September 1, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1654-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model, July 15 2016.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and their approximately 250,000 employed physicians, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) physician fee schedule (PFS) proposed rule for calendar year (CY) 2017. The AHA supports a number of the proposals in this rule, which would expand Medicare beneficiaries’ access to critically-needed services. These include the addition of new telehealth services for Medicare beneficiaries in rural areas; coverage for new primary care, care management and behavioral health integration services; and national expansion of the Diabetes Prevention Program (DPP) model. In addition, while we are pleased that CMS has acknowledged the complexity of implementing appropriate use criteria (AUC) for advanced diagnostic imaging, stating it will not begin penalizing providers for failure to consult AUC until at least Jan. 1, 2018, we urge the agency to provide sufficient time for implementation once mechanisms to consult AUC are available. Below we provide additional feedback on specific aspects of the proposed rule.

Medicare Telehealth Services

The AHA supports the agency’s proposal to add new Current Procedural Terminology (CPT) codes to its list of approved Medicare telehealth services. Specifically, CMS proposes
to pay for the following services when provided via telehealth: certain end-stage renal disease services for dialysis (90967, 90968, 90969, 90970); advanced care planning (99497, 99498) and critical care consultations (new codes GTTT1 and GTTT2). Covering these telehealth services will expand access to care for Medicare beneficiaries in rural areas.

At the same time, we note that limited Medicare coverage and payment for telehealth services remains a major obstacle for providers seeking to improve patient care. We acknowledge that many of the limitations on the expansion of Medicare coverage for telehealth are statutory. However, CMS should use its own authority to identify services that could be effectively and efficiently furnished using telehealth and add those to the list of approved Medicare telehealth services. Currently, the agency approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only a small percentage of services when they are delivered via telehealth. However, this process should be simplified, such as by a presumption that Medicare-covered services also are covered when delivered via telehealth, unless CMS determines on a case-by-case basis that such coverage is inappropriate.

The AHA will continue to urge Congress to remove the statutory barriers to increased Medicare coverage of telehealth services, including the geographic and practice setting limitations on where Medicare beneficiaries may receive telehealth services and the limitations on the types of technology that providers may use to deliver services via telehealth.

**APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES**

The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to establish a program that promotes AUC for advanced diagnostic imaging. The statute requires that, beginning Jan. 1, 2017, payment will be made only to the furnishing professional for an applicable advanced diagnostic imaging service if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable AUC. This policy will apply only when applicable imaging services are provided in certain settings – a physician’s office, hospital outpatient department (including an emergency department), an ambulatory surgery center, and any other provider-led outpatient setting as determined by CMS.

CMS took initial steps to implement this policy in the CY 2016 PFS rule by defining AUC and specifying the process for developing the criteria. This year’s rule proposes policies addressing the next key portion of implementation – designation of qualified CDSMs. Significantly, CMS acknowledges that because of the complexity of implementation, the agency will not meet the statutory requirement that ordering professionals must consult qualified CDSMs by Jan. 1, 2017. Under the timelines proposed in this rule, the first qualified CDSMs will be specified on June 30, 2017. The agency anticipates that furnishing professionals may begin reporting on AUC consulted by the ordering professional as early as Jan. 1, 2018.

The AHA supports CMS’s deliberate, stepwise implementation of the AUC requirement and is pleased that the agency will not hold providers responsible for meeting the
requirement until the related policies are fully developed. However, the potential timeframe described by CMS leaves providers very little time – a mere six months after specification of the first qualified CDSMs – to acquire access to and deploy qualified CDSMs. Specifically, providers will need time to determine which entity or entities has the relevant criteria set for a physician’s patient base. In addition, because ordering professionals may not use the same information technology (IT) systems as the imaging provider or interpreting professional, time is needed to prepare providers’ IT systems to ensure that they can connect with the CDSM systems and transmit information to hospitals/imaging centers and interpreting professionals. We urge CMS to delay the payment reduction associated with a lack of consultation of, and compliance with, AUC until at least 12 months from the date that approved CDSMs are announced.

