September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1715-P
PO Box 8016
Baltimore, MD 21244-8016

RE: CMS-1715-P; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Updates to the Quality Payment Program

Comments submitted electronically via www.regulations.gov

Dear Administrator Verma:

The American Society of Echocardiography (ASE) appreciates the opportunity to comment on *CMS-1715-P; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Updates to the Quality Payment Program.* ASE is an organization of over 17,000 professionals committed to excellence in cardiovascular ultrasound and its application to patient care. ASE members include physicians, cardiac sonographers and others dedicated professionals to the provision of high-quality cardiovascular ultrasound services in both hospital and non-hospital settings.

There are other several provisions in the proposed rule that impact practicing echocardiographers and the Medicare beneficiaries they treat. In this letter, we offer comments on the following provisions.

- Medicare Physician Fee Schedule
  - Clarification of clinical labor for new CPT code +93356
  - E/M Office Visit Services
  - Physician Supervision for Physician Assistant (PA) Services

Myocardial Strain (CPT Code +93356)

ASE appreciates CMS acceptance of the RUC recommended work RVUs and direct PE inputs for CPT Code +93356. In the proposed rule CMS required further explanation of the clinical labor activity for CA021- perform procedure/service---NOT directly related to physician work time. This the activity indicates that the clinical staff works independently of the physician to, in the case of this service, provide imaging. Granular detail regarding what the clinical staff completes during the intra-service (of service period) clinical activity, perform procedure/service---NOT directly related to physician work time, is provided in the PE Summary of Recommendation (SOR) included with the RUC direct practice expense inputs recommendation for these services. For this service L050A Cardiac Sonographer requires 12 minutes for the clinical staff to acquire the myocardial strain echocardiographic images. Additional detail regarding the activities that are typically performed by the cardiac sonographer for CPT code 933X0 are as follows:

> *The sonographer will capture 2D cine loops from three standard apical images, adjusting the image for depth to include a portion of the left atrium and ensuring the LV is not foreshortened. A frame rate of > 50 fps is needed for resolution of the endocardium. The apical three chamber (Ap3C) cine loop is captured with the aortic valve adequately visualized. Aortic valve closure (AVC) time will be measured either by direct visualization of the valve or measured with spectral Doppler. The AVC time is necessary for calculation of peak systolic strain. (Depending on the echo machine, the AVC may be electronically calculated, but verification is needed by the sonographer before accepting AVC time.) Utilizing the vendor's strain measurement package on the echo machine, automated tracking of the endocardium is visualized. Careful attention to the automated tracking of the endocardium is necessary and manual adjustments are performed by the sonographer as needed. This critical attention to detail is the most time-consuming portion of the procedure. The process is repeated for both the apical four chamber (Ap4C) and apical two chamber (Ap2C) 2D cine loops after again adjusting for depth, frame rate and resolution. After acquiring three separate apical strain images, an automated 'bulls-eye' view of the systolic strain pattern is revealed, and the image is acquired for regional assessment of segmental strain values.*

If there are further questions regarding activities during the clinical labor intra service time, ASE is happy to respond.

E/M Office Visit Services

In the CY 2019 final rule, CMS finalized several coding, payment, and documentation changes for office/outpatient E/M visits (CPT codes 99201-99215). In response to these finalized policies, the AMA/CPT established a Joint AMA CPT Workgroup on E/M to develop an alternative solution. The CPT Editorial Panel adopted revisions to the E/M code descriptors and revised the CPT prefatory language and interpretive guidelines that instruct practitioners on how to bill these codes. ASE appreciates CMS' proposal to align its E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. ASE members participated in

the CPT workgroup as well as the Specialty Society Relative-Value Scale Update Committee (RUC) survey.

