Calendar Year 2014 Medicare Physician Fee Schedule Final Rule

Non-facility Cap
After receiving many negative comments on this issue from physician groups, along with the House GOP Doctors' Caucus letter organized by SVS, the Centers for Medicare and Medicaid Services (CMS) has deferred issue this for future consideration. For now, this is a victory for vascular surgeons who own office-based angiography suites. They would have had payment rates for 15 codes used for services performed in these suites capped at either hospital outpatient or ambulatory surgical center rates, even though these services are rarely or never performed in either setting.

Ultrasound Equipment Recommendations
CMS has decided to take a broader examination of all equipment packages after requesting comments on proposed definitions of rooms. SVS concurred with the Relative Value Update Committee – based on CMS' own guidelines, none of the proposed definitions were appropriate.

The Multiple Procedure Payment Reduction (MPPR) Policy
SVS was dismayed with expansion of this policy to include the technical component of certain cardiovascular diagnosis tests in last year's Final Rule. However, there were no additions to the MPPR policy in the 2014 Final Rule.

Complex Chronic Care