In addition, while we understand that this is a mandated policy, we have concerns regarding the impact on Medicare beneficiaries’ ability to access needed advanced diagnostic imaging. Hospitals will have limited ability to assure that ordering professionals have consulted and complied with AUC before a beneficiary arrives for imaging services, which could result in disruption of services. It is the provider of imaging services (such as a hospital), not the ordering professional, that will not receive payment if the ordering professional does not comply with the requirement. Therefore, we urge CMS to develop a process by which the imaging providers themselves, such as hospitals, may consult and apply relevant AUC to ordered imaging; when the ordered imaging complies with AUC, this should be sufficient to satisfy the requirement. When the ordered imaging does not comply with AUC, it should prompt a conversation between the imaging provider and the ordering professional on the most appropriate resolution to satisfy the beneficiary’s health needs. However, this suggested consultation of AUC by imaging providers in order to guarantee access to services for beneficiaries and payment for services provided should not supplant the requirement that ordering professionals consult AUC. We also urge CMS to develop a system to identify and monitor ordering professionals who consistently fail to consult AUC. This is necessary because the law provides consequences for outlier professionals who consistently fail to comply with AUC, but not for those that consistently fail to consult AUC at all.

PAYMENT FOR PRIMARY CARE AND CARE MANAGEMENT SERVICES

The AHA supports CMS’s proposals to pay separately for certain primary care, care management and cognitive services beginning in CY 2017. Specifically, the agency proposes to create and pay for new codes that would include the following services:

- The billing practitioner’s time spent assessing and creating a care plan for patients with cognitive impairment (GPPP6);
- Prolonged evaluation and management (E/M) services before and/or after direct patient care, to better account for the additional resource costs of physicians and other practitioners when they spend time caring for the individual needs of their patients outside the in-person office visit (99358 and 99359);
• Resource-intensive services for patients who require use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts and adjustable padded leg supports) during an E/M visit (GDDD1); and
• Complex chronic care management (CCM) and subsequent CCM services (99487 and 99489). CMS proposes these new codes to supplement the existing CCM code (99490).

We agree with CMS that current codes may not reflect all of the services and resources required to furnish comprehensive, coordinated care management, and are pleased that the agency proposes to better compensate physicians and other professionals for the work they perform providing and managing care for Medicare beneficiaries, particularly those with complex or chronic health issues.

We also support CMS’s proposed changes to the scope of service requirements for providers of CCM services, which would help decrease the administrative burden associated with billing these services. Since CMS implemented these codes, the AHA has consistently warned that overly stringent requirements could be prohibitively burdensome to physicians who want to provide CCM services. We are pleased that the agency recognizes that these requirements may be driving underutilization of CCM services and has proposed changes accordingly.

**Behavioral Health Integration**

The AHA supports CMS’s proposal to improve payment for care management services provided for the care of beneficiaries with behavioral health conditions, including services for substance use disorder treatment. Specifically, CMS proposes new codes to pay for:

• Services provided under the Psychiatric Collaborative Care Model (CoCM), in which a primary care team, consisting of a primary care provider and a behavioral health care manager, work in collaboration with a psychiatric consultant, such as a psychiatrist. (GPPP1, GPPP2, GPPP3)
• Care management costs incurred by primary care practices that treat patients with behavioral health conditions under behavioral health integration models other than the CoCM. (GPPPX)

The AHA is pleased that CMS is proposing policies to increase integration of behavioral services with primary care. Our members frequently express concern that the delivery of behavioral health services is usually separate from, and uncoordinated with, the broader health care delivery system. This fragmentation compromises quality of care and clinical outcomes for individuals with both behavioral and physical health conditions. Research shows that integration of behavioral health services and general medical care, such as through collaborative models, can reduce costs and improve outcomes for these patients. We appreciate also that CMS’s proposal is not limited to one model for behavioral health integration, but recognizes that providers may take different approaches to accomplishing this critical goal.
CCM AND TRANSITIONAL CARE MANAGEMENT (TCM) SUPERVISION REQUIREMENTS IN RURAL HEALTH CLINICS (RHCs) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs)

CMS finalized policies, effective Jan. 1, 2016, for payment of CCM services in RHCs and FQHCs in the PFS CY 2016 final rule. The agency also finalized payment for TCM services furnished by a RHC or FQHC practitioner, effective Jan. 1, 2013. Currently, auxiliary staff in RHCs and FQHCs, including nurses, medical assistants and other clinical staff who work under the direct supervision of a RHC or FQHC practitioner, may only furnish CCM and TCM services incident to a RHC or FQHC visit. Many RHCs and FQHCs indicated concerns that this direct supervision requirement for auxiliary staff would limit their ability to contract with third parties to furnish some components of the CCM and TCM services. As a result, CMS proposes to allow these services to be furnished under general supervision of a RHC or FQHC practitioners. The AHA supports this proposal.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