Revised Inherent Complexity Code GPC1X

In addition to the CPT and RUC recommended changes, CMS proposes to implement a Medicare-specific add-on code for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient's single, serious, or complex chronic condition. ASE appreciates CMS' recognition of complex conditions, CMS does not provide any specific assumptions regarding the projected utilization for this new add-on code. A comparison between CMS impact tables indicate that more than $1.5 billion will be redistributed between specialties if this code is implemented. **We support implantation of HCPCS code GPCIX but would request that CMS articulate all of the underlying assumptions regarding the potential use of this add on code and the E/M codes (work RVU and PE) in the Final Rule indicating the impact by specialty. We applaud CMS' intent to ensure that physicians are adequately paid for those patients seen in office visits. However, we feel that further detail is required to ensure adequate analysis and feedback. Additionally, we also encourage CMS to provide guidance to providers regarding appropriate use of the code to ensure it is used as the Agency intended and to protect physicians should they be audited.**

Physician Supervision for Physician Assistant (PA) Services

CMS received input that PAs are now practicing more autonomously and that, in some instances, some states have changed state scope-of-practice laws to reflect this. Stakeholders claim that some states have already relaxed their requirements for PAs related to physician supervision, some states have made changes and are now silent about their physician supervision requirements, while other states have not yet changed their PA scope of practice in terms of their physician supervision requirements. Stakeholders expressed concern that "the current regulatory definition of physician supervision could inappropriately restrict the practice of PAs in delivering their professional services to the Medicare population" and, further, the Medicare requirement for general supervision of PA services may become increasingly out of step with current medical practice, imposing a more stringent standard than state laws governing physician supervision of PA services.

CMS proposed to redefine the physician supervision requirement for services delivered by a PA to state that the supervision requirement is met when "the PA furnishes their services in accordance with state law and state scope of practice rules for PAs in a state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed." CMS also stated that if there is no state law governing physician supervision of PA services, "the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services."

We appreciate that CMS is investigating how to reduce complexity for rules governing PAs. Currently, regulation of PAs is not only governed by the states, but individual insurers also set requirements for use of PAs within their plans. This multi-layered network of rules places a burden on practices to know and understand the nuances of state law and their patients' individual insurance policies before scheduling a patient's appointment. Additionally, our members often feel they must over-document after a PA has seen the patient, which adds to physician documentation burden and limits the effective usage of advanced practice providers (APPs), like PAs. **However, we believe this area may require more research on the impact of state laws and insurer policies regarding use of APPs on practices before finalizing new policies or changes to existing definitions.**

Review and Verification of Medical Record Documentation

CMS proposed to "establish a general principle to allow the physician, the PA, or the APRN who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team." CMS' proposal would apply to all Medicare-covered services paid under the Medicare PFS. CMS added that this includes notes documenting the practitioner's presence and participation in services and clarified that it does not modify the scope of or standards for documentation that is needed in the medical record to demonstrate medical necessity of services. Additionally, CMS also proposed conforming amendments to the regulations specific to teaching physicians to allow "physicians, residents, nurses, students, or other members of the medical team" to enter information in medical record that can be "reviewed and verified" by the teaching physician.

We support CMS' proposal to further clarify and build upon the policies CMS has put in place to reduce documentation burden for teaching physicians. We believe the changes will lessen documentation burden while still maintaining safeguards to ensure that medical records include necessary information to demonstrate medical necessity and accurately document clinical findings, treatments, and ongoing care planning, as applicable.

Echocardiography services regulatory pathways of engagement

Ensuring a high level of quality in echocardiography is a primary goal of the ASE. Establishing a definition of quality in cardiovascular imaging has been challenging - quality can be measured as adherence to established guidelines for the use of a technology to ensure patient satisfaction and outcomes. A goal of the ASE is that the ordering, acquisition, interpretation, and communication of all echocardiographic studies adhere to high- quality standards. Including specific criteria to ensure quality must be established for each phase of the process, from considering a test for a patient to incorporating the results of the test appropriately into patient care.

