September 11, 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 Avenue SW
Washington, DC 20201

Ref: CMS-1676-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program 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 health care industry. We are concerned, however, about the effect on essential hospitals and their communities of steep cuts to Medicare payments for off-campus provider-based departments (PBDs) under the Bipartisan Budget Act (BBA) of 2015. These cuts deter hospitals from expanding access in communities where there is most need for health care services and run counter to CMS’ goal of integrated, coordinated health care. In fact, CMS’ proposed policy to drastically reduce payment non-exceptioned PBDs by an additional 50 percent would severely limit the ability of essential hospitals to expand access to vulnerable populations.

America’s Essential Hospitals is encouraged by CMS’ proposals to reduce administrative burden in the Medicare Shared Savings Program (MSSP), but we also have concerns about the proposed revisions related to quality metrics. Specifically, changes to the criteria used to establish quality performance could have unintended consequences if measures do not adequately account for sociodemographic factors.

America’s Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our more than 300 member hospitals
provide a disproportionate share of the nation’s uncompensated care and devote nearly three quarters of their inpatient and outpatient care to Medicare, Medicaid, and uninsured patients. Essential hospitals treat more patients dually eligible for Medicare and Medicaid than the average hospital. These patients often have multiple comorbidities and chronic conditions and are among the most difficult to treat. Further, more than a third of patients at essential hospitals are racial or ethnic minorities who rely on the culturally and linguistically competent care that only essential hospitals can provide. Our members provide state-of-the-art, patient-centered care while operating on margins substantially lower than the rest of the hospital field: 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 primary through quaternary care, including trauma care, outpatient care in their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services critical to disadvantaged patients.

Essential hospitals play a vital role in providing ambulatory care to their communities. The average member operates a network of more than 30 ambulatory care sites, and in 2015, saw nearly three times more non-emergency outpatient visits than other acute-care hospitals nationwide.2 Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—that freestanding physician offices typically do not offer. Our members’ ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

The high cost of providing comprehensive, complex care to low-income and uninsured patients leaves essential hospitals with limited resources, which compels them to find increasingly efficient strategies for providing high-quality care to their patients. Several essential hospitals participate in the MSSP and have made the needed investments to participate as accountable care organizations (ACOs). However, our members face challenges as they continue to make investments necessary for ACO participation, including capital investments in technology, process redesign, personnel, care coordination, quality measurement, risk management, compliance, network development, governance, and in their legal structure.

Improving care coordination and quality while staying true to a mission of helping those in need can be a delicate balance. This balance is threatened by payment cuts to hospitals, such as those under the BBA and CMS’ proposed payment policy for non-excepted PBDs. To ensure our members have sufficient resources to advance their missions and are not unfairly disadvantaged for providing comprehensive care to complex patients, we urge CMS to consider the following recommendations when

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2Ibid.
finalizing the above-mentioned proposed rule.

1. CMS should ensure that non-exceptioned PBDs are adequately reimbursed for the costs of care.

As mandated by Section 603 of the BBA, CMS on January 1, 2017, discontinued paying certain off-campus PBDs under the Outpatient Prospective Payment System (OPPS). The BBA instructed CMS to pay these non-exceptioned PBDs under a Part B “applicable payment system” other than the OPPS; CMS determined the Physician Fee Schedule (PFS) to be such a system. America’s Essential Hospitals urges CMS to reimburse non-exceptioned PBDs at no lower than 75 percent of the OPPS payment rate. Doing so would ensure hospital PBDs are adequately reimbursed for the cost of providing comprehensive, coordinated care to complex patient populations in underserved areas.

In the calendar year (CY) 2017 OPPS final rule, CMS established an interim payment rate under the PFS for non-exceptioned items and services provided at non-exceptioned off-campus PBDs that is equivalent to 50 percent of the OPPS payment rate. CMS arrived at the 50 percent figure by comparing the PFS technical component payment rate to the OPPS payment rate for the 25 highest-volume services in off-campus PBDs, excluding office visits. Without any justification for the lower payment rate or any analysis of how reduced reimbursement might affect patient access to care in PBDs, CMS in this year’s PFS rule proposes to further reduce the interim payment rate to 25 percent of the OPPS payment rate. This proposal would devastate essential hospitals and patients who seek care in their off-campus PBDs, and we therefore urge CMS to withdraw its proposed 25 percent payment rate.

