September 6, 2023

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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]

Dear Administrator Brooks-LaSure:

The College of Healthcare Information Management Executives (CHIME) respectfully submits our comments on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2024 Medicare Physician Fee Schedule and Quality Payment Program (QPP) proposed rule, as published in the *Federal Register* on August 7, 2023 (Vol. 88, No. 150).

Background

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With over 5,000 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate for the effective use of information management to improve the health and healthcare in the communities they serve.

Key Recommendations

In our comments, CHIME provides responses to address the proposals included in this Notice of Proposed Rulemaking (NPRM). Additionally, we offer feedback and recommendations to constructively improve the final rule.

CHIME believes the following areas are especially important for CMS to consider when finalizing the provisions in this important proposed rule, and our detailed recommendations are included below.

- Changes to the Promoting Interoperability (PI) Performance Category
    - Promoting Interoperability Performance Category Performance Period
    - Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians Proposed Change to the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Measure

- Updates to the Definitions of Certified Electronic Health Record Technology & Certified Electronic Health Record Technology Requirements
- Align CEHRT Requirements for Shared Savings Program ACOs with MIPS
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)
- Appropriate Use Criteria for Advanced Diagnostic Imaging
- Reporting Home Address for Telemedicine Visits

Detailed Recommendations

Promoting Interoperability (PI) Performance Category

Promoting Interoperability Performance Category Performance Period

CMS is proposing to modify the PI performance category performance period to remove the reference[1] to subsequent years after the CY 2024 MIPS payment year, and instead specify that the policy applies only through the CY 2025 MIPS payment year. Additionally, CMS is proposing to require a continuous 180-day performance period for the PI performance category beginning with the CY 2024 performance period/2026 MIPS payment year. CHIME broadly supports this proposal. However, we respectfully request that CMS consider offering an "exception" or flexibility for providers that may be switching their electronic health records (EHRs) during the performance period/payment year. EHR implementations extend well beyond a 180-day timeframe and without such an exception, or some flexibility in enforcement – such as offering providers that have changed from one EHR vendor to another during a performance period/payment year the flexibility to report two continuous 90-day periods within the performance period - this will create significant burdens for some providers.

Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians Proposed Change to the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Measure

CMS is proposing to modify their requirements for the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure beginning with the CY 2024 performance period and subsequent years, to require MIPS eligible clinicians to conduct, and therefore attest "yes," an annual self-assessment of their CEHRT using the High Priority Practices SAFER Guide[2] at any point during the calendar year in which the performance period occurs. Under this proposal, although the SAFER Guides measure would continue to be required with no associated points, an attestation of "no" would result in the MIPS eligible clinician not meeting the measure's requirements and therefore not a meaningful user of CEHRT, warranting a score of zero for the Promoting Interoperability performance category.

For reasons further outlined in CHIME's comment letter to CMS regarding the hospital inpatient prospective payment system (IPPS) proposed rule for fiscal year (FY) 2024, CHIME strongly opposes implementing a mandatory requirement for all MIPS eligible clinicians to attest to the High Priority Practices SAFER Guide in CY 2024.

[1] § 414.1320(h)
[2] SAFER Guides | HealthIT.gov. (n.d.). https://www.healthit.gov/topic/safety/safer-guides

CHIME believes that the fragmentation of the current SAFER Guides requires inefficient, redundant reporting from providers. As proposed, CMS will simply shift more burden onto clinicians who are already severely strained, understaffed, and under-resourced. It furthermore could constitute a significant burden on small and under-resourced clinicians. Most clinicians and providers are experiencing significant challenges related to post-pandemic burnout, workforce shortages, and rising cybersecurity attacks. Thus, CHIME urges CMS to consider the implications of imposing this new requirement. **Again, while we agree that the concept is well-intended, we worry this will result in an unfunded mandate and will not address some of the key challenges – specifically, patient safety – it aims to solve. Therefore, CHIME is respectfully requesting that CMS not move forward with implementing this proposal at this time.**

There should be a delay of this proposal until CMS completes the following recommendations: 1) reviews the High Priority Practices SAFER Guide to update it and reduce redundancies; 2) offer an easily accessible free resource center for MIPS eligible clinicians to utilize in reviewing the revised SAFER Guide; and 3) after reviewing and updating the SAFER Guide, ensure that it is applicable to and across the healthcare continuum and different settings of care. CHIME is recommending CMS delay moving forward with this proposal until the above recommendations are complete, or at least three years (i.e., CY 2027).

The COVID-19 pandemic produced unparalleled changes in clinician work life. Since the start of the pandemic, clinicians have faced new sources of stress – leading to clinician exhaustion and burnout, and a degree of turnover and exit from practice that is unsustainable.[3] Standardization and updates throughout the High Priority Practices SAFER Guide would offer a significant reduction in burden on clinicians across the care continuum, decreasing the current urgent clinician burnout and workforce shortage that our country is facing.

Importantly, reducing the substantial time providers must spend navigating regulatory changes and their evolving requirements would “unlock” countless hours of time. In turn, this time could be used to improve patient care and innovate around new workflow and care processes – including improving the High Priority Practices SAFER Guide. **Before CMS requires the complex process of attesting to the High Priority Practices SAFER Guide, we recommend that they address the foregoing issues related to the guide.**

CHIME members are executives and senior healthcare IT leaders; thus, we are offering to continue to serve as a resource to CMS as they potentially refine the SAFER Guides and continue towards the goal of enabling providers to make improvements to safety and safe use of EHRs as necessary over time – which CHIME members staunchly support. We wish to work with CMS as partners and share the goal of strongly promoting safety and the safe use of EHRs. However, we believe that it needs to be done judiciously, with a stepwise approach.

Updates to the Definitions of Certified Electronic Health Record Technology & Certified Electronic Health Record Technology Requirements

The Office of the National Coordinator for Health IT (ONC) Certification Program supports the use of certified health IT (CEHRT) under the programs that CMS administers, including, but not limited to, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), the Shared Savings Program, and the Quality Payment

[3] Linzer, M., Jin, J. O., Shah, P., Stillman, M., Brown, R., Poplau, S., Nankivil, N., Cappelucci, K., & Sinsky, C. A. (2022). Trends in Clinician Burnout With Associated Mitigating and Aggravating Factors During the COVID-19 Pandemic. *JAMA health forum*, *3*(11), e224163. https://doi.org/10.1001/jamahealthforum.2022.4163

Program, which includes the MIPS Promoting Interoperability performance category and the Advanced Alternative Payment Models (Advanced APMs).

In the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule[4], (i.e., "HTI-1" proposed rule) – which appeared in the April 18, 2023 *Federal Register*, ONC has proposed to discontinue the year-themed "editions," which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC is proposing to instead maintain a single set of "ONC Certification Criteria for Health IT," which would be updated in an incremental fashion in closer alignment to standards development cycles and regular health information technology (IT) development timelines.[5] CMS is proposing to modify the definition of CEHRT for purposes of the Quality Payment Program[6] to no longer refer to year-specific editions, and to incorporate any changes made by ONC to its definition of Base EHR and its certification criteria for health IT.

CHIME provided extensive feedback on ONC's HTI-1 proposed rule – which, notably and of great concern as it related to this proposed rule – has not yet been finalized. Please see CHIME's comment letter to ONC on their HTI-1 proposal here in its entirety. With the insight CHIME and its members have from being at the forefront of health IT issues, we urged ONC when finalizing the HTI-1 proposed rule – to at a minimum, delay the proposed timelines and prioritize reducing provider burden across the whole healthcare continuum when implementing provisions of the 21st Century Cures Act and updating ONC's CEHRT Program.

In our comments to ONC, we reiterated that CHIME remains supportive of efforts to promote accessibility to healthcare services including technology and devices, as well as expanding data collection, reporting, and analysis to identify disparities and track any improvements. ***However, we encouraged ONC to ensure coordination with the Department of Health and Human Services (HHS) and other agencies, including CMS, which has ongoing efforts focusing on enhanced payment policies to improve access to those who experience social risk factors that impact their health outside of the four walls of their provider's office and those who may experience other barriers to accessing the care they need.*** Our members are dedicated to making care safer and encouraging the highest-quality care. Patient safety, not just for all or some patients, but for each individual patient, is of the utmost importance across the healthcare continuum.

Similar to ONC's proposal to move away from "editions" and toward incremental changes to its certification criteria, CMS has also focused on implementing incremental changes to individual measures under, but not limited to, the Medicare Promoting Interoperability Program, the Shared Savings Program, the Quality Payment Program, in recent years. CMS states that they "expect to continue to prioritize incremental changes in future years to reduce burden on participants in these programs (including eligible hospitals and CAHs and MIPS eligible clinicians) and build on the established base of available certified health IT capabilities." CMS believes this approach is consistent with the strategy discussed in the ONC HTI-1 proposed rule, in which ONC proposes to pursue a framework for the ONC CEHRT Program that focuses on incremental updates to a single set of certification criteria. It remains unclear to us just what this new schedule will be.