Beneficiary Attestation. The AHA supports CMS’s proposal to incorporate beneficiary preference into the assignment process for MSSP accountable care organizations (ACOs), a change we have long urged for adoption. Specifically, CMS proposes to design a process by which beneficiaries could designate their “main doctor” or another health care provider that they believe is primarily responsible for their care. If that provider participates in an MSSP ACO, the beneficiary would be assigned to that ACO. CMS proposes to incorporate voluntary beneficiary alignment for all three MSSP ACO tracks, beginning in performance year (PY) 2018. If the agency is unable to develop an automated system in time for PY 2018, it would implement a manual attestation process for Track 3 ACOs only until an automated system could be developed.

Providing beneficiaries the opportunity to align voluntarily with an ACO would balance the important considerations of beneficiaries’ freedom to choose their providers with ACOs’ interest in reducing churn, which would help provide a more defined and stable beneficiary population. This, in turn, would allow ACOs to more effectively manage and coordinate care of beneficiaries for whose care they will ultimately be held accountable. In addition, allowing beneficiaries to attest to the provider they want to manage their care may help increase beneficiary engagement in that care. We urge CMS to prioritize timely development of an automated system for attestation that minimizes the burden for beneficiaries and ACOs, and that would be accessible to ACOs in all three tracks beginning with PY 2018.

Quality Reporting. CMS proposes a number of changes to the MSSP quality reporting program, in part to align it with the recommendations of the Core Quality Measures Collaborative as well as measures proposed for the Quality Payment Program (QPP) required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Below we comment on specific proposals.
Measure Additions. CMS proposes to add three measures.

- **We support CMS’s proposal to incorporate ACO-12**, Medication Reconciliation Post Discharge as a replacement for ACO-39, Documentation of Current Medications in the Medical Record. We agree this change would promote alignment across quality reporting programs.

- **We do not support the addition of ACO-44**, Use of Imaging Studies for Low Back Pain, because we do not believe its use in this instance is a good fit. The measure is specified for the full array of patients 18-50 years of age, but CMS will collect it using Medicare claims data. Thus, while the measure is specified for a more general population, CMS proposes to use it to assess the care for a complex set of patients – specifically, those under 50 who qualify for Medicare. As CMS points out, the sample sizes may be small, which makes the data less reliable. The AHA supports the concept of quality measures that can promote improvement in the appropriate use of medical studies but recommends that CMS redesign and retest this measure to align it more closely with the Medicare claims data source. If CMS does adopt this measure for the MSSP program, we urge the agency to incorporate it as pay-for-reporting only.

- **We do not support the inclusion of ACO-43**, Ambulatory Sensitive Condition Acute Composite, because we are skeptical about its ability to provide reliable data and believe it needs rigorous clinical risk adjustment. Although the agency states the measure will be risk adjusted for demographic variables and comorbidities, the proposed rule does not elaborate on when and how that process will take place. Based on information contained in a separate proposed rule, it does not appear that the risk-adjustment process has begun. CMS should re-propose this measure after it has been risk adjusted.

Measure Removals. **We support CMS’s proposals to retire the following measures:**

- ACO-9 and ACO-10, two Agency for Healthcare Research and Quality ambulatory sensitive conditions admission measures;
- ACO-21, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented;
- ACO-31, Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD); and
- ACO-33, Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker Therapy – for patients with Coronary Artery Disease and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%).

Measure Modifications. The AHA supports CMS’s proposal to modify the title and specifications of ACO-11, Percent of PCPs Who Successfully Meet Meaningful Use Requirements. Currently, this measure assesses the level of certified electronic health record (EHR) use by primary care physicians (PCPs) who participate in an ACO. CMS would alter the specifications of the measure to assess an ACO on the level of certified EHR use by *all* providers
and suppliers designated as eligible clinicians under the QPP proposed rule who participate in the ACO. **We support CMS's proposal to designate the ACO-11 as a new measure to ensure it will be pay-for-reporting for PYs 2017 and 2018.** The criteria for successful certified EHR use will be new in 2017 due to the launch of the advancing clinical information (ACI) performance category under the QPP. ACOs must have adequate time to become proficient in reporting new measures before they become pay-for-performance. Further, we support the agency’s proposal to require that while the measure is pay-for-reporting at least one eligible clinician (as defined in the QPP rule) participating in the ACO must meet the reporting requirements under the ACI category under the QPP.

CMS notes that, as an alternative, it is considering requiring the EHR measure to be pay-for-performance in all PYs (including the first year of the first agreement period) and to require the measure to remain pay-for-performance even if it is modified or a new EHR measure is introduced. **The AHA strongly opposes this idea.**

**Minimum Attainment.** We ask CMS to modify its proposal related to minimum attainment levels. The MSSP has quality performance requirements for measures as well as domains, and CMS will take compliance action if an ACO does not achieve the minimum attainment level on at least 70 percent of the pay-for-performance measures (versus pay-for-reporting measures) in each domain. In the rule, CMS proposes to change this policy and take all measures into account when determining whether a compliance action should be taken based on ACO quality performance at the domain level. The minimum attainment level for pay-for-performance measures would remain at the 30th percent or 30th percentile of the quality benchmark, and the minimum attainment level for pay-for-reporting measures would be at the level of complete and accurate reporting. However, when new measures are included in a reporting program, it takes time for providers to gain experience and proficiency in reporting the data. **Therefore, the AHA believes that pay-for-reporting measures should not be included in this proposed policy unless it is evident that the vast majority of ACOs understand how to accurately submit the data.**

**Alignment with the QPP.** CMS proposes regulatory text changes to sunset MSSP alignment with the Physician Quality Reporting System (PQRS) and EHR Incentive programs and promote alignment with proposed QPP requirements under the MACRA. To avoid duplication in rulemaking, the agency also proposes that future changes to the CMS web interface measures will be made through QPP rulemaking, but would still apply to MSSP quality reporting. **We support these proposals.**

**PQRS and Value-based Payment Modifier (VM) Proposals**

The AHA supports CMS’s proposal to allow individual eligible professionals (EPs) and group practices participating in the MSSP to submit their own PQRS and VM data if their ACO fails to submit quality data. Current MSSP regulations do not permit EPs and groups in MSSP ACOs to participate in PQRS or VM separately from their ACO. However, this policy means that if the ACO fails to submit quality data, EPs would automatically be subject to a
negative payment adjustment. Thus, the AHA appreciates that, for CYs 2017 and 2018, CMS would allow individual EPs participating in MSSP to report quality data separately for the purposes of PQRS and VM, and to have that data used in PQRS in the event their MSSP ACO fails to report quality data.

The AHA also supports CMS’s proposed changes to the informal review process for the CYs 2017 and 2018 VM program. In previous rulemaking, CMS established policies in which it would attempt to re-calculate the quality and cost composite scores when the informal review process found errors in the calculation. However, CMS indicates that re-calculating the quality composite score is operationally complex, and makes it difficult to meet timelines for applying payment adjustments. We believe CMS’s proposals – which would largely result in individual EPs and groups receiving not less than “average” quality scores if errors are found – is reasonable.

**Expansion of the Diabetes Prevention Program Model**

The AHA supports CMS’s proposal to expand the Center for Medicare & Medicaid Innovation DPP demonstration and make it a permanent program, beginning Jan. 1, 2018. As CMS notes in the proposed rule, diabetes is a serious national health issue which affects a significant percentage of Medicare beneficiaries, at substantial cost to the Medicare program. Further, evidence shows that Type 2 diabetes can be prevented with appropriate lifestyle changes. Expansion of the DPP would allow more beneficiaries diagnosed with prediabetes access to this evidence-based program that provides training in long-term dietary changes, increased physical activity and problem-solving strategies for overcoming challenges to sustaining weight loss and a healthy lifestyle. These interventions can make a real difference in helping reduce the progression from prediabetes to Type 2 diabetes. In addition to the individual benefits gained by Medicare beneficiaries improving their health and potentially avoiding diabetes, the CMS Actuary has certified that expansion of the DPP would produce savings for the Medicare program. We urge CMS to move forward with expansion of the DPP by proposing the details of a national DPP program through future notice-and-comment rulemaking.

Thank you again for the opportunity to comment. If your team has any questions or would like to discuss our comments, please have them contact our lead on physician payment, Melissa Myers, senior associate director of policy, at mmyers@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President