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transforming health through information and technology™

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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Administrator Verma:

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 Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1716-P). HIMSS appreciates the opportunity to leverage our members' expertise in offering feedback on the Promoting Interoperability Programs, as well as Inpatient Prospective Payment System (IPPS) quality measurement initiatives, and we look forward to continued dialogue with the Centers of Medicare & Medicaid Services (CMS) on these topics.

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. Through our innovation companies, 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.

As an association, HIMSS encompasses more than 77,000 individual members and 650 corporate members. We partner with hundreds of providers, academic institutions, and health services organizations on strategic initiatives that leverage innovative information and technology. Together, we work to improve health access, and the quality and cost-effectiveness of health care. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, United Kingdom, the Middle East, and Asia Pacific.

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

Electronic Clinical Quality Measure (eCQM) Reporting for the Inpatient Quality Reporting Program (IQR)

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 risk adjusted decision support. These actions drive improved adherence by clinicians to recognized standards of care. All quality measurement and reporting programs launched by government as well as private payers should reinforce the utilization of clinical interventions, which have the most significant impact on improving patient outcomes. The information collected through these programs must be utilized by the healthcare industry to identify gaps in care and opportunities to improve care outcomes.

In calendar year (CY) 2020, the CMS Inpatient Quality Reporting (IQR); Hospital Acquired Conditions (HAC) and Infections (HAI) Program; Hospital Readmissions Reduction Program (HRAP); and, the Promoting Interoperability Program (PIP) will soon reach a significant milestone—a full decade of quality data collection. During that time, CMS has collected a significant amount of process improvement measurement and outcome measurement data on the healthcare industry in the United States. However, HIMSS notes that despite the adoption of the Meaningful Measures Initiative criteria, the quality measurement programs discussed in the IPPS NPRM have seemingly stagnated.

Beyond removal of topped out measures and the addition of new measures focused around public health concerns like opioid addiction, HIMSS encourages CMS to leverage the data already collected since 2011. HIMSS has showcased evidence based use cases for leveraging information and technology in ways to improve outcomes through the Davies Award program. The Davies Award program has demonstrated how, in an individual health system setting, standardizing care and improving outcomes like reducing hospital acquired conditions and hospital readmissions by using information and technology to enforce and enable consistent practices consistent with the standard of care is within reach of every healthcare system. However, CMS has volume of data around process based measures which could demonstrate, through statistically significant evidence from a wide range of health systems, which processes for treatment to a specific clinical condition correlate consistently to improved outcomes across the country. CMS has an opportunity to frame the most impactful opportunities for health systems to improve care quality outcomes by sharing data which correlates which practices drive improved outcomes. The data demonstrating which processes correlate to improved outcomes also should drive CMS's development of priority measures for inclusion in future iterations of the CMS eCQM measure set.

In past iterations of the IPPS rulemaking process, HIMSS offered the following additional overarching recommendations for the development of quality reporting policies for the IQR program:

- CMS should select eCQMs that are feasible, actionable in as close to real time as possible, accurately reflect the quality of care delivered, and are designed to capture data as part of a normal care delivery workflow.
- CMS quality reporting policies should strive to enhance the value proposition of participating in quality reporting programs and ensure that eCQMs are actionable and meaningful for eligible hospitals (EHs) as well as patients to drive improvement in care

outcomes. As previously discussed, highlighting which measures directly correlate to the most significant improvement in outcomes will be a significant demonstration of the value proposition of delivering quality care.

- While CMS policies should reduce the implementation and data collection burden on eligible hospitals and health information technology developers by using data already collected for care and without introduction of new inefficient workflows, the removal of a measure from the CMS measure set should not come at the expense of creating a potential gap in care.
- CMS should select eCQMs that are proven to be feasible across all care delivery environments and ensure that eCQMs accurately reflect the quality of care delivered.
- CMS should incentivize, perhaps through scoring bonuses, eligible hospital participation in the development and testing of new eCQMs.
- CMS should incentivize, perhaps through scoring bonuses, utilization of technology which visualizes real-time performance on eCQMs.
- HIMSS encouraged CMS to continue to collaborate with accreditation organizations (e.g., the Joint Commission), private payers, and state governments to develop consensus, supporting a core measure set that closely aligns to the CMS eCQM menu set.

With the exception of the inclusion of new opioid-related eCQMs and the Hybrid Hospital-Wide All-Cause Readmission measure by 2024, HIMSS members have observed very little movement to adopt new measures that meet the above criteria. In this proposed rule, CMS proposes for EHs to report four eCQMs in CY 2020-CY 2021 for 90 days, and reduces that number to three eCQMs for any self-selected quarter within the calendar year. The proposed rule also includes mandatory reporting of the Safe Use of Opioids Concurrent Prescribing and Hospital Harm-Opioid Related Adverse Events eCQMs starting in CY 2021. Other eCQMs (Pressure Ulcer, Hypoglycemia) were floated as future eCQMs. With the IPPS being an annual publication, it will least 2 more reporting cycles before potential pressure ulcer and hypoglycemia measures can be included in the menu measure set. HIMSS encourages CMS to explore a more flexible to allow and give organizations some type of incentive for early adoption of new measures. This will allow a head start on identifying potential mapping and workflow issues which can be shared when the measures are finalized as part of the menu measure set. Otherwise, the adoption of meaningful measures which address care gaps will continue at a slow pace.

There is a significant gap in the availability of measures that are meaningful based on the Meaningful Measures Initiative to a multitude of specialties in the acute care space. Once new eCQMs that meet the Meaningful Measures Initiative criteria become available, HIMSS strongly encourages CMS to expand the measure set to target gaps in care and meaningful opportunities to improve care quality outcomes.

Opioid-Related Measures Should be More Outcomes-Focused

As noted in our comments on the FY 2019 IPPS Proposed Regulation, HIMSS is encouraged by CMS exploring the adoption of measures associated with battling the opioid addiction crisis that are more outcomes-oriented than measures previously proposed for federal quality reporting programs. The two proposed eCQMs (Mandatory Reporting of the Safe Use of Opioids—Concurrent Prescribing; and, Hospital Harm—Opioid-Related Adverse Events), reflect model clinical practices currently being employed at several HIMSS Davies Award of Excellence recognized hospitals, most notably at Ochsner Health System and Sparrow Health System.

However, while the proposed measures fill a significant public health need and are more outcomes-oriented, HIMSS members and several HIMSS collaborative partners have expressed concern about the feasibility and accuracy of the measures. The data elements and measure logic, particularly for the Opioid-Related Adverse Event measure, also have a high level of complexity. Mapping the necessary data elements from the electronic health record (EHR) to the appropriate format, and learning how to collect and transmit such data through the QualityNet portal will take some time.

Notwithstanding these concerns, we do support CMS's proposal for mandatory reporting of the two new opioid measures starting in CY 2022, and would encourage CMS to look for avenues to make these mandatory before that time. HIMSS has observed that voluntary reporting for CMS measures does not historically generate the capture and reporting of the measure in enough volume to identify solutions to challenges with data mapping and capture. However, given the identified issues with these measures, HIMSS strongly recommends that CMS not include the results in any public reporting or factor these results into payment adjustments until the data has been tested and affirmed for validity and reliability.

Proposed Mandatory Reporting of the Hybrid Hospital-Wide Mortality (HWR) Measure Starting in 2023

HIMSS strongly encourages moving away from claims-based measurement for CMS programs measuring patient outcomes. Using the Meaningful Measures Initiative criteria, HIMSS has the following observations regarding the proposed voluntary reporting Hybrid Hospital-Wide Mortality (HWR) with EHR Data quality measure in CYs 2021 and 2022, as well as the mandated reporting of the Hybrid HWR measure starting on July 1, 2023, as part of the IQR program.

Since the Hybrid HWR uses clinical data elements, it is more conducive to quick and detailed root-cause analysis, and therefore is a more meaningful driver of care improvement. It also negates the need for burdensome manual chart abstraction and review. However, reporting data through Quality Reporting Document Architecture (QRDA) I for hybrid measures continues to be burdensome for EHs.

In addition, HIMSS has concerns with respect to using a voluntary approach for reporting the Hybrid HWR as it may not generate the capture and reporting of the measure in enough volume to identify solutions to challenges with data capture in CYs 2021 and 2022. This proposal could lead to significant challenges with the capture of accurate and meaningful performance data by EHs when mandatory reporting starts in CY 2023. Past quality reporting initiatives conducted on a voluntary basis, for example, voluntary electronic reporting of quality measures in Stage 2 of the Meaningful Use program, failed to generate enough voluntary submissions to identify potential problems with electronic data submissions once it became a requirement.

HIMSS also expresses concern about CMS's proposal for a full-year data capture period starting every July. For other quality programs, CMS uses a calendar year framework for reporting periods.

Based on these concerns, HIMSS recommends the following to CMS regarding the adoption of the Hybrid HWR measure:

- CMS should start mandatory reporting of the Hybrid HWR measure starting in CY 2021. However, CMS should not include the results in any public reporting or use this measure as a factor in payment adjustments until the data has been tested and affirmed for validity

and reliability. Once CMS confirms that the data generated by Hybrid HWR measure submissions is a feasible, properly risk adjusted, and accurate reflection of the care delivered in cases of mortality, the Hybrid HWR should be factored in determining payment adjustments.

- CMS should collect Hybrid HWR data for a full CY for each payment period. HIMSS recommends CMS not utilize a July 1-June 30 reporting period for the HWR measure.

In addition, several HIMSS members expressed concern that the clinical data elements in the Hybrid HWR measure alone may not risk-adjust thoroughly to truly reflect the level of acuity of most of their patients. HIMSS is encouraged by the recent development of risk adjustment models using EHR data elements and the potential for inclusion of sociodemographic adjustment in future Hybrid Readmission measures. HIMSS strongly encourages CMS to explore utilizing more robust elements reflecting social determinants of health and behavioral health data to more effectively risk adjust scoring performance on the HWR measure.

HAC and HAI Program Outcomes Reporting

HIMSS members also noted the discussion about potential future eCQMs for patient safety on clinical issues like hypoglycemia, pressure ulcers, and caesarean births. We are encouraged that CMS is exploring the use of eCQMs to measure patient safety outcomes and urge CMS to expedite the measure development process for these measures, focused on what are meaningful and actionable measures of care, are not overly burdensome to collect and report, and are fully tested and field tested to produce comparable and consistent results against the measure's intent.

HIMSS supports the idea that the accuracy and the ability to report measures across the nation are better supported by capturing the actual clinical data elements that demonstrate a quality measure was met. While HIMSS understands the appeal of using different types of coding schemes and repurposing them as proxy measurements of quality, we are not convinced they truly capture the quality of care provided to patient populations. Using the Meaningful Measures Initiative criteria, HIMSS feels that claims-based measurement for the HAC and HAI program is not patient centered and meaningful to patients and does not reflect a significant opportunity for improvement.

The specifications and rules regarding how a coding professional determines the codes to associate with a specific patient encounter are completely removed from how a quality measure abstractor determines how a measure was or was not met. Some HIMSS members report that their quality measure abstractors interact frequently with their coding department personnel to request coding corrections that support a quality measure specification, only to be informed that the coding, submitted for reimbursement, does not support the quality abstractor's finding. More often, provider resources are used to make documentation improvements rather than clinical care improvements, to support claims-based quality reporting and, in some cases, providers are driven to forgo higher levels of reimbursement to meet quality measure criteria.

In essence, the majority of decisions regarding these types of codes are driven towards optimizing the provider's reimbursement and Diagnosis-Related Grouping (DRG), not to support measuring the quality of care provided. In addition, claims-based codes do not incorporate nor support robust risk adjustment models that would make comparability of providers' performance across the nation more accurate and reflective of their patient population. While HIMSS supports the inclusion of these claims code systems in quality measurement for the purpose of risk adjusting measure

performance, we believe they should be used to strengthen the validity of eCQMs and not as a stand-alone quality measure.

Organizations involved with the feasibility testing of de-novo eCQMs designed to extract data from an EHR-enabled clinical workflow have indicated that significant progress is being made to extract meaningful clinical data from EHRs while minimally affecting current workflow. eCQMs are much more meaningful measures of care than claims data, and can be much easier to risk adjust to account for socioeconomic status and health history that leads to appropriate national comparisons of care.

HIMSS strongly recommends that these and other future proposed eCQMs must be thoroughly tested for validity, reliability, and feasibility. Field-testing prior to general release would improve the quality of the specifications (e.g., endorsement by National Quality Forum (NQF)) and ensure that the measures produce comparable and consistent results against the measure's intent. We continue to recommend that the eCQM testing process include the target system to be tested, and include sample testing at each site implementation. To this end, CMS should continue to provide measure implementers (vendors), a set of sample data, testing examples/decks, and an Implementation Guide that can be used by vendors during their implementation and testing.

Proposed New Technology Add-On Payment Pathway for Devices

HIMSS is encouraged that CMS is looking to find more ways to facilitate Medicare beneficiary access to transformative technologies that treats serious or life-threatening diseases or conditions for which there are unmet medical needs. We support the intention to allow medical devices that have participated in one of the Food and Drug Administration's (FDA) expedited Breakthrough Device programs and received FDA market authorization to bypass certain existing barriers and become immediately eligible to receive an add-on payment. However, we do have reservations that this FDA program is still in its relative infancy.

HIMSS equates support for the intention of this program with our endorsement of the concept underlying FDA's Digital Health Software Precertification (Pre-Cert) Program. The Pre-Cert Program provides for a more streamlined and efficient regulatory oversight of software-based medical devices developed by manufacturers who have demonstrated a robust culture of quality and organizational excellence, and who are committed to monitoring real-world performance of their products once they reach the U.S. market. HIMSS has emphasized support for the concept underlying Pre-Cert in previous public comment letters.

HIMSS recommends that if CMS finalizes the add-on payment pathway proposal, the agency should continuously work in tandem with FDA to better understand the evolving successes and challenges of this program and how that will affect CMS reimbursement policies for medical device technology. We urge CMS to ensure that it fully appreciates and maximizes the potential of this proposed pathway. The streamlined concept underlying the Breakthrough Device Program is sound and aligned with the rationale behind previous FDA proposals that have emphasized the benefit of restructuring pathways for medical device technology to enter the market with FDA approval.

These past proposals have also helped advances in technology to flourish more rapidly. We supported recent proposals put forth by FDA that attempted to communicate the same desire to

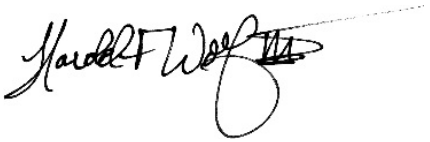
expedite the processes involved in introducing evolving technologies in a timely manner, without losing sight of good manufacturer processes or quality standards as well as assurances.

Overall, we find this program to be forward-thinking and one that could eventually be seen virtually setting-neutral, considering the existing possibilities of medical device technology as well as those that come in the future. We urge CMS to prioritize the importance of ongoing inter-agency discussions on this topic as well as promote the idea of extending the dialogue and collaboration opportunities into the health care technology community participating in these programs.

Such discussions should include evolving developments as well as the accompanying reimbursement components. We also emphasize the need to continuously monitor and publicly communicate the progress of these new programs through annual reports and official agency communications. This is necessary to ensure that the major aims of these programs continue to be consistent with protecting and promoting public health.

We look forward to the opportunity to further discuss these issues in more depth. Please feel free to contact Jeff Coughlin, Senior Director of Federal & State Affairs, at 703.562.8824, or Eli Fleet, Director of Federal Affairs, at 703.562.8834, with questions or for more information.

Sincerely,



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