In the HTI-1 proposal, ONC both assumed and acknowledged that health IT developers will pass up to $742 million – in the first year alone – in costs onto healthcare delivery organizations

[4] 88 FR 23758
[5] 88 FR 23750
[6] § 414.1305

(HDOs). In our comments to ONC, we asserted that these costs will be insurmountable for some – especially safety-net, critical access hospitals (CAHs), and rural hospitals and health systems. Additionally, our members will need to address EHR usability challenges and concerns because of this proposal. Further, they will need to create and implement significant clinician and staff education efforts. These proposals will necessitate arduous workflow and configuration of EHRs, which requires individual EHR system usability and safety testing – a resource intensive and costly undertaking. As one member shared, **"**Impaired with the cost of having to use temporary staff at higher rates the constraint on resources has never been more daunting. This will be the 'straw that will break the camel's back'." **CHIME strongly believes that the ONC HTI-1 proposal – and, in turn, this proposal from CMS – will, if finalized as proposed, impose a substantial financial and clinician burden in terms of implementation without providing clear or defined advantages or benefits.**

CHIME has and continues to be a staunch champion when it comes to the need for the use of technology standards aimed at facilitating better patient care. However, a "one size fits all" approach – as this rule proposes – will be especially detrimental to long-term and post-acute care providers that have invested in EHRs, including CEHRT. It furthermore could constitute a significant burden on small, rural, and under-resourced clinicians and providers. Many HDOs and healthcare providers are experiencing significant challenges related to pandemic burnout and workforce shortages. **Therefore, CHIME is concerned that this proposal could inadvertently hinder the success of advancing interoperability across the healthcare continuum – which even ONC has acknowledged is an ongoing challenge.**

CMS also notes that they will continue to determine when new or revised versions of measures that require the use of CEHRT would be required for participation under the Medicare Promoting Interoperability Program and the Quality Payment Program. CMS states that, in determining requirements for any potential new or revised measures, they will consider factors such as implementation time and provider readiness to determine when CMS will mandate participants complete measures that require the use of CEHRT.

CHIME believes that imposing mandates of this magnitude disproportionately impacts some clinicians and providers in our sector more unevenly – especially safety-net providers and long-term and post-acute care providers who never received EHR incentives. While the Health Information Technology for Economic and Clinical Health (HITECH) Act[7] made significant investments in certain areas of our sector, more robust funding is needed to improve interoperability across the entire care continuum, a reality previously acknowledged by CMS.

Additionally, the overall privacy and cybersecurity landscape has become infinitely more complex for all providers. Cybersecurity attacks are on the rise for providers of all sizes which pose a direct threat to patient safety. In fact, this issue has garnered so much attention that HHS issued a landmark report in April on this very issue, the Hospital Cyber Resiliency Initiative Landscape Analysis.[8] **Hospitals and other healthcare clinicians and providers are under siege from cyberattacks and already challenged to locate the resources needed to mitigate these hostilities. These issues are particularly exacerbated for small, rural, and safety-net providers, and LTPAC providers that never received EHR incentives. Any new CMS mandates must be carefully balanced with the needs of providers to fend off these**

[7] Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009), codified at 42 U.S.C. §§300jj et seq.; §§17901 et seq.
[8] 405d-hospital-resiliency-analysis.pdf (hhs.gov)

attacks on them and their patients – which is a threat to patient safety and our national security.

CMS – in summary – is proposing to revise the definitions of CEHRT for the Medicare Promoting Interoperability Program[9], and for the Quality Payment Program.[10] Specifically, CMS is proposing to add a reference to the revised name of "Base EHR definition," proposed in the ONC HTI-1 proposed rule, to ensure, if finalized, it is applicable for the CEHRT definitions going forward.[11] CMS is also proposing to replace references to the "2015 Edition health IT certification criteria" with "ONC health IT certification criteria" and add the regulatory citation[12] for ONC health IT certification criteria. CMS is also proposing to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria[11] "as adopted and updated by ONC." CMS believes that these revisions to the CEHRT definitions, if finalized, would ensure that updates to the definition in current statute[13] and updates to applicable health IT certification criteria[11] would be incorporated into the CEHRT definitions, without additional regulatory action by CMS.

CHIME strongly believes that advancing interoperability will improve healthcare, but reducing financial burden and complexity must take a front seat with realistic implementation expectations. As proposed, we are concerned that these policies, while well-intended, will not achieve this goal. Furthermore, it could threaten to upend access to care which is already seeing erosion among some providers due to the aforementioned post-pandemic burnout and workforce challenges.

Additionally, in a "post-meaningful use era," clinicians and providers have made dramatic advancements in healthcare – especially in analytics – and are beginning to realize what their data can do to suggest patient-tailored, precision medicine in how treatment plans and care pathways are ultimately activated and determined by a clinician. **By adding additional regulatory burden, the ability for providers and clinicians to leverage significant IT investments, which support safer and higher quality care, will be ultimately slowed down. We respectfully request that CMS be cognizant of these, and other unintended consequences, as they finalize this rulemaking.**

Furthermore, research has found that:

> *Use of electronic health records (EHRs) is directly associated with physician burnout. Many physicians have voiced dissatisfaction with the click-heavy, data-busy interfaces of existing EHRs. Other factors associated with EHR frustration include scrolling through pages of notes and navigating through multiscreen workflows in the search for information. Excess EHR screen time leads to emotional distress in physicians and limits face-to-face contact with patients, resulting in higher rates of medical errors. Thus, common attitudes among physicians toward the EHR include "inefficient," "time-consuming," and "exhausting."*[14]

As with many other peer-reviewed research findings, this study noted in its findings that "future research is needed to better understand the complex association between EHR-related fatigue

[9] 42 CFR 495.4
[10] 42 CFR 414.1305
[11] 88 FR 23759
[12] 45 CFR 170.315
[13] 45 CFR 170.102
[14] Khairat S, Coleman C, Ottmar P, Jayachander DI, Bice T, Carson SS. Association of Electronic Health Record Use With Physician Fatigue and Efficiency. *JAMA Netw Open.* 2020;3(6):e207385. doi:10.1001/jamanetworkopen.2020.7385

and care outcomes." Until CMS has a full understanding of the relationship between "alert fatigue," solutions that can ultimately improve patient care and outcomes will elude the healthcare industry.

CMS notes that, "while this proposal is consistent with the approach in ONC's HTI-1 proposed rule[15], we do not believe that ONC must finalize its proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT."

In the HTI-1 proposal, ONC noted that the National Coordinator's authority "to regulate developers of certified health IT under the Program is separate and distinct from other federal agencies' regulatory authorities focused on the same or similar entities and technology." **It will be incumbent upon both ONC and CMS – as well as other agencies under the HHS umbrella – to work together to ensure that there are not redundant regulatory requirements for healthcare stakeholders. CHIME members have expressed concern regarding existing regulatory authorities, which may result in a duplication of efforts with differing requirements, meaning providers and EHR vendors would need to satisfy two or even three sets of regulations.**

CHIME is extremely concerned that, given the ONC HTI-1 proposed rule and its deadlines are yet to be finalized, combined with CMS's proposals and statutory deadline of the Medicare Physician Fee Schedule and Quality Payment Program (QPP) final rule – that there will ultimately be a confusing, illogical set of deadlines for healthcare providers. The multiple deadlines may or may not be in sync, and healthcare providers will potentially have less than 8 weeks to comply with the magnitude of policies in both of these proposed rules. Further, CHIME believes that these timelines, as proposed, are overly ambitious at best, aggressive and detrimental at worst. **Taken in totality, we believe these regulations are likely to contribute to further provider burnout, dissatisfaction, and alert fatigue**.

CMS "reminds readers that ONC sets timelines through their rulemaking for when health IT developers must ensure their health IT products meet ONC's new or updated certification criteria to maintain certification under the ONC Health IT Certification Program, including time for health IT developers to implement these updates for their customers who may participate in programs that require use of CEHRT."[16]

Many of our members are extremely concerned about the proposed timelines; their EHR vendors must comply with the magnitude of policies in this proposed rule. They are skeptical and unsure if their EHR vendor will realistically be able to meet these deadlines – and, in turn, their organizations will be unable to support and financially bear the burden of the continuous, ongoing series of upgrades. The timelines need to be extended, and the operational expenses passed onto healthcare providers need to be limited. Furthermore, given the uncertainty around when EHR updates are delivered by vendors, providers need adequate time for testing and training that takes unpredictable delivery dates into account and sufficient time to work out any bugs.

In CHIME's comments to ONC's HTI-1 proposed rule, we recommended that ONC implement a reasonable timeline that takes into account not only the timelines required for both EHR vendor development and provider training and implementation, but also one that factors in workforce shortages and other competing mandates including existing ones (i.e., providers are still wrestling

[15] 88 FR 23746 through 23917
[16] 88 FR 23761

with implementing Information Blocking rules, which had a deadline of October 6, 2022 – less than a year ago) and forthcoming ones (i.e., CMS's recently finalized Medicare Promoting Interoperability (PI) Program mandated reporting of the Safety Assurance Factors for EHR Resilience (SAFER) guides in the annual proposed inpatient prospective payment system (IPPS) proposed rule for fiscal year (FY 2024). **Therefore, we strongly recommend that any timelines related to CEHRT definitions and/or requirements in this proposed rule not be effective any sooner than 24 months following the publication of the final rule.**

The HTI-1 proposal – once finalized – as well as this proposed rule will require that our members develop guidelines, policies, procedures and gather the data required to meet the requirements along with their vendor partners. Once that work is complete, the decisions need to be implemented and communicated across their organizations. **The work to implement HTI-1 alone, once finalized, will take a minimum of 18 to 24 months.** Moreover, ONC and CMS must ensure that providers have the time needed to understand the significance of the policies included in the final rule/s, are prepared to meet its/their requirements, and have the technology and funding to support safe implementation. **Thus, at the earliest, CHIME recommended that the compliance deadlines for HTI-1 should be December 31, 2026. We respectfully request that CMS ensure that their proposed timelines are aligned with ONC's HTI-1 finalized timelines in order to reduce financial strain across the entire healthcare continuum, as well as decreasing provider burden and burnout as much as possible.**

Finally, ONC asserted that the HTI-1 proposed rule would "provide transparency; ***advance […] innovation,*** [emphasis added] and interoperability; and support the access, exchange, and use of electronic health information (EHI)." **CHIME members have expressed significant concerns that this proposal may unintentionally stifle innovation in the healthcare industry.** While we acknowledge the importance of government oversight, it is essential to strike a balance that fosters a culture of innovation and advancement in healthcare. Excessive regulation can inadvertently impede progress and hinder the development of innovation and interoperability, which we agree with ONC can greatly benefit patients, providers, and the healthcare system as a whole - when balanced correctly.

Align CEHRT Requirements for Shared Savings Program ACOs with MIPS

In order to streamline CEHRT threshold requirements for ACOs and align with MIPS, CMS is proposing to sunset the Shared Savings Program CEHRT threshold requirements and modify existing regulations[17] to indicate that they will be applicable only through performance year 2023. CMS is further proposing, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) participating in the ACO, regardless of track, satisfy all of the following: 1) Report the MIPS PI performance category measures and requirements to MIPS and; 2) Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

CHIME opposes CMS' proposal to require all clinicians, regardless of QP status or model track, to report MIPS PI measures and earn a PI score, and for ACOs to publicly report the number of clinicians in that ACO that earn a PI score. CMS asserts that this proposal will "alleviate burden" on ACOs because ACOs will no longer have "the burden of managing

[17] § 425.506(f)

compliance with two different CEHRT program requirements." However, we believe that this proposal would inadvertently increase burden on MSSP ACOs because it requires all participants to meet the more burdensome MIPS criteria.

CHIME believes it is ineffective and inappropriate to require providers to bear the cost and burden of data collection through PI measures. Rather, CMS could gather more informative data on EHR adoption and interoperability while reducing burden on providers by working more collaboratively with ONC, and leveraging data that is already being collected. This could be achieved by requesting that EHR developers pull data automatically from CEHRT systems and report this data – specifically as it relates to EHR functionalities and interoperability between systems – and is something that providers do not have control of or over. Instead of extending MIPS PI requirements to QPs and Partial QPs participating in ACOs, CMS could seek interagency cooperation in order to leverage information that is already being collected. This would provide CMS with more useful data regarding adoption, use, and interoperability of CEHRT while reducing the reporting burden on providers. Furthermore, this would continue to incentivize clinicians to join APMs.

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

The Consolidated Appropriations Act of 2022[18] amended section 1834(m) of the Act to extend several flexibilities that were in place during the Public Health Emergency (PHE) for COVID-19 for 151 days after the end of the PHE. Additionally, the Consolidated Appropriations Act of 2023[19] extended certain key telehealth flexibilities through December 31, 2024 (i.e., through the end of CY 2024).

We appreciate CMS's intent in this proposed rule to clarify that certain telehealth flexibilities that were previously extended 151 days after the end of the PHE have been extended until December 31, 2024. CHIME further appreciates that CMS' goals related to telehealth policies are to seek to retain payment stability, reduce confusion and burden, and conform to all statutory requirements without unnecessary restrictions on beneficiaries' access to telehealth care.

CHIME understands that CMS requires additional authority (i.e., Congress granting rulemaking authority to federal agencies) and continues to endorse and support legislation that would expand access to virtual care beyond CY 2024. Access to telehealth and virtual care has been transformational – patients now expect and often prefer telehealth as a key component of our healthcare system and providers have been able to reach many patients that previously had access barriers through virtual care.

While CHIME appreciates the temporary extensions CMS is proposing, we would like to reiterate that the short-term nature continues to heighten the significant uncertainty into our healthcare system. Providers must weigh the costs of investing in the technological and clinical infrastructure required to maintain telehealth programs at scale against the uncertainty of when these telehealth policies may end. Further, patients who utilize telehealth as part of their care plan face the possibility of a forced return to in-person care. This is particularly concerning for patients utilizing telehealth to reach experts at longer distances and those receiving ongoing remote care for chronic conditions. **CHIME continues to respectfully request that CMS create a more flexible**

[18] The Consolidated Appropriations Act, 2022 (2022 CAA), Pub. L. 117-103, March 15, 2022. https://www.congress.gov/117/plaws/publ103/PLAW-117publ103.pdf

[19] The Consolidated Appropriations Act, 2023 (2023 CAA), Pub. L. 117-328, December 29, 2022. https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf

reimbursement policy around the use of telehealth – such that Medicare pays providers for using it and supports patient care when and where they need it.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

CHIME continues endeavors in ongoing efforts to address treatment of Opioid Use Disorder (OUD) through our Opioid Task Force (OTF). CHIME's OTF was founded in 2018 to address the opioid epidemic through the use of technology-based solutions. Unfortunately, COVID-19 has created a "crisis on top of a crisis" – with the opioid epidemic worsening since the start of the pandemic. **Therefore, CHIME continues to support and appreciate CMS's proposals to modify and expand the regulations and policies governing Medicare coverage and payment for OUD treatment services furnished by Opioid Treatment Programs (OTPs).**

CHIME supported CMS' prior revisions to the definition of "Opioid disorder treatment service"[20] to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls – rather than two-way interactive audio/video communication technology after the conclusion of the PHE for COVID-19 in cases where audio/video communication technology is not available to the beneficiary, provided all other applicable requirements are met.[21] Further, CHIME supported the additional modifications and expansions to covered services for the treatment of OUD by OTPs in the CY 2023 PFS final rule.[22] During the COVID-19 pandemic, substance use disorder (SUD) treatment facilities increased telemedicine offerings by 143 percent, and as of 2021, almost 60 percent of SUD treatment facilities offer telehealth.[23]

To better align coverage for periodic assessments furnished by OTPs with the telehealth flexibilities provided by law,[24] CMS is proposing to extend the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024. Under this proposal, CMS would allow periodic assessments to be furnished audio-only when video is not available, to the extent that use of audio-only communications technology is permitted under the applicable Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) requirements at the time the service is furnished and all other applicable requirements are met. **CHIME supports this proposal and agrees with CMS that extending this flexibility would promote continued beneficiary access to these services following the end of the PHE and for the duration of CY 2024.**

Notably, telephone-based (that is, audio-only) therapy and recovery support services provided by SUD programs have been found to be one of the most common modes of telehealth for treatment of OUD.[25] **Therefore, CMS believes that extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE; CHIME agrees with this assertion.**

Additionally, this proposal notes that extending these flexibilities another year will allow CMS time to further consider this issue, including whether periodic assessments should continue to be

[20] § 410.67(b)
[21] 86 FR 65342
[22] 87 FR 69768 through 69777
[23] https://pubmed.ncbi.nlm.nih.gov/34407631/
[24] § 4113 of the CAA, 2023
[25] Hughes, P. M., Verrastro, G., Fusco, C. W., Wilson, C. G., & Ostrach, B. (2021). An examination of telehealth policy impacts on initial rural opioid use disorder treatment patterns during the COVID-19 pandemic. *The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association*, *37*(3), 467–472. https://doi.org/10.1111/jrh.12570

furnished using audio-only communication technology following the end of CY 2024 for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs.

CHIME acknowledges that the majority of telehealth access has been possible only under the flexibilities and waivers granted under the previous COVID-10 PHE. Furthermore, a recent study found that the emergency authorities used by CMS to expand telehealth utilization during the COVID-19 PHE – in particular, providing flexibilities to provide patients with medications for OUD - were associated with improved retention in care and reduced odds of medically treated overdose.[26] During the COVID-19 pandemic, SUD treatment facilities increased telemedicine offerings by 143 percent, and as of 2021, almost 60 percent of SUD treatment facilities offer telehealth.[27]

Strategies to expand provision of medications for opioid use disorder (MOUD) and increase retention in care are urgently needed. Emergency authorities to expand telehealth utilization and provide MOUD flexibilities during the COVID-19 pandemic were used among Medicare beneficiaries and were associated with improved MOUD retention and lower odds of medically treated overdose, lending support for permanent adoption.[28]

In 2021, 45 people died each day from a prescription opioid overdose, totaling nearly 17,000 deaths.[29] According to data from the Centers for Disease Control and Prevention (CDC), in 2021, opioids were involved in over 75% of all drug overdose deaths in the U.S. The age-adjusted rate of overdose deaths increased by 14% from 2020 to 2021.[30] **Healthcare providers and industry stakeholders are and will continue to need more resources to fight the opioid epidemic. Therefore, CHIME fully supports any efforts to provide essential, timely access to OUD treatments – especially to communities that need it the most. This includes supporting proposals to continue to allow for periodic assessments to be furnished using audio-only telephone calls – if all other applicable requirements are met – in cases where a beneficiary does not have access to two-way audio-video communications technology. As CMS notes in this proposal, "evidence has shown that Medicare beneficiaries from historically underserved populations are more likely to be offered and use audio-only telemedicine services than audio-video services."**

Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List

To avoid potential continuing confusion among those who submit requests to add services to the Medicare Telehealth Services List, and as CMS considers the expiration of the Medicare telehealth flexibilities extended by the CAA, 2023 through the end of CY 2024, CMS believes it would be beneficial to simplify their current taxonomy and multicategory approach to considering submitted requests. Further, CMS believes that this simplification could address the confusion they have noticed from interested parties submitting requests during the PHE. Thus, CMS is proposing to simply classify and consider additions to the Medicare Telehealth Services List as either permanent, or provisional. **CHIME broadly supports this proposed approach.**

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[26] Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry.* Published online August 31, 2022. doi:10.1001/jamapsychiatry.2022.2284

[27] Cantor, J., McBain, R., Kofner, A., Hanson, R., Stein, B. D., & Yu, H. (2022). Telehealth adoption by mental health and substance use disorder treatment facilities in the COVID-19 pandemic. *Psychiatric Services*, *73*(4), 411-417. https://doi.org/10.1176/appi.ps.202100191

[28] JAMA Psychiatry. 2022;79(10):981-992. doi:10.1001/jamapsychiatry.2022.2284

[29] *Opioid overdose | Drug overdose | CDC Injury Center*. (n.d.). https://www.cdc.gov/drugoverdose/deaths/opioid-overdose.html

[30] *Drug overdose deaths | Drug overdose | CDC Injury Center*. (n.d.). https://www.cdc.gov/drugoverdose/deaths/index.html

The proposed assignment of a "permanent" or "provisional" status to a service and changes in status reflects the proposed stepwise method to consider future requests to add services to, remove services from, or change the status of, services on the Medicare Telehealth Services List, beginning for the CY 2025 Medicare Telehealth Services List, which will include submissions received no later than February 10, 2024.

CMS notes that the timeline for the proposed process to analyze submissions would remain the same. In other words, CY 2025 submissions would be due by February 10, 2024. Additionally, CMS would continue to address each submitted request for addition, deletion, or modification of services on the Medicare Telehealth Services List through annual notice and comment rulemaking. Therefore, CMS requests must be received by February 10, 2023, to be considered during the 2024 rulemaking cycle that establishes physician fee schedule rates for January 1, 2024.

In order for healthcare stakeholders to have time to adjust to this new stepwise approach – as well as other massive policy shifts resulting from the end of the PHE – CHIME respectfully requests that for the 2025 rulemaking cycle, the submission date of February 10 be delayed by at least three months. Providing stakeholders with a temporary extension on the deadline will give CMS ample time for their review period before the PFS proposed rule for CY 2024 is released (typically in mid to-late July).

CMS is further proposing to inform each submitter in the confirmation whether the submission was complete, lacking required information, or outside the scope of issues CMS considers under the process for considering changes in the Medicare Telehealth Services List. CMS notes that they also expect submissions to include copies of any source material used to support assertions, which has been the longstanding direction included in their website instructions. **CHIME applauds this proposal, as we have strongly encouraged CMS to provide additional education, guidance, and information relevant to how stakeholders can meaningfully engage in and successfully request to add services to the Medicare Telehealth Services List (i.e., supporting documentation required, the review process, details on the criterion and processes established by CMS, etc.).**

Appropriate Use Criteria for Advanced Diagnostic Imaging

CMS is proposing "to pause implementation of the [Appropriate Use Criteria] AUC program for reevaluation, and rescind the current AUC program regulations from §414.94." CMS notes that at this time, they "have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization." CMS states that as a result, they are proposing to pause implementation of the AUC program for reevaluation – and expects "this to be a hard pause to facilitate thorough program reevaluation and, as such, [is] not proposing a time frame within which implementation efforts may recommence."

While we appreciate CMS's acknowledgment and are supportive of this proposal – CHIME is concerned that the CMS could – at any time in the future – decide to "restart" or "unpause" implementation of the AUC program. Our members have spent millions of dollars and countless workforce hours to operationalize the AUC program each year, through each phase of the program, since 2015. After nearly a decade of effort and funds exhausted by healthcare providers

– they should not have to be concerned about further expenses and time needed to spend on a program that simply does not work.

Having the AUC program looming over them to be restarted at any given time in the future, without any indication of "a time frame within which implementation efforts may recommence" – is wasteful and shortsighted. **Therefore, with CMS admittedly having "exhausted all reasonable options for fully operationalizing the AUC program," in conjunction with the fact that healthcare providers have already spent countless dollars and hours on implementation and compliance, CMS should fully repeal the current AUC program regulations from §414.94.**

Generally, federal agencies are empowered to amend or repeal existing rules that were issued pursuant to discretionary authority.[31] To amend or repeal an existing legislative rule, federal agencies generally must comply with the same notice-and-comment rulemaking procedures that governed the original promulgation of the rule, as outlined in §553 of the Administrative Procedure Act (APA).[32] **We respectfully request that CMS do so, and remove the AUC program in its entirety from statute, permanently. This would offer healthcare providers a nominal measure of certainty in a regulatory landscape – where some of our members are budgeting millions of dollars for both known and unknown regulatory changes each year.**

Reporting Home Address for Telemedicine Visits (not addressed in proposal)

During the COVID-19 PHE, CMS allowed clinicians to deliver telehealth services from their homes without having to report their home address to Medicare. Medicare policies dictate that the location where a service is rendered must be included on claims. We have begun to hear feedback from our members who report their clinicians are extremely worried that CMS will require them to report their home address on telehealth claims starting in 2024 if they continue delivering telehealth services from home.

Since Congress has permitted pandemic telehealth flexibilities to continue past the end of the PHE through the end of 2024, we believe this issue must be addressed quickly to bring certainty and safety to clinicians. CHIME is therefore very concerned that CMS has not discussed this topic in this proposed rule. Given the alarming increase in workplace violence in healthcare settings against clinicians,[33,34] we strongly recommend that CMS continue to allow clinicians to report an address other than their home address when they deliver telehealth services from their home. We furthermore recommend the agency make this announcement as soon as possible so as to avoid clinicians deciding to stop delivering telehealth services which could result in access to care issues.

Conclusion

In closing, we respectfully request that as CMS considers stakeholder feedback and works to finalize this regulation, that they adopt policies that do not inadvertently create overly duplicative requirements, penalize healthcare providers unfairly, and add burden to an already highly

[31] Encino Motorcars, LLC v. Navarro, --- U.S. ---, 136 S. Ct. 2217, 2125 (2016) ("Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change."). An agency may not be permitted to repeal rules that are mandated either by statute or judicial order as such actions would not be "in accordance with law."
[32] Administrative Procedure Act (APA), 5 U.S.C. §§551 et. seq.
[33] Fact Sheet: Health Care Workplace Violence and Intimidation, and the Need for a Federal Legislative Response | AHA
[34] Attacks at US medical centers show why health care is one of the nation's most violent fields - ABC News (go.com)

regulated industry. Additionally, fully understanding the long-term ramifications of these proposed policies is crucial.

We appreciate the opportunity to comment and the chance to help inform the important work being done by CMS. We look forward to continuing to be a trusted stakeholder and resource to CMS and continuing to deepen the long-standing relationship we have shared. Working together through the rulemaking process, such as with the PFS, is just one way we can accomplish our shared goals and make meaningful changes in healthcare.

Should you have any questions or if we can be of assistance, please contact Chelsea Arnone, Director, Federal Affairs at carnone@chimecentral.org.

Sincerely,

Russell P. Branzell, CHCIO, LCHIME
President and CEO, CHIME