shares risk factors/conditions; (2) addressing needs of unserved or underserved patients and advancing the equitable provision of healthcare; (3) augmenting population health management practices; and (4) otherwise advancing the Quadruple Aim.
- CMS should ensure that its process provides as many incentives as possible for participation in the TCET pathway by clarifying that a company may withdraw from the program following an evidence review without proprietary data in those findings being shared with MACs (further, as the TCET process can happen in parallel to a FDA review, the release of such information may be prejudicial to an

FDA decision). CMS' retention of its proposal to share findings from withdrawn TCET evidence reviews will create a disincentive to companies that rely on MAC coverage.

- To advance transparency and predictability, CMS is encouraged to provide a publicly accessible tool that provides for the tracking of TCET requests prior to a NCD being initiated, including the date of nomination, the date of acceptance or rejection, and the date the NCD process was initiated.

IV. CMS Must Take Comprehensive Action Past its Transitional Coverage of Emerging Technology Pathway to Bring Digital Health Innovations to Medicare Beneficiaries

From a coverage standpoint, we agree with CMS' own assessment in its proposed rule that illustrates the disjointed and complex pathways to device coverage in today's regulatory environment. We are supportive of CMS' goal to realize innovation and value in Medicare, which can be accomplished through regulatory changes encouraging the responsible deployment and utilization of digital health technology. In this respect, the proposed TCET pathway should be viewed as an important but incremental step to much-needed modernizations for Medicare coverage, including the harmonization of descriptive terms and the synchronization of associated clinical evidentiary standards for FDA approval, CPT coding, and CMS coverage focused on the clinical meaningfulness of the output from the digital device.

Accordingly, past its TCET pathway, CMS must take much broader steps at the policy level to enable responsible support for digital health products. Under its existing authority, CMS can and should exercise flexibility when determining whether a potential device or diagnostic falls within a Medicare benefit category by considering how such a solution may already be eligible for inclusion in an existing benefit category even if not explicitly outlined in statute. Notably, CMS should bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as SaMD, are included in existing benefit categories and if so, which category.

a. An Opportunity to a Advance a Common Understanding of the Impact of Output from AI/ML in Medicine and the Associated Clinical Evidentiary Standards

Further, as part of this broader approach to support appropriate coverage of SaMD, CMS should recognize that the success of the TCET program will rely in part on a common lexicon for SaMD, which would enable (a) harmonization of labeling, coding, and coverage policy; (b) synchronization of the respective clinical evidentiary standards; and (c) alignment on the impact of the output. Regarding the impact of output, the term

"clinical meaningfulness" as used by CMS regarding TCET criteria, Evidence Development Plans, CED design, and Evidence Review for NCDs, is in synchrony with CPT's use of the term in coding. CMS' focus on output also aligns well with CPT coding, particularly for the Augmentative and Autonomous categories as represented by CPT Codes 92229 and 7X005. FDA's Breakthrough Device Designation and *de novo* review process [culminating in new product codes and predicate devices] represent opportunities for harmonization of terms, synchronization of evidentiary standards, and alignment on the impact of output across the continuum from FDA to CPT and CMS.

AI/ML is beginning to augment some functions typically performed by physicians, qualified health professionals, or clinical staff or medical providers through sophisticated SaMD, i.e., algorithms, that are increasingly being developed and deployed. The replacement of humans in mundane medical tasks frees humans to practice at the top of their licenses, serving as a force multiplier and providing greater professional satisfaction to providers. Progressively more sophisticated AI/ML will simultaneously enhance, and expand access to, the standard of care. This new age of work being performed by machines raises the need to have a consistent nomenclature framework by which to classify SaMD as it is used in healthcare according to the type of work they perform. In medicine, AI will need to be categorized and assessed according to the level of risk associated with the output from the algorithm, and in complement to that, the involvement or level of oversight required of the human provider.

An AI Taxonomy used in common across labeling, coding, valuation, coverage, and payment is essential to synchrony in clinical evidentiary standards across FDA (clinical validity), CPT (clinical meaningfulness), and CMS and private payers (medical necessity). Furthermore, alignment on the impact ofoutput will contribute to decisions regarding which software warrants special regulatory designation if not also the equipoise in prospective clinical trials, editorial decisions in high-impact journals, accelerated incorporation by medical specialty societies into Clinical Practice Guidelines, new reimbursement codes, and coverage by public and private payers. Therefore, synchrony and alignment would facilitate the progressive assessment of product performance by all parties (FDA, CPT, CMS, et al.) to the continuum from regulatory oversight to clinical adoption. Particularly when Coverage with Evidence Development may be invoked through the proposed TCET program, which will be determined while the initial product label remains under FDA review, synchrony and alignment should provide the predictability and streamlining of oversight that are crucial to the vibrancy of innovation with outcomes of importance to payers, providers, and patients.