Over the past 2 decades, echocardiography has established itself as a useful diagnostic tool in detecting cardiovascular disease. As utilization has increased, ASE has become increasing concerned with the proliferation of this service to non-echocardiographers (intensivists,

emergency care physicians, internists, and medical students). As every healthcare organization establishes some sort of internal standards and rules for operations. ASE would like to collaborate with CMS to ensure that all echocardiography services performed meet specific regulations and standards set by the Agency. We would propose to achieve this through accreditation.

The volume of echocardiography services provided to Medicare patients dwarfs the volume of cardiac MRI, cardiac CT and nuclear cardiology procedures, and the clinical indications for echocardiography are considerably broader. Echocardiography is in a substantially different regulatory posture than most other diagnostic imaging services, since non-hospital facilities that provide diagnostic imaging services are required to be accredited while echocardiography laboratories are not. To the extent that concerns are raised regarding the appropriate use of echocardiography, we would urge the requirement of the accreditation of echocardiography laboratories as a first step.

Ultimately, the purpose of accreditation in healthcare is to maintain compliance with healthcare laws and regulations and keep up to date with industry standards. We want to ensure that our members and others performing echocardiography services provide high-quality care with images that are actionable for patient management. This also will assist in decreasing variability in the care for patients, ensuring that patients will receive consistent, excellent clinical management during their episode of care.

Quality Payment Program

Merit-based Incentive Payment System (MIPS)

ASE welcomes the opportunity to comment on specific changes to the MIPS for the 2020 performance year. We wish to point out, however, that analysis of CMS' proposals and offering suggestions for improving the Merit-based Incentive Payment System (MIPS) remains challenging due to the limited availability of data and information. For example, the 2017 Quality Payment Program (QPP) Experience Report did not include information by site of service, which would be particularly useful in the future for cost episodes. We also still have no way of knowing the number of clinicians by specialty and practice size that do not meet the case minimums for the Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost (TPCC) measures. We were also disappointed with the lack of information in the report by specialty, including top measures and activities reported. Starting with performance year two (2018), it would be useful if the Experience Report includes information related to performance during that performance period, as well as comparisons to the prior performance year, including improvement rates.

CMS Should Not Require QCDRs to Audit All Three MIPS Performance Categories (Quality, Improvement Activities, and Promoting Interoperability)

Currently, CMS permits QCDRs to submit data for Quality, Promoting Interoperability, and Improvement Activities under MIPS. Under the current proposed rule language, CMS proposes that by the 2021 performance period QCDRs must be able to submit data for all three MIPS performance categories. ASE agrees with this proposal, as the ImageGuide Registry® has supported and will continue to support all three performance categories for the benefit of registry participants. Further requiring other QCDRs to align with this best practice would foster a more cohesive participation experience across all performance categories under MIPS.

However, ASE opposes a policy requiring QCDRs to audit all three performance categories, as this requirement would place undue burden on QCDRs, especially with regard to auditing improvement activities. The proposed rule additionally fails to fully define what, if any, documentation would be required to demonstrate that such an audit occurred. Therefore, ASE urges CMS to avoid requiring QCDRs to audit all three MIPS performance categories.

Further, for the quality performance categorically particularly, CMS should be aware that a large percent of clinicians who are manually entering data do not complete this task until late in the 4th quarter or even into the 1st quarter of the following year. Consequently, these physicians will not be included in the randomized audit as it is not feasible to wait and complete this task immediately prior to submission. In order to complete the required audit activity in a timely manner, QCDRs will need to initiate these activities early in the 4th quarter to ensure completion prior to CMS submission. While ASE encourages all participating clinicians to enter data often and in a timely manner for quality improvement, clinicians are extremely busy, reliant upon others for data entry, and not all practices have incorporated this activity into their daily/weekly flow. ASE therefore urges CMS to avoid requiring such practically infeasible timelines and requirements into the audit plans for 2021.

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On behalf of ASE, we appreciate the opportunity to provide feedback on these important issues contained in the CY2020 MPFS. If you should have any questions or concerns with the information contained, please feel free to contact Irene Butler at ibutler@asecho.org.

Sincerely,

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President, American Society of Echocardiography