July 8, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals [CMS-1735-P] RIN 0938-AU11

Dear Ms. Verma:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 5,000 members representing the majority of practicing interventional cardiologists and cardiac catheterization teams in the United States including those treating high-risk Acute Myocardial Infarction (AMI) patients. SCAI promotes excellence in invasive and interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care.

SCAI raises concerns about the steep reductions in payments for DRG 2015 and we support a new add-on payment for supersaturated oxygen therapy.

We reiterate the comments we made on last years proposed hospital inpatient rule. A 26% reduction in payments could have negative impacts on patient care:

> "**Proposed Significant Reduction for DRG 215**
> MS-DRG 215 (Other Heart Assist System Implant). DRG 215 applies to patients in shock requiring implantation of a heart-assist device after a heart attack or to treat decompensating heart failure; in such patients, these devices are life-sustaining. These critically ill patients commonly require intensive care in an ICU environment and experience lengthy hospital stays. DRG 215 is again slated for a significant reduction with a proposed decrease in the relative weight of 29.6%. This proposed reduction will result in a cumulative three-year decrease of 43%.

There have been extensive coding changes for percutaneous ventricular assist device procedures over the past two years. Hospitals have been slow to implement and adopt these coding changes. SCAI has been advised that many hospitals still have not correctly implemented these coding Seema Verma June 24, 2019
changes and the majority of claims do not reflect the cost of the percutaneous ventricular assist device.

While we appreciate IPPS is a prospective payment system and future claims data should result in an appropriate upward adjustment in the 2021 rate for DRG 215, hospitals should not be temporarily disincentivised throughout 2020. We request that CMS maintain the FY19 payment rate for DRG 215 through FY20 to avoid patient access issues to these life sustaining technologies."

Support for Super Saturated Oxygen Therapy

SCAI supports TherOx's request for new tech add-on payment (NTAP) for "SSO2 Therapy" (supersaturated oxygen therapy). It is used for patients with anterior ST-Elevation Myocardial Infarction (STEMI) due to left anterior descending artery occlusion and meets the established requirements for new tech add-on payment.

Even after percutaneous coronary interventions (e.g., angioplasty, stenting), many AMI patients suffer irreversible damage to the heart muscle. SSO2 Therapy, consisting of a 60-minute infusion of super oxygenated blood to the target ischemic area of the heart represents a novel, new therapy designed to salvage heart muscle and reduce infarct size supporting a substantial clinical improvement.

The procedure meets CMS's newness criteria because it was FDA approved in 2019.

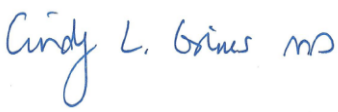
The procedure meets your cost criteria because this technology requires significant time and effort on the part of interventional cardiologists and catheterization laboratory staff. Specifically, it requires additional arterial access and catheter placement to initiate SSO2 therapy followed by an hour of monitoring the patient in the cath lab This serves as a disincentive to provide this service (particularly when it occurs during nights or weekends), increases overall catheterization lab time, and represents a significant additional cost. An NTAP payment will help to offset these disincentives.

Our primary focus is on CMS's third criteria, clinical improvement. We believe that the current data demonstrates a clinically important improvement in outcomes. An analysis of one-year follow-up data provides additional effort of large and sustained improvement in outcomes with SSO2 therapy. We expect an article presenting this data to be published soon and will provide it to CMS when it is available.

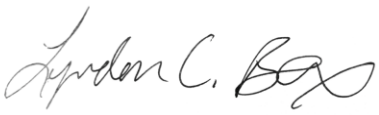
In conclusion, SCAI appreciates the opportunity to provide comment to CMS on issues of high interest to the interventional cardiology community. If SCAI can be of any assistance as CMS continues to

consider and review this or related issues, please do not hesitate to contact Wayne Powell at wpowell@scai.org or 703.772.7910.

Sincerely,



Cindy L. Grines, MD, MSCAI
President



Lyndon Box, MD, FSCAI
Chair of Government Relations Committee

CC: Francesca Dea
Michele Hudson
Donald Thompson
Curtis Rooney