In January 2022 the CPT Editorial Panel made effective "Appendix S: AI Taxonomy for Medical Services and Procedures"[5] to provide a framework with descriptors necessary

[5] https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

to create discrete and differentiable reimbursement codes for SaMD. New codes are only accepted into the CPT code set after rigorous review of the supporting evidence in peer-reviewed, high-impact journals, and from the FDA clearance process. The CPT code structure articulates the input, the action, and the output.. This information is necessary for CPT codes which are discrete and differentiable, analogous to CMS' requirement for "a beginning, a middle, and an end" to recognize the separateness of a service or procedure suitably for inclusion in the New Technology APC. The structure of CPT codes for algorithms/software articulates this triad of an input, an action, and an output. CPT Appendix S created new terms to describe the output of AI/ML as either Assistive, Augmentative, or Autonomous as it relates the output from the algorithm to the work performed by the physician.

The criteria for choice of descriptor from CPT Appendix S rely on the output of the AI/ML device, similarly as the FDA determine the risk classification and evidentiary standards based on the output. This synchrony between FDA and CPT also extends to CMS' proposed TCET program, which relies on FDA's decision criteria for Breakthrough Device Designation.

These codes will then serve as the basis for valuation, coverage, and payment for the procedure. Therefore, Appendix S transcends all of medicine by creating a framework which can be harmonized across regulatory labeling, claims coding, and coverage and payment policy. A harmonized use of the framework of descriptors in Appendix S would represent a unique opportunity to:

1. Align FDA, CPT, and CMS/payers' perception of the impact of innovative SaMD; and
2. Synchronize the respective evidentiary requirements across FDA, CPT, and CMS.

This will be particularly important as CMS identifies a permanent mechanism by which to provide coverage and payment for work performed by the machine on behalf of the provider. FDA have continually adapted their regulatory oversight pathways through (a) its Breakthrough Device Designation[6] (which serves as one criterion for CMS' proposed Transitional Coverage for Emerging Technologies program); (b) its *de novo* review process (to classify novel medical devices for which there is no legally marketed

[6] The FDA's Breakthrough Devices Program was created to help expedite medical device development as legislated by the 21st Century Cures Act of 2016. Breakthrough designation affords the applicant FDA feedback and priority review of novel devices which offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases. However, and importantly, Breakthrough does not provide market authorization but is adjunct to FDA market authorization. Thus, manufacturers must still meet statutory obligations through 510(k) clearance, premarket approval, and De Novo market authorization based on the risk categorization of their device.

predicate device); and (c) its proposed Predetermined Change Control Plan guidance[7] (to enable changes that are supported by evidence as pre-agreed with FDA but without the burden of a full supplement to the 510k), in addition to leading the SaMD work group of the International Medical Device Regulatory Forum.[8] These instances illustrate the benefit of harmonizing taxonomy in coding, coverage, and labeling as the basis for synchronizing evidentiary standards and aligning on the impact of the output.

In 2022 CMS held a series of public stakeholder meetings on the TCET concept to solicit public comments on how to address priorities for timely access of breakthrough devices through existing or new coverage pathways. CMS also convened the Medical Evidence Development Coverage Advisory Committee to solicit input for reconsideration of the CED guidance last issued in 2014, resulting in the publication of a notice of a proposed update to the CED Guidance (published on the same date as the TCET proposal).

As part of the TCET, CMS proposed it may conduct an "Evidence Preview" to identify gaps in the evidence required to achieve the "reasonable and necessary" criteria for a National Coverage Decision. The applicant may then offer an "Evidence Development Plan" as the basis for the clinical trials program to satisfy the CED requirement to qualify for TCET - as well as any post-market requirements of the FDA. By requiring CED as a condition of providing coverage with immediate effect from FDA clearance/approval, TCET compresses the continuum across FDA to CPT to CMS in anticipation of the evidence to support "Reasonable and Necessary" above and beyond FDA's "Safety and Efficacy" (balance of benefits and harms).

In order for CED to begin with immediate effect from FDA clearance, CMS must engage the innovator and FDA to agree the protocol design supplemental to the FDA's requirements, prior to FDA clearance of the product and, therefore, in parallel with FDA's deliberations of final labeling and any post-market requirements. These decisions will be of particular importance because many of the products qualifying for Breakthrough Designation, and therefore also for TCET, would represent new predicate devices.

The evidentiary standard required by FDA would represent the baseline from which the evidentiary standard for CMS would be achieved. Any post-marketing requirements of

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[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial.

[8] The IMDRF's basis for evidentiary standards, "Possible Framework for Risk Categorization and Corresponding Considerations" was established in 2014 and adopted by FDA in their SaMD guidance in 2017. These currently rely on a biaxial framework including ill-defined terms like "inform/drive/treat" and "critical/serious/non-serious," and would become clearer were they to consider the taxonomic framework in CPT Appendix S as a third axis. This third factor would facilitate risk stratification and labeling of multi-functional devices with features at different levels, as well as progressive post-marketing development of a product from augmentative to autonomous output.

FDA's could be achieved in the CED trials. A common understanding and description of the output from these devices, as represented by the AI Taxonomy in CPT Appendix S, would anchor this continuum. The descriptors Assistive, Augmentative, and Autonomous, as they apply to the output of these devices, are rigorously and consistently applied in the creation of new reimbursement codes consistent with the clinical evidence supporting their meaningfulness. By harmonized use of these same descriptors in FDA labeling and CMS coverage policy, each would have its own set of progressively developed and synchronous evidentiary standards based on a shared understanding of the impact of the output, thus avoiding mis-alignment among labeling, coding, valuation, and coverage.

In CPT coding, "clinically meaningful" refers to the output from a procedure or service. The output must be sufficiently well validated [clinically, as distinct from technically] that, in the judgement of a prudent physician or other qualified health professional, it is likely to contribute directly to decision-making for an individual patient's care pathway leading to a beneficial outcome. The use of the term "Clinically Meaningful" is also synchronous with FDA's requirements for clearance/approval of AI/ML. As an example, the Guidance for Quantitation requires that the manufacturer provide sufficient information that the practitioner understands how to use the output in patient care; this too is consistent with the CPT requirement for Augmentative.

To qualify for these terms in a CPT code, validation of the output, as documented in medical literature and clinical practice guidelines or FDA-cleared or -approved labeling, may be achieved by:

1. Direct association with clinically meaningful differences in outcomes, similarly as characterized by CMS and AHRQ in the Evidence Development Plan, CED Guidance, and NCA Evidence Review; or
2. Correlation with the output from another procedure or service which is currently considered "usual care" because it has been proven to contribute directly to clinically meaningful differences in outcome.

In CMS's proposals for TCET and CED, this term "clinically meaningful" is used as a standard for the outcome metrics and the statistical analysis plans for the clinical trials. It is distinct from closely related terms such as "Medically Necessary" as judged by CMS in determining coverage policy, "Clinically Valid" as judged by FDA in determining balance of harms and benefits for market entry, and "equipoise" as used by IRBs in adjudicating the ethics of clinical experimentation.

In the Evidence Development Plan, in order to sufficiently address evidence gaps identified by CMS and AHRQ in the Evidence Preview, the applicant is required to include *clinically meaningful benchmarks for each study outcome*. Designing the trial for CED in consultation with CMS and AHRQ to meet the Objective Success Criteria, the applicant must establish an evidentiary threshold for the primary *outcome to demonstrate clinically meaningful differences and adequate numbers of subjects to*

achieve the precision necessary for *values that indicate a meaningful effect.* Finally, the proposed National Coverage Assessment Evidence Review (to provide a framework for more predictable and transparent evidence development) stipulates that an intervention's *benefits should generally be clinically meaningful*, characterizing "strong evidence from clinical trials" including those which may have been published during the period of CED, include adequate numbers of patients to demonstrate improvement in outcomes which are not only statistically significant but also *clinically meaningful.* A current example can be found in CMS' requirements for clinical studies of a monoclonal antibody directed against amyloid approved by FDA, which include that they adhere to the standards of scientific integrity that have been identified by AHRQ (i.e., that the principal purpose of the study is to test whether the *item or service meaningfully improves health outcomes* of affected beneficiaries represented by the enrolled subjects). These uses of the term "clinically meaningful" are aligned with those of CPT, and synchronous in setting standards for clinical evidence.

In summary, synchrony on the evidentiary standards and alignment on the impact of output across FDA, CPT, and CMS will streamline access to the benefits of AI/ML in medicine. Harmonious utilization of the descriptors in CPT Appendix S, such as Augmentative and Autonomous, will contribute to this synchrony in the evidentiary standards, for example as reflected in the requirement for "clinical meaningfulness" in CPT coding and CMS coverage. CMS should encourage this in the TCET program; alignment on the impact of output, for example as reflected in the criteria for Breakthrough Designation and TCET, will ensure the most necessary innovation will be brought to bear on patient outcomes, most expeditiously.

V. Conclusion

CHI appreciates the opportunity to submit comments to CMS on its TCET pathway proposal and urges its thoughtful consideration of the above input.

Sincerely,

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