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September 30, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-1850

Dear Mr. Slavitt:

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 CMS-5519-P Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR), which was published in the Federal Register August 2, 2016. HIMSS appreciates the opportunity to leverage our members' expertise in commenting on this NPRM. We look forward to continuing our dialogue with the Centers for Medicare & Medicaid Services (CMS) on the continued shift of Medicare payment from quantity to quality in hopes of delivering better care to patients at a lower cost.

HIMSS is a global, cause-based, not-for-profit organization focused on better health through information technology (IT). In North America, HIMSS focuses on health IT thought leadership, education, market research, and media services. Founded in 1961, HIMSS North America encompasses more than 64,000 individuals, of which more than two-thirds work in healthcare provider, governmental, and not-for-profit organizations, plus over 640 corporations and 450 not-for-profit partner organizations, that share this cause.

HIMSS commends CMS for developing this NPRM and financially incentivizing episode payment model (EPM) participants to engage in care redesign efforts to improve quality of care and reduce Medicare spending. CMS and the Center for Medicare & Medicaid Innovation (CMMI) should continue to pursue efforts to facilitate the creation of innovative care delivery models and learn from their advances what works for certain populations and in particular geographic areas.

We offer the following comments and recommendations on the relevant areas of this NPRM to HIMSS:

Section III.A. Selection of Episodes for Episode Payment Models in the Rulemaking and Potential Future Directions

HIMSS appreciates CMS and CMMI's goal in seeking public feedback on the various parameters for future rulemaking requirements. We offer a few suggestions on how to possibly improve the selection of episodes for EPMs in the future.

HIMSS recommends ensuring that the disclosure of partner contracting is required for the episode payment models included in this NPRM. It is crucial that in order to receive the bundled payment, hospitals must demonstrate that they have contracts in place with all the involved clinicians and post-acute care providers. HIMSS members reported that there have been many instances where some post-acute care providers have been reluctant to negotiate contracts because they want to avoid any additional payment requirements under these kinds of arrangements. Including partner contract disclosure as a rulemaking requirement should help ease those concerns.

HIMSS also recommends that CMS require full disclosure of the total bundle payment amount and how much is being distributed to each participant in a patient's care. We want to ensure the cost of care delivery is as transparent as possible.

In addition, HIMSS suggests that CMS facilitate the creation of an electronic tool with a standardized methodology to compare costs, so participants can know that they are selecting the most cost-effective partner in care, and that they know that the true costs of care are being covered. The community needs effective software tools to help practices or hospitals calculate their true costs of providing care, as well as to help practices or hospitals estimate the risk they are incurring. Predictive modeling software systems are a key component here. Having one participant in the bundle that is actually subsidizing the bundle, knowingly or unknowingly, will lead to the failure of that bundle to survive and thrive.

Overall, our members expressed concern that without transparent contracting and financial data requirements, many independent (non-hospital owned) practices will be hesitant to participate in bundled payment arrangements managed by hospitals.

Third, HIMSS recommends CMS provide a timely feedback loop with all bundle participants to challenge and correct payment results that are not accurate. At this time, there is no process or data system in place for this function. The lack of a feedback loop will be an increasingly critical barrier to participation as the current system has been known to make errors. We must avoid the situation where a partner group drops out of this model because they missed targets on account of inaccurate data.

Finally, a key component of any bundled payment model is the ability of clinicians to communicate across settings of care. There are certain communications that do require documentation, such as operative reports, pathology reports, or imaging, so it is helpful to have interfaces that allow clinicians to pull data from their participating systems and practices. HIMSS encourages CMS to be explicit in this Final Rule on encouraging and fostering the use of health information exchange mechanisms to ensure that the right information on the right person is available to the clinician at the right time.

Section III.C. Episode Definition for EPMs

HIMSS supports the provision in the NPRM that all related services supporting all three EPM models should be included in the coding and reimbursement structure with exclusions only for related services that are irrelevant to the diagnosed EPM procedures. The proposed approach appears to be a significant step toward simplification of the reimbursement process.

HIMSS asks for reconsideration of the inclusion of related services in this provision to ensure that "new technology" can be accessed, utilized, and reimbursed as part of EPMs. Related services, categorized as "new technology" or other examples, that at some point may result in improved outcomes and increased care coordination benefits, are not included in the EPM models because of their potential for upward distortion in the creation of accurate cost basis information for EPM reimbursement rates. While their usage is not prohibited by EPMs, their reimbursement process will be separate and apart from EPMs. This will add complexity and potentially hinder their usage in normal day-to-day care protocols.

Section III.D. Methodology for Setting EPM Episode Prices and Paying EPM Participants in the AMI, CABG, and SHFFT Models

HIMSS endorses the methodology and considerations represented in Section D. Overall, the measures and information described in this section are well thought out and well-constructed.

In the Final Rule, HIMSS asks CMS for clarification on the trend calculations. The NPRM describes Program Year 1 and Program Year 2 as well as the data for calculating the benchmark prices for both years. We request that CMS apply more trend data when the move to the program year timeframe is implemented. Specifically, we would like to see an additional two years of trend data for Program Year 1, to bring the data up from 2015 to the 2017 program level. In addition, we would like to see CMS apply another three years of trend data to bring the 2015 claims up to the 2018 level. Similar trend errors are being proposed in additional program years, where CMS is trending to the end of the benchmark three-year period, but not trending from the end of the benchmark period to match the time period for which the prices will be applied to reimburse providers.

HIMSS also notes that the proposed timeframes for reconciliation are reasonable. CMS is attempting to get this process done quickly with two months of claims run-out for the prior calendar year. However, the agency reserves the right to perform a second reconciliation given the one-year Medicare claims submission rules. HIMSS supports both processes as necessary, as this creates a good faith effort to pay incentives in a timely manner, while reserving the right to appropriately ensure delayed claims submissions do not create aberrations in the process.

Section III.E. EPM quality measures, public display, and use of quality measures in the EPM payment methodology

CMS is proposing a quality measure structure in this section of the NPRM that builds on its other innovative payment and service-delivery models. The real issue for participants is ensuring that they have enough capacity to collect the appropriate information and the ability to ensure data alignment as those factors are most critical for programmatic success.

During an episode, care can be provided at a variety of locations. HIMSS is concerned that it will be difficult to link episode data from all the various sources (hospitals, skilled nursing facilities, clinical practices, and other providers). A unified analysis of these episodes of care requires detailed data for both the hospitalization and the post-discharge period. Gathering that data can be a daunting exercise; however, the anchor facility needs the comprehensive view in order to

properly assess episode outcomes to identify areas of success or needing improvement. Such a scenario places a high premium on the importance of standardized quality measure reporting and the use of health information exchange mechanisms—ensuring that the right information on the right person is available to the clinician at the right time.

For example, the NPRM cites both the Hybrid AMI Mortality (NQF #2473) measure as a replacement for the current publicly-reported MORT-30-AMI (NQF #0230) measure in the EPM models, but does not provide a clear definition of what is meant by 'when appropriate.' To ensure consistent application, HIMSS recommends that CMS clarify when it is appropriate to use each Acute Myocardial Infarction (AMI) model quality measure.

In terms of submission of AMI voluntary data, the NPRM discusses how model participants that are voluntarily submitting data will receive hospital-specific reports that detail submission results from the most recent performance period. However, for the measures that are not all claims based, the NPRM proposes to use a simple spreadsheet in year 1 and Quality Reporting Document Architecture (QRDA)-I files in subsequent years. This scenario requires extra work and puts a burden on providers to implement one solution for the first year, then a completely different implementation after one year. Also, additional details about the spreadsheets will be needed, including how standardized they will be and who will specify the format, will it be IT vendors or will it be CMS be providing the spreadsheets?

Section III.I Financial Arrangements under EPM

The NPRM excludes the proposed EPM episodes beneficiaries who are aligned to the Next Generation Accountable Care Organization (ACO) model or tracks of the Comprehensive End-Stage Renal Disease (ESRD) Care Model incorporating downside risk for financial losses. But the question remains how EPM participants will identify these individuals. An organization's participation in these programs is not necessarily known to the beneficiary or clearly indicated on a beneficiary's health insurance card or medical record. CMS needs to clarify how an EPM participant would know who these individuals are and that they should not be included in their EPM-related activities.

In addition, CMS asks for feedback on its definition of EPM collaborators. HIMSS supports the idea that CMS not restrict the categories of EPM collaborators, but it should allow market forces to feed the creative innovation of EPM participants and their community partners to determine the financial partnerships that would be most beneficial to achieving the overarching goals of the EPM. Organizations whose business models do not provide a good fit for this type of financial arrangement will automatically exclude themselves. In addition, being too prescriptive in the rule regarding who can and cannot participate does not allow for the introduction of new players in the market that may have the potential to generate substantial cost savings for providers participating in the episodes.

Moreover, in terms of the requirement that all technology be returned to EPM participants at the end of the episode, there may be situations where the patient may continue to benefit from use of the technology beyond the 90-day post-discharge window. These benefits could reduce the future need for urgent or emergent care and impact the overall future cost to Medicare to care for this beneficiary. HIMSS asks CMS to establish a process or criteria to evaluate whether a beneficiary

should be able to keep the technology and continue using it, ensuring that any new policies take into the account the need for flexibility at the local level to provide benefits to patients, the community, and the health system as a whole.

If CMS decides not to establish a process here, HIMSS suggests that documentation of beneficiary engagement incentives include written acknowledgement by the patient or their representative that the technology remains the property of the EPM entity and must be returned upon completion of the episode of care.

Section III.J. Proposed Waivers of Medicare Program Requirements

HIMSS supports the waivers included in the NPRM, particularly for telehealth services in EPMs. We urge expansion of the role of both telehealth technology and program requirements in this final rule. It is important for achieving the overall goals and objectives of healthcare transformation to facilitate the use of remote patient monitoring and telehealth tools in EPMs. CMS's regulations and policies should reflect the dynamic and transformative nature of telehealth-related solutions, and enable innovation that can continually improve patient care.

The agency is proposing to waive the geographic site requirement and the originating site requirement for telehealth services to permit telehealth visits to originate in the beneficiary's home or place of residence. This waiver would allow providers and suppliers furnishing services to EPM beneficiaries to utilize telehealth for beneficiaries who are not classified as rural and to allow the greatest degree of efficiency and communication between providers, suppliers and beneficiaries. In addition, the facility fee paid by Medicare to an originating site for a telehealth service is waived if the service was originated in the beneficiary's home. However, the rule does stipulate that all telehealth services will be furnished in accordance with all other Medicare coverage and payment criteria.

In this implementation, CMS should allow even greater flexibility for EPM bundled payment services and proceed further by allowing a waiver for technological restrictions.

Given the extraordinary advances occurring in the health IT field, CMS's 15-year old definition of the statutory term "telecommunications system" requiring the use of "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication" is out-of-date. The agency's position that no form of asynchronous communication may be used to provide covered telehealth services is based on a rigid interpretation under Section 1834(m) of the Social Security Act; instead, only asynchronous communication utilizing store-and-forward technologies are not permitted except in specified demonstration projects. There is no statutory restriction prohibiting CMS from replacing its outdated reference to "audio and video equipment permitting two-way, real-time interactive communication" in 42 CFR 410.78(a)(3).

In addition, it is important to note the HIMSS perspective on the following telehealth-related definitions:

Store and Forward: The store and forward restriction overlooks the value of information (such as patient generated and remote patient monitoring data) that is not gathered during a telehealth visit.

Patient generated health data is routinely highlighted as an enabler of engaged, patient centric models of healthcare. Many recent technological developments rely on discrete and structured data elements which can enhance a telehealth encounter. Many new platforms that enable remote patient monitoring rely on store and forward practices. There is an opportunity to gain better historical information and improve patient outcomes by relaxing the store and forward exclusions. Further, advancements in technology beyond simple two-way communications have eclipsed the need to preclude store and forward limitations.

Two-way audio/visuals: The two-way audio/visual requirement restricts the range of telehealth interactions that can occur between clinicians and patients as it rejects e-mail, phone conversations, and other modes of asynchronous telecommunication relying only on real-time/active audio and video interactions. As noted above, many new and novel health interventions, several which are low cost, rely on store and forward technology or leverage an active alert management structure beyond audio-visual communication.

We note that communication occurs when a remote monitoring device generates data. Further, the two-way visual/audio requirement may preclude telehealth services in rural areas inaccessible due to limited or unreliable broadband connectivity. We remain cautious about the narrow definition of an interactive telecommunications system that could potentially be leveraged which confines greater access to innovative technology.

Section III.K. Data Sharing

HIMSS supports much of what CMS is proposing for data sharing in EPMs. What the agency is proposing is similar to its approach for ACOs and other value-based programs. From our perspective, the most significant issue is CMS' ability to manage the number of data extracts and reports along with other workloads to ensure quality, timeliness, and proper assigning of data. Much like the agency has implemented in other initiatives, HIMSS encourages CMS to use master data management technology to help ensure correct patient/provider alignment across these programs.

HIMSS remains committed to fostering a culture where health IT is optimally harnessed to transform health and healthcare by improving quality or care, enhancing the patient experience, containing cost, improving access to care, and optimizing the effectiveness of public payment. 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.

Thank you for your consideration.

Sincerely,

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