In the aggregate, members of America’s Essential Hospitals operate on margins half that of other hospitals nationally. For safety-net hospitals operating on these narrow (often negative) margins, this payment rate reduction is unsustainable. The effect of the proposed payment rate would be felt even more profoundly by patients of essential hospitals, given our members’ wide networks of ambulatory care in otherwise underserved communities. Essential hospitals often are the only providers willing to take the financial risk of opening a clinic in a community with many clinically complex and low-income patients. The BBA adversely affects patient access by limiting incentives for essential hospitals to bring health care into these communities of need. CMS’ implementation of Section 603—especially the inadequate payment rate proposed in the PFS rule—might cause some essential hospitals to reevaluate the sustainability of expanding their provider networks into underserved areas.

We hope CMS recognizes the role the BBA and its implementation have played in limiting health care access for the country’s most disadvantaged patients. Patients seeking care at essential hospitals’ off-campus PBDs typically are low-income and racial and ethnic minorities. Essential hospital clinics often fill a void by providing the only source of primary and specialty care in their communities. Because of their integrated health systems, essential hospitals can help drive down overall health
care costs, including for the Medicare program, by efficiently providing coordinated
care through ambulatory networks.

It is worth noting that PBDs must comply with provider-based regulations, which
include requirements pertaining to billing, medical records, and staffing. For
example, an outpatient department must be clinically and financially integrated
with the main provider, and have full access to services at the main hospital, to
qualify as a provider-based facility and receive Medicare reimbursement. The
department also must integrate its medical records into the main provider’s system.
These and other requirements impose additional compliance costs on hospitals that
are not borne by freestanding physician offices.

As CMS has acknowledged in the past, payment to hospital PBDs and freestanding
clinics cannot be directly compared because payment under the OPPS accounts for
the cost of packaging ancillary services to a greater extent than under the PFS. For
many services paid under the OPPS, including comprehensive ambulatory payment
classifications, CMS makes a single payment for the main service and related
packaged services. The PFS likely would make a separate payment for each service.
Comparing payment under the OPPS and PFS without accounting for the higher
level of packaging that occurs under the OPPS understates the costs of services in
hospital PBDs. The Medicare Payment Advisory Commission (MedPAC) in a June
2013 report discussed equalizing payment across settings. MedPAC noted that any
adjustment in payment rates to hospital PBDs should account for the higher level of
packaging in the hospital setting by paying the hospital department at a higher rate
than the physician freestanding office.³

To adjust for the higher level of packaging in the OPPS, as well as higher costs
incurred by hospital PBDs compared with freestanding offices, CMS should
revise its payment rate for non-exceptioned items and services to 75 percent of the
OPPS payment rate. In proposing to further reduce the interim payment rate for
non-exceptioned items and services, CMS provides no explanation of why an additional
reduction from 50 percent is necessary other than that the relativity adjuster
finalized for CY 2017 might be “too small.” The agency provides no data supporting
this suggestion. CMS acknowledges in the rule that it does not have adequate claims
data on non-exceptioned items and services for CY 2017 to establish a payment rate.
The agency notes that it implemented a transitional policy until “more precise data”
are available.⁴ The agency’s decision to further reduce the payment rate is especially
questionable given that the agency concedes that there is a lack of available data to
establish a payment rate. Most important, CMS does not indicate in the rule what
effect the payment change would have on hospital PBDs or patient access.

Last year, CMS deliberately chose to exclude clinic visits from its calculation of the
interim payment rate due to issues in comparing the 10 PFS current procedural

³Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care
⁵Ibid.
terminology codes for clinic visits to OPPS’ one Healthcare Common Procedure Coding System (HCPCS) code for clinic visits. Instead, CMS examined the 25 highest-volume procedures in off-campus PBDs, excluding clinic visits. This year, CMS chose to disregard that decision and focus on clinic visits. By paying non-excepted hospital PBDs at 25 percent, CMS would grossly undercompensate hospitals for the services they provide to complex patients.

We urge CMS to increase the payment rate for non-excepted PBDs to adequately account for the higher acuity of patients they treat compared with physician offices. Payment rates also should reflect the requisite resources, staff, and capabilities necessary for PBDs to both comply with other CMS regulations and provide high-quality care to all patients. Essential hospital PBDs offer culturally and linguistically competent care tailored to the disadvantaged patients in their communities. Whether due to the clinical complexity of their patients or the additional resources needed to provide translators and wraparound services, essential hospitals incur higher costs in treating their patients than other facilities. By considering the recommendations above, CMS can lessen the negative effect of Section 603 on disadvantaged patients’ access to care.

2. **CMS should continue to refine the measure set used to establish ACO quality performance standards under the MSSP so it contains only reliable and valid measures that provide an accurate representation of quality of care.**

America’s Essential Hospitals supports programs that encourage quality improvement. However, CMS must verify that quality improvement program measures are properly constructed and do not lead to unintended consequences and administrative burden on hospitals. This is especially important for essential hospitals that already operate with limited resources.

a. **CMS should account for sociodemographic factors, including socioeconomic status, by risk adjusting the measures used to establish ACO quality performance.**

America’s Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. However, before including measures in the MSSP, CMS must verify the measures would not lead to unintended consequences. As quality reporting programs move toward outcomes-based measures and away from process measures, CMS must ensure measures chosen for these programs accurately reflect quality of care and account for factors beyond the control of a hospital. The agency should ensure the measure set includes metrics that are valid and reliable, aligned with other existing measures, and risk adjusted for sociodemographic factors. **CMS should not include measures in ACO quality performance standards until those measures have been appropriately risk adjusted 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.\(^6\) Outcome measures, especially those focused on readmissions, 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 are more likely to be readmitted to a hospital or other institutional setting. Reducing preventable readmissions is of paramount concern to America’s Essential Hospitals and its members. We believe that any program directed at reducing readmissions and improving beneficiaries’ health through the episode of care must target readmissions that are preventable and include appropriate risk-adjustment methodology.

Essential hospitals support quality and accountability. What they want, and what their patients and communities deserve, is an equal footing with other hospitals for quality evaluation. When calculating quality measures, Medicare programs should account for the socioeconomic and sociodemographic complexities of disadvantaged populations to ensure hospitals are assessed on their work, rather than on the patients they serve. Differences in patients’ backgrounds might affect complication rates and other outcome measures; ignoring these differences would skew quality scores against hospitals that provide essential care to the most complex patients, including those with sociodemographic challenges and the uninsured.

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 in which the connection between social risk factors and health care outcomes was clearly shown.\(^7\) The report provides 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 examine the recommendations found in the ASPE report for future incorporation in MSSP.**

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.”\(^8\) We urge CMS to closely examine the considerations provided by the Academies for risk adjustment in federal programs.

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Like the growing body of research on socioeconomic risk adjustment, NAM found that community-level elements that providers are unable to change can indicate risk unrelated to quality of care.9 We urge CMS to examine these criteria, as identified by the Academies, for choosing the risk factors for an adjustment methodology:

- conceptual relationship with the outcome of interest;
- empirical association with the outcome of interest;
- risk factor presence at the start of care;
- risk factor modifiability through the provider’s actions; and
- risk factor resistance to manipulation or gaming.

We urge CMS to examine the Academies’ report for examples of currently available data to include in measure risk adjustment in the MSSP. The agency also should develop analytic methods for integrating patient data with information about contextual factors that influence health outcomes at the community or population level. Identifying which social risk factors might drive outcomes and determining how to best measure and incorporate those factors into payment systems is a complex task, but doing so is necessary to ensure better outcomes, healthier populations, lower costs, and transparency. We look forward to working with CMS to account for social risk factors and reducing health disparities across Medicare programs, including the MSSP.

b. CMS should seek to align and simplify quality reporting across programs and settings.

We urge the agency to seek greater alignment in quality measurement across Medicare programs and to focus measurement on areas of highest priority—i.e., areas that represent the best opportunities to drive better health and better care, based on available literature. As highlighted by the Institute of Medicine’s (IOM’s) Committee on Core Metrics for Better Health at Lower Cost, there is a need to reduce the burden of unnecessary and unproductive reporting by reducing the number, sharpening the focus, and improving the comparability of measures.10 We, along with other hospital organizations, support the committee’s core measure set of “vital signs” for tracking progress toward improved health and health care in the United States. This starting measure set emphasizes the importance of streamlining measures to promote greater alignment and harmonization and to reduce redundancies and inefficiencies in health system measurement.

3. CMS should finalize proposals aimed at reducing administrative burden within the MSSP and examine the program for ways to further encourage participation by essential hospitals.

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America’s Essential Hospitals appreciates CMS’ efforts to achieve transparency, flexibility, simplification, and innovation in the MSSP. We applaud CMS in recognizing that some requirements in the MSSP’s waiver and program application process might impose an unnecessary burden on applicants, without a corresponding sufficient benefit to program administration.

a. To reduce administrative burden on ACO participants, CMS should finalize the removal of certain requirements for the skilled nursing facility (SNF) three-day waiver.

CMS proposes to revise two requirements related to the SNF three-day waiver available to certain participating ACOs. The SNF three-day waiver aims to provide additional flexibility to ACOs in the Track 1+ and Track 3 models to increase quality and decrease costs. Specifically, CMS waives the requirement for a three-day inpatient hospital stay before a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries prospectively assigned to an ACO who receive care through an eligible SNF. Based on initial experiences and stakeholder comments, CMS believes revisions to the waiver now are warranted.

First, CMS proposes to no longer require ACOs applying for the SNF three-day waiver to submit a narrative describing any financial relationship that exists between the ACO, SNF affiliates, and acute-care hospitals. This requirement is overly burdensome and we support its removal from the MSSP. Second, CMS proposes to no longer require waiver applicants to submit documentation demonstrating that each SNF affiliate on their list has an overall rating of three stars or higher under the CMS five-star Quality Rating System. As noted by CMS, this information is easily retrieved by the agency. We support the removal of this requirement and also urge CMS to examine the star rating system, generally, to ensure appropriate risk adjustment is incorporated into its methodology.

b. CMS should finalize its proposed removal of initial MSSP application requirements that are overly burdensome to potential ACO participants.

Essential hospitals often face challenges finding the resources necessary to upgrade technology, redesign processes, and develop a care coordination network; these challenges can preclude them from participation as ACOs. CMS proposes modifications to reduce administrative burden in the MSSP initial application process. We support such efforts, as they encourage essential hospital participation in the program.

To determine whether it meets participation requirements for the MSSP, a prospective ACO must submit a complete application by the deadline established by CMS. The materials for submission substantially increase application and review burden without offering significant value to CMS’ eligibility review.

As such, CMS proposes to reduce application burden by no longer requiring ACOs to submit supporting materials and documentation at the time of application. Rather, CMS proposes to require that ACOs certify they meet the applicable eligibility and documentation requirements, while retaining the right to request the
submission of supporting materials and documentation in cases when it could help determine the ACO’s eligibility. CMS proposes to retain all requirements related to ACO eligibility criteria and public reporting, as specified under the MSSP regulations, including that ACOs must publicly report information on their dedicated web pages about their shared savings and shared losses. **We support the proposed revisions to the MSSP initial application process, and we urge CMS to seek further refinements to reduce burden and encourage participation by essential hospitals.**

4. **CMS should further delay the implementation of patient relationship categories and codes to allow adequate time for physicians and hospitals to become familiar with the new codes.**

We appreciate CMS’ effort to obtain information about clinicians’ relationships with patients. Determining who has responsibility for a patient’s health outcomes when multiple providers deliver care is a complex undertaking, but it is important as the industry moves rapidly to value-based payments. Attribution is necessary to link patient-level health care quality and spending indicators to specific providers for accountability; however, we urge CMS not to rely solely on one source of data for such attribution.

To facilitate the attribution of patients and episodes to one or more clinicians, Section 1848 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. Claims submitted for items and services furnished by a physician are required to include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories, as well as the national provider identifier of the ordering physician.

CMS proposes a list of level II HCPCS modifiers to capture patient relationship categories required by MACRA for improved cost measurement. **CMS acknowledges a “learning curve with the use of the modifiers to report patient relationships.”** As such, the agency proposes voluntary reporting of the modifiers on Medicare claims for items and services furnished by a physician on or after January 1, 2018, to allow clinicians time to gain familiarity.

We believe clinicians will need significant education regarding the use of these categories and codes. Additionally, clinicians already are under pressure to adapt to the Quality Payment Program and new quality reporting requirements. Reporting a new set of patient relationship codes during the same period would require additional changes to workflow and added burden, with the potential for inconsistencies in reporting because of differing clinician interpretations of patient relationships. **We support the delay of required reporting of these modifiers and encourage CMS to further delay their introduction to ensure minimal reporting burden and confusion among clinicians.**
America’s Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Erin O’Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO