

October 16, 2017

Seema Verma, MPH Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Hubert H. Humphrey Building, Room 445-G 200 Independence Ave. SW Washington, DC 20201

Ref: CMS-5524-P: Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model

Dear Ms. Verma,

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates and supports the Centers for Medicare & Medicaid Services' (CMS') work to encourage improved care delivery across the entire health care industry. We are pleased the agency recognizes the provider burden and challenges presented by mandatory participation in new and existing episode payment models (EPMs). America's Essential Hospitals appreciates CMS' proposed actions to ameliorate the models' overwhelming pace and scope, which impede the ability of essential hospitals—those dedicated to serving the vulnerable—to enhance patient experience, improve health outcomes, and lower costs. However, we ask CMS to consider the unique challenges inherent to caring for vulnerable patients when making final changes to current models, such as the Comprehensive Care for Joint Replacement (CJR) model, and carrying out future demonstrations.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including low-income Americans and others who face economic and social hardships. Filling a vital role in their communities, our 325 member hospitals provide a disproportionate share of the nation's uncompensated care, with nearly 75 percent of their patients receiving Medicaid or Medicare coverage. Our member hospitals also drive significant economic activity in their communities, directly employing thousands and supporting other employment and commerce far beyond their walls.

Essential hospitals treat more patients who are dually eligible for Medicare and Medicaid than the average hospital. These patients often have comorbidities and

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chronic conditions and are among the most complex to treat. Our members provide state-of-the-art, patient-centered care while operating on margins less than half that of other hospitals: 3.2 percent in aggregate compared with 7.4 percent for all hospitals nationwide.¹ Through their integrated health systems, members of America's Essential Hospitals offer the full spectrum of primary through quaternary care, including trauma care, outpatient care in ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services critical to vulnerable patients. Many of the specialized inpatient and emergency services they provide are not available elsewhere in their communities. In some cases, our members provide the only source of high-acuity services, such as level I trauma care, for multiple states.

The high cost of providing complex care to low-income and uninsured patients leaves essential hospitals with limited resources, driving them to find increasingly efficient strategies for providing high-quality care to their patients. Essential hospitals constantly engage in robust quality improvement initiatives, from reducing patient harm by preventing falls and bloodstream infections to reducing readmissions. For example, one essential hospital in Missouri developed a care transitions program that led to fewer hospital admissions, fewer emergency department visits, and cost savings. This hospital identified the need to establish a multidisciplinary team, bringing together licensed clinical social workers, client-community liaisons, and advanced practice registered nurses, among other staff, so that the hospital could focus on not only the clinical, but also the social issues affecting their patients.

But improving care coordination and quality while maintaining a mission to serve those in greatest need is a delicate balance. Some essential hospitals were selected to participate in the mandatory CJR model and are currently in the second performance year of that model. Others have voluntarily opted to participate in alternative payment models, such as the Medicare Shared Savings Program, investing in infrastructure development to become part of an accountable care organization. Whether through mandatory or voluntary payment models, our members face challenges finding the resources necessary for participation, including technology upgrades, process redesign, personnel changes, care coordination, expanded quality measurement, risk management, compliance, network development, governance, and legal restructuring. These resource constraints will continue to affect essential hospitals that have been selected for continued mandatory participation in the CJR model, as well as future models, both voluntary and mandatory.

Also, quality measures chosen for the CJR model continue to lack appropriate risk adjustment for factors outside a hospital's control. As such, essential hospitals participating in the CJR model are disproportionately disadvantaged based on the quality metrics used to evaluate performance and calculate reconciliation payments.

For these reasons, America's Essential Hospitals supports the cancellation of the EPMs and CR incentive payment model, as well as the proposed reduction in

¹ Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2015 Annual Member Characteristics Survey. America's Essential Hospitals. June 2017. www.essentialdata.info/. Accessed September 27, 2017.

overall number of hospitals required to participate in the CJR model. But we urge CMS to consider the following comments when modifying provisions for the remaining years of the CJR model and developing future voluntary initiatives.

1. CMS should finalize the cancellation of the EPMs, including the expanded CJR model—i.e., surgical hip and femur fracture treatment (SHFFT) model—and the CR incentive payment model.

America's Essential Hospitals previously voiced its concerns about the mandatory nature, scope, and implementation speed of demonstrations put forth by CMS' Center for Medicare and Medicaid Innovation (CMMI) in recent years. These mandatory models are particularly concerning when other providers have the option of voluntarily participating in demonstration models, such as bundled payments for care improvement (BPCI). CMS only recently released the second-year evaluation of BPCI and the results from the first year of the CJR model. CJR model participants have had minimal experience and need to become familiar with one demonstration before they are required to participate in two or more simultaneous models—i.e., the EPMs for heart attack, bypass services, and SHFFT, as well as the CR incentive payment model. America's Essential Hospitals does not support mandatory participation in demonstration payment models.

In the proposed rule, CMS concluded that certain aspects of the design of the EPMs and CR incentive payment model should be improved and more fully developed. We agree and emphasize the concern raised by stakeholders, and acknowledged by the agency, related to the quality measures established for the SHFFT model. Specifically, that the measures chosen are not clinically related to the target population and are inappropriate for assessing care provided to beneficiaries in the SHFFT model. Based on this and other concerns, CMS proposes to cancel the EPMs and CR incentive payment model before they begin. We are pleased CMS acknowledges the provider burden and challenges these new EPMs present, and support the agency's proposed cancellation of the EPMs and CR incentive payment model.

2. CMS should limit the size and scope of the CJR model, ensure flexibility for participants that choose to continue on a voluntary basis in the model, consider the amount of resources required for participation by essential hospitals in remaining mandatory metropolitan statistical areas (MSAs), and adjust the quality measures to account for social risk factors.

The CJR model, which began April 1, 2016, is in its second performance year, and currently requires participation by all hospitals, with limited exceptions, in 67 MSAs. Participating hospitals must stay in the model through December 31, 2020.

CMS seeks to limit the geographic reach of the CJR model by proposing that it continue on a mandatory basis in only 34 MSAs. Hospitals in the remaining 33 MSAs would continue voluntarily. Further, CMS proposes that low-volume or rural hospitals also would continue on a voluntary basis in all 67 MSAs. These hospitals would have a one-

time election to continue their participation in the CJR model voluntarily (opt-in) for performance years three through five.

We believe demonstrations should be used in a manner that drives quality improvement without placing undue burden on essential hospitals. As such, we support CMS' reduction in the overall number of hospitals required to participate in CJR and the option for hospitals to elect to participate voluntarily moving forward. However, we offer the following considerations regarding how participants would opt in to continue voluntarily, as well as concerns about the model itself and about the essential hospitals still required to participate through December 31, 2020.

a. CMS should ensure flexibility and reduce the burden for participants that decide to voluntarily continue in the model.

For hospitals eligible to opt in to the CJR model and that continue their participation, CMS intends to provide a template that must be completed and submitted by the proposed January 31, 2018, submission deadline. Current CJR participants must evaluate their first performance year results and balance the potential for reconciliation payments under the CJR model against the administrative burden participation requires. As such, we believe the proposed January 31, 2018, deadline for submission of intent to continue in the model voluntarily is reasonable. However, we urge CMS to ensure the template is clear and concise, so that hospitals can easily submit their intent to voluntarily participate in the CJR model.

Further, we ask CMS to clarify the duration of a hospital's voluntarily participation. Specifically, CMS proposes that a hospital's participation election letter, if received no later than January 31, 2018, would serve as the model participant agreement. Voluntary participation would begin February 1, 2018, and continue through the end of the CJR model—i.e., December 31, 2020. We urge CMS to provide flexibility to those participants electing to continue voluntarily, such that these participants retain the ability to voluntarily terminate their participation at any time before the end of the model. Assuring participants in the 33 voluntary participation MSAs, and rural and low-volume hospitals, that a one-time voluntary participation election does not bind them to three additional performance years in the model might increase the number of hospitals that elect to continue voluntarily.

b. We urge CMS to consider the amount of resources required to coordinate care for patients with social factors affecting treatment plan adherence, as well as the challenges essential hospitals face caring for vulnerable patients with complex, post-discharge needs.

The CJR model places financial risk solely on participant hospitals—as the episode initiators—based on CMS' assumption that "hospitals are more likely to have resources that would allow them to appropriately coordinate and manage care throughout the episode." By holding only hospitals accountable, CMS fails to recognize that not all hospitals have these resources and that significant up-front investments are necessary to control downstream episode costs. Essential hospitals often lack the ability to make

significant early investments, which can lead to poor performance in the CJR model and unfair penalties. They will not receive reconciliation payments and will be responsible for repaying Medicare simply because they lack the resources other hospitals have to build a care coordination infrastructure.

The financial preparations essential hospitals must make to participate in the CJR model—while operating on margins substantially lower than other hospitals—have proved substantial. For example, an essential hospital in Colorado committed significant resources to preparing for mandatory CJR participation, including fully examining its process for providing joint replacement services, identifying areas for improvement, training staff, developing patient education, and collaborating with post-acute care providers.

In selecting the MSAs that would continue mandatory participation in the CJR model, CMS ranked the 67 MSAs now required to participate in the model by average, wage-adjusted, historic lower extremity joint replacement episode payments and selected the 34 MSAs with the highest average payments. This selection method includes essential hospitals that lack the resources or ability to succeed under CJR. CMS concedes that hospitals within the higher-cost MSAs—i.e., those 34 MSAs that would continue on a mandatory basis—still have significantly varied characteristics and experiences. Essential hospitals face the compounded task of identifying a patient's or caregiver's capability and availability to provide necessary post-discharge care, as well as the availability of community-based services, including non-health care services, such as transportation, meal services, housing for homeless patients, and language assistance. We urge CMS to consider the amount of resources required to treat certain patients, such as those with complex conditions and social risk factors, as well as the readiness of certain providers to adopt new payment models, such as CJR model.

c. CMS should include only quality measures closely related to the procedures targeted in the CJR model, appropriately adjusted to account for social risk factors, and monitor for unintended consequences of participation by essential hospitals that serve the vulnerable.

America's Essential Hospitals continues to have concerns about the measures in the CJR model—particularly for outcomes measures, as these measures are not adjusted for social risk factors and, therefore, do not accurately represent the quality of care essential hospitals provide. CMS should modify the methodology for calculating a participant hospital's quality threshold to include adequate risk-adjustment for sociodemographic factors, including socioeconomic status.

In previous comments on hospital inpatient quality reporting programs, we urged CMS to consider the sociodemographic factors—language and existing level of post-discharge support, for example—that might affect patients' outcomes and include such factors in the risk-adjustment methodology. We made these comments out of a preponderance of

evidence that patients' sociodemographic status affects outcomes of care.² Outcome measures do not accurately reflect quality of care if they do not account for sociodemographic factors that can complicate outcomes. For example, patients who do not have a reliable support structure at discharge are more likely to be readmitted to a hospital or other institutional setting.

As required by the Improving Medicare Post-Acute Care Transformation Act, HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) in December 2016 released a report that clearly showed the connection between social risk factors and health care outcomes.³ The report provided evidence-based confirmation of what essential hospitals and other providers have long known: Patients' sociodemographic and other social risk factors matter greatly when assessing the quality of health care providers. We urge CMS to further consider the ASPE report recommendations for incorporation in the CJR model.

Further, as noted by the National Academies of Sciences, Engineering, and Medicine (the Academies) in its series of reports on accounting for social risk factors in Medicare programs, "achieving good outcomes (or improving outcomes over time) may be more difficult for providers caring for patients with social risk factors precisely because the influence of some social risk factors on health care outcomes is beyond provider control."

Failing to account for sociodemographic factors in savings models, such as the CJR, can have the perverse effect of harming rather than helping patient outcomes and health care disparities—making essential hospitals responsible for repayment to CMS diverts crucial resources away from improving care for vulnerable patients. Lack of risk adjustment also can mislead and confuse patients, payers, and policymakers by shielding them from important, community-level factors that contribute to worse outcomes. America's Essential Hospitals urges CMS to include in the CJR model only measures that are risk-adjusted for factors related to a patient's background, such as socioeconomic status, language, and post-discharge support structure.

Additionally, we continue to disagree with CMS' inclusion of the Hospital Consumer Assessment of Healthcare Providers and Systems survey measure in the CJR model. A measure assessing patients' experience with inpatient care is a poor measure of quality across a 90-day episode, most of which will occur after the patient leaves the hospital. We point CMS to its discussion in this proposed rule, based on comments received by stakeholders, on the cancellation of the EPMs—namely, that the quality measures

² See, e.g., America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. October 21, 2015. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed August 2017.

³ Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Washington, D.C.; December 2016.

https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf. Accessed April 7, 2017.

⁴ National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in

Medicare Payment. Washington, D.C.: The National Academies Press; January 2017. http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx. Accessed April 7, 2017.

chosen for the SHFFT model are not clinically related to the target population and are inappropriate for use in assessing care provided to beneficiaries in the model. Likewise, **CMS should include in the CJR model only measures closely related to the procedures targeted in the model and that accurately represent quality of care across a 90-day episode.** Doing so will assist hospitals as they work to improve outcomes for these conditions and benefit the public by accurately reflecting the care offered by hospitals.

3. CMS should minimize the administrative burden of provisions related to identifying clinicians who support CJR model participant hospitals.

We support CMS' efforts to help CJR model providers qualify for additional financial rewards through the advanced alternative payment model (APM) definition under the Quality Payment Program (QPP), created by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). In passing MACRA, Congress clearly intended to create an accelerated pathway for physicians to move from fee-for-service to APMs. Under the QPP, the Advanced APM track of the CJR model includes eligible clinicians on an affiliated practitioner list, maintained by CMS. Clinicians on this list have a contractual relationship with the Advanced APM entity—i.e., the participant hospital, for CJR purposes. Further, a clinician financial arrangements list would include sharing arrangements, distribution arrangements, or downstream distribution arrangements, as applicable, and this list would be considered an affiliated practitioner list. CMS uses the clinician financial arrangements list to identify eligible clinicians who will be assessed as qualifying APM participants (QPs) for the year. CMS makes QP determinations individually for these eligible clinicians.

To increase opportunities for QP status for eligible clinicians supporting CJR model participant hospitals (i.e., by performing CJR model activities and supporting participant hospital quality or cost goals under the model) but who do not have a financial arrangement under the CJR model, CMS proposes to add these clinicians to a "clinician engagement list." CMS would consider this list, along with the clinician financial arrangement list, to determine QP eligibility under the QPP. CMS proposes that the clinician engagement list submission for the CJR model would require that hospitals submit, not more frequently than once a quarter, a list of clinicians who are not CJR model collaborators during the model performance year but who have a contractual relationship with a participant hospital. We support CMS' recognition of clinicians with no financial arrangement under the CJR model but who are directly employed or contractually engaged by a participant CJR hospital to perform clinical work that at least partly supports the model's costs and quality goals.

Additionally, CMS proposes that a hospital would be required to attest, in a form and manner required by CMS, that there are no individuals to report on such a clinician engagement list. In other words, a CJR hospital participant would be required to submit a clinician engagement list or an attestation that no individuals meet the requirements to be reported on such a list. This effort is unnecessary, and we urge CMS to minimize the administrative burden on CJR participant hospitals by not requiring attestation that there are no clinicians eligible for the clinician engagement list.

4. CMS should work with stakeholders to develop voluntary models that encourage participation by essential hospitals and recognize the resources required for improved care coordination and cost savings.

We applaud CMS for developing new initiatives that meet the Advanced APM definition under the QPP, and we encourage CMS to further develop APMs and Advanced APMs that are voluntary. Providers need adequate time to invest resources in development of infrastructure and care coordination. We urge CMS to limit the size and scope of these demonstrations and ensure open, transparent communication with stakeholders in the development or modification of CMMI models.

Additionally, some essential hospitals have invested their scarce resources to prepare for the EPMs proposed to be cancelled. While we support CMS stepping back to re-evaluate these models, we urge the agency to recognize and engage stakeholders that are demonstrating innovation in care delivery aimed at improving patient experience, population health, and reducing costs. Future initiatives ideally would require limited resources to administer, overlap with programs already in place, and build upon existing efforts by providers.

5. CMS should mitigate concerns about the effect of proposed removal of total knee arthroplasty (TKA) procedures from the inpatient only (IPO) list on the CJR model.

In the recently released Outpatient Prospective Payment System proposed rule for calendar year (CY) 2018, CMS proposes removing total knee arthroplasty (TKA) from the IPO list. Procedures found on the IPO list usually are performed only in the inpatient setting and are reimbursed at inpatient rates, not under the OPPS. Each year, CMS reviews this IPO list for procedures that should be removed because they can be provided in the outpatient setting.

We have concerns about how removing TKA from the IPO list would affect Medicare payment models, such as the CJR model, that include the TKA procedure. Under the CJR model, services are paid on a fee-for-service basis with retrospective reconciliation against target prices based on historical costs associated with the procedure, for a defined period. Given that the TKA procedure has been on the IPO list to date, CMS lacks claims history for beneficiaries receiving TKA on an outpatient basis. If CMS finalized the removal of TKA from the IPO list, some patients who previously would have received a TKA procedure in an inpatient setting could receive the procedure on an outpatient basis. Therefore, establishing an accurate target price based on historical data becomes more complicated within the CJR model. Further, the historical episode spending data might no longer accurately predict episode spending for beneficiaries receiving inpatient TKA procedures. Modifications to the CJR model would be required if the TKA procedure is removed from the IPO list. Further, we urge CMS to mitigate concerns related to regulatory changes that might affect the administration of current or future Medicare payment models before finalizing and implementing those changes.

There also are differences in patient population for which the TKA procedure is performed on an outpatient basis—i.e., they are younger, more active, have fewer complications, and have more support at home than most Medicare beneficiaries. Further, many Medicare patients have comorbidities and would require intensive rehabilitation after a TKA procedure, making it best performed in an inpatient setting. As such, TKA procedures performed on an outpatient basis might be appropriate only for a small number of Medicare beneficiaries. If finalized as proposed in the CY 2018 OPPS rule, we urge CMS to identify a methodology for CJR model participants that appropriately adjusts target prices for inpatient procedures to reflect the shift of less complex procedures to the outpatient setting.

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Erin O'Malley, director of policy, at eomalley@essentialhospitals.org or 202-585-0127.

Sincerely,

Bruce Siegel, MD, MPH President and CEO