September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Washington, DC 20201

Dear Administrator Brooks-LaSure:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide written comments to the Notice of Proposed Rule Making (NPRM) regarding 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; Continued Implementation of Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts; Medicare Advantage (CMS-1784-P.) HIMSS appreciates the opportunity to leverage our members' expertise to share feedback on the adoption of new quality measures for the Quality Payment Program and the Medicare Shared Savings Program, the pause for Appropriate Use Criteria, the extension of telehealth coverage, and the incorporation of SDOH screenings into annual wellness visits for Medicare beneficiaries. We look forward to continued dialogue with the Centers for Medicare & Medicaid Services (CMS) on these topics.

HIMSS is a global advisor, thought leader, and member-based society committed to reforming the global health ecosystem through the power of information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology driven by health equity. Through our innovation engine, HIMSS delivers key insights, education, and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision. HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include over 120,000 individuals, 480 provider organizations, 470 non-profit partners, and 650 health services organizations. Our global headquarters are in Rotterdam, Netherlands, and Americas headquarters are in Chicago, Illinois.

For our public comment, HIMSS offers the following thoughts and recommendations on this NPRM:

Proposed Changes in Telehealth Requirements

HIMSS supports CMS proposal to extend reimbursement for a wide variety of telehealth services through December 31, 2024. In addition, HIMSS supports CMS delay for requiring an in-person encounter within six months of a telehealth mental health

encounter. Currently, more than 150 million people live in federally designated mental health professional shortage areas, and with a significant increase in mental health challenges across the world since the beginning of pandemic, there is a critical need for a solution. Removing additional barriers for telehealth services for healthcare providers and patients will have an immediate positive impact on the lives of countless Americans. What's more, a HIMSS November 2020 report showed that telehealth has the ability to drive operational efficiency, reduce care team burden, shape patient engagement and improve quality and safety. Telehealth, particularly for mental health services, played a pivotal role in managing public health and maintaining continuity of care, and ensured the sustainability of health care delivery overall, during the COVID-19 pandemic.

HIMSS strongly encourages CMS to permanently end the requirement for Medicare beneficiaries in-person visit within six months of being treated via telehealth for mental and behavioral health services. Eliminating this arbitrary requirement will ensure that patients can fully leverage telehealth to get the care they need from home. HIMSS also asks CMS to consider, in addition to allowing audio/video-based counseling and therapy, to provide Medicare and Medicaid coverage for FDA-cleared prescription digital therapeutics for substance use and opioid use disorders and mental health conditions. Drug overdose deaths among U.S. adults aged 65 years and older quadrupled over roughly the last 20 years, and nearly 110,000 people died from drug overdoses in the United States in 2022. Leveraging telehealth to ensure these life-saving interventions reach the patients who need them can mitigate preventable deaths.

HIMSS supports CMS proposal to allow the teaching physician to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually through December 31, 2024. Furthermore, HIMSS calls on CMS to continue to allow a virtual presence for supervision in teaching settings beyond December 31, 2024. The HIMSS community has shared extensive feedback that virtual presence and supervision for residency programs has been very effective, with no drop in quality or safety outcomes. HIMSS would welcome the opportunity to connect CMS with HIMSS members in clinical settings to share additional observations and feedback.

Quality Payment Program and Medicare Shared Savings Program Quality Measurement and Reporting

Core to the HIMSS mission is promoting the use of health information and technology to improve the quality of healthcare delivery through effective performance measurement and decision support. HIMSS believes that digital health information can identify gaps in care, optimize clinical care delivery, and improve patient outcomes.

HIMSS does not offered recommendations on the clinical appropriateness of clinical quality measures proposed for inclusion in CMS programs. Instead, HIMSS cross-references proposed measures against a series of criteria to ensure those measures are accurate; meaningful to improving clinical care and patient outcomes; not overly burdensome to collect and report; and are actionable to improve clinical care. At a high level, the framework calls for new measures to be a(n):

A. **Meaningful measure of care quality:** Any new quality measure should utilize data to present a meaningful and actionable assessment of patient care. Emphasis

should be placed on the development of clinician-driven measures to support care-delivery meeting clinical standards of care, not merely meeting the data collection needs of payers.

B. **Accurate measure of care quality:** Any new quality measure should be lab/simulation tested, field-tested, and validated to produce comparable and consistent results against the measure's intent.
C. **Actionable measure of care quality:** Whenever possible, clinical quality measure data should be available in as close to real-time as possible to drive needed changes in workflows to eliminate gaps in care. The latency of data for clinical quality measures should be dictated by measure type. Performance data should be interoperable with data visualization tools that can easily identify gaps in care at the patient level.
D. **Not overly burdensome to collect and report:** Any new quality measure and associated policies should reduce the implementation and data collection burden on health systems, providers, and health information technology developers by using data already collected for care and without the introduction of new, inefficient workflows. We must ensure that data facilitates effective process change without overwhelming clinicians and resources.

Accordingly, HIMSS makes the following recommendations associated with electronic clinical quality measures (eCQMs) quality reporting for the QPP and MSSP programs:

1. In the 2024 IPPS proposed rule, CMS proposed new eCQMs, with the implementation date in reporting period 2025/payment year 2027. HIMSS recommends CMS consistently utilize the recommended 18-month implementation timeline for future eCQMs across all CMS quality reporting programs to ensure measure accuracy.

   Accuracy against the measure's intent and burden are often associated with rushed implementation deadlines. The healthcare industry cannot initiate the implementation of new measures until the measure's full set of specifications and code sets are finalized and available to the public. In previous public comments in response to Physician Fee Schedule proposed rules, HIMSS indicated that, on average, the industry needs 18 months from the moment that a new measure's specifications and code sets are available to implement the measure within the workflow of a healthcare organization in a manner where the data can be collected to produce comparable and consistent results with the measure's intent. In this proposed Physician Fee Schedule rule, CMS established a 2024 reporting year/2026 payment determination date for including the new proposed measure, Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level). By including the measure for 2024, there are only two months at best to implement the measure and incorporate the measure into clinical workflow in a manner consistent with HIMSS recommended glidepath for implementation. Further, the allotted implementation timeline is inconsistent with CMS own precedent for the Inpatient Prospective Payment System program.

2. In the 2024 IPPS proposed rule, CMS included detailed testing and feasibility data for each new quality measure. These types of data and testing information were not included as part of the Physician Fee Schedule proposed rule for the newly

proposed eCQM. HIMSS strongly recommends CMS include testing data, including the vendors participating and the number of test sites in future Physician Fee Schedule rulemaking.

Physician practices and healthcare systems often have unique configurations despite using the same electronic health record. As a result, there is significant variation in clinical documentation workflows from one EHR to another and from one healthcare organization to another. Field testing is critical to ensure accurate and valid data collection when the measure is implemented nationwide.

3. As CMS works towards transitioning to quality measurement programs, addressing the need for more robust and diverse testing will be critical to successful adoption. To facilitate increased participation, HIMSS recommends CMS consider the following policies:

    1) Ensure that the testing cohort for new and/or substantively updated eCQMs and dQMs include a significant sample size, including eligible clinicians across a wide array of care settings, geographic locations, and patient demographic spectrum.
    2) Provide a significant scoring bonus for eligible clinicians and other incentives for participants to support real world testing of eCQMs in the Quality Payment Program and other value-based care models. End to end testing of eCQM measure specifications is a multifaceted process requiring significant resources with complementary skill sets, including CQL, data and terminology standards, clinical/EHR workflows, data capture, mapping to local codes, data quality, and statistical analysis. Participation in testing by healthcare providers is costly, labor intensive, and have very little return on investment for the participating health systems and providers outside of an early opportunity to implement the measure. As a result, most end-user participation in the testing program comes from large, well-resourced organizations that may not reflect the configurations and support capabilities for a large portion of the healthcare ecosystem. CMS must ensure that measures produce accurate and actionable results in all potential care settings.
    3) A requirement for CMS-funded measure development and testing contracts to allocate sufficient funding to facilitate testing, mapping, and implementation work for field testing at testing sites.

4. Most current MVPs often include both eCQMs and abstracted clinical quality measures (CQMs.) HIMSS believes that MVPs will be more effective and meaningful if all elements are ultimately collected via eCQMs that meet the above criteria. Given the complexity of MVP reporting, HIMSS recommends CMS consider allowing eligible clinicians the option to meet the reporting requirements of the MVP by reporting the available eCQMs only and make CQM components of the MVP optional if all the eCQMs are reported in a manner consistent with the form, fashion, and data completeness requirements set by CMS.

    Members of the HIMSS community who are working to implement subgroup reporting using current MVPs in a multi-specialty group setting have indicated that several vendors are not supporting all MVPs. Multi-specialty practices looking

to implement MVPs are being forced to contract with multiple vendors to submit all clinician types within a practice. These organizations will also have to submit some NPIs via traditional MIPS reporting as there are not MVPs available for all specialties. This increases cost and complexity to reporting and disincentivizes providers acting in good faith to adopt the newest methods of quality measurement and reporting. HIMSS recommends CMS explore this issue before mandating the use of MVPs in measurement programs. HIMSS would welcome the opportunity to connect CMS leaders with practices experiencing these challenges.

The Promoting Interoperability Program: Reporting and Certification

As a matter of principle, HIMSS believes seamless, secure, ubiquitous, and nationwide data access and interoperable health information exchange should ensure that the right people have the right access to the right health information in a usable format at the right time to provide the optimal level of care. As proposed in the Physician Fee Schedule Proposed Rule, the Promoting Interoperability Program reporting requirements for the Quality Payment Program and the Medicare Shared Savings Program ensure eligible clinicians are meaningfully using certified health information technology to exchange vital health information to improve patient care and public health functionality.

HIMSS supports the proposed Promoting Interoperability Program reporting requirements for the Quality Payment Program and Medicare Shared Savings Program for calendar year 2024. Earlier this year, the Office of the National Coordinator published HTI-1, a proposed rule overhauling requirements for the functionality of certified health IT modules in the future. Striking the right balance between healthcare consumer expectations and market supplier and healthcare system capabilities is important to successful advancements in digital health transformation. After careful consideration, HIMSS recommended a modest delay for the deadline of December 31, 2024, for incorporating the complete set of new and revised certification criteria to December 31, 2025. The Office of the National Coordinator's proposed date does not allow for enough time to successfully complete the extensive work required to implement and test the certification changes across the healthcare ecosystem, while ensuring quality, safety, and patient privacy are not compromised. In addition, HIMSS recommended that new certification requirements have an 18-month implementation timeline following their finalization in rulemaking.

HIMSS does not want providers and health systems acting in good faith to be penalized by the Promoting Interoperability Program because of insufficient implementation time due to cascading delays associated with standards development, vendor implementation timelines, and staffing shortages that are impacting the whole community. Such a scenario would be more likely to negatively impact end-users who care for underserved and underinsured communities. Accordingly, HIMSS recommends CMS allow 18 months from publication of a final rule changing certification requirements before mandating their use as part of the Promoting Interoperability Program requirements for QPP and MSSP. In this scenario, if a change in certification requirements is published in rulemaking in October 2024, eligible clinicians should be utilizing certified health IT modules meeting those certification requirements starting in January 2026, not 2025.

Regarding CMS's proposal for certification criteria to be applicable for the CEHRT definitions in the QPP and MSSP Promoting Interoperability Program requirements automatically and without additional rulemaking if ONC updates relevant certification criteria, HIMSS supports this measure. HIMSS recommends CMS collaborate with ONC to actively promote certification comment opportunities through all available channels. This will ensure that stakeholders. especially eligible clinicians, are robustly and actively informing the development of certification policy. Active participation in the public comment process ensures federal regulators are aware of unintended challenges to implementation and resulting burden.

Appropriate Use Criteria Pause

HIMSS supports CMS temporary pause to the implementation of digital imaging Appropriate Use Criteria (AUC). While HIMSS did not receive feedback from the healthcare community regarding the real time claims issue cited as the rationale for the pause in the proposed rule, the HIMSS community did indicate that challenges with implementation and poor usability within clinical workflow mitigated the value added by AUC for digital imaging. While members of the community indicated some benefit through a reduction in inappropriate orders and some minimal cost savings, the clinical decision support mechanism (CDSM) tools were difficult to implement, not intuitive to use, and require a significant number of interruptive clicks within clinical workflow that disrupt patient care.

HIMSS would welcome the opportunity to connect CMS subject matter experts on AUC with our members discuss these usability issues and potential methods to improve the CDSM tools. There is potential for AUC to deliver ROI to both CMS and providers if these issues are corrected.

Health Related Social Needs (SDOH) Screening Reimbursement

HIMSS supports CMS for taking the initial steps to reimburse eligible clinicians for conducting social determinants of health screenings to identify health-related social needs (HRSNs) in Medicare beneficiaries. These initial steps, including the introduction of HRSN screening reporting in the last round of Physician Fee Schedule rulemaking, can generate insight into how to improve care access and quality for all people. The collection of SDOH data and incorporation of that data into risk stratification of patients and care decision-making should be a best practice adopted by all health systems. Furthermore, HRSN data can identify critical community needs that impact the health and wellbeing of vulnerable patient populations. Medicare and Medicaid payment and incentive models of care that embrace community-based solutions to address outcomes exacerbated by health insecurities currently don't pay at levels to sustain the needed capital investment and staffing to provide those services effectively.

In addition, HIMSS continues to encourage CMS to leverage work currently underway within consensus-driven efforts like the HL7 Gravity Project to develop standards for social determinants of health (SDOH) data to enable more efficient and actionable data collection. HIMSS also encourages CMS to publish an action plan detailing a pathway for creating more actionable SDOH-driven measurements.

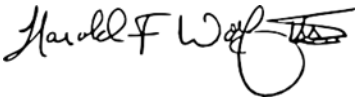
While CMS has suggested the person administering the screening does not have to have certain licensure to be performing the screening and documenting HRSNs on the problem list, HIMSS recommends CMS clarify this issue in future rulemaking. Clarifying that members of the healthcare team other than clinicians who are permitted to document within EHR's can administer and document the screening will allow providers to deploy SDOH screening in a broader manner.

HIMSS would be happy to facilitate discussions between CMS staff, HIMSS Davies Awards recipients and Stage 7 awardees, and HIMSS members with unique subject matter expertise who have launched programs to address HRSNs within their own patient population.

We look forward to the opportunity to discuss these issues in more depth. Please feel free to contact Jonathan French, Senior Director of Public Policy and Content Development with questions or for more information.

Thank you for your consideration.

Sincerely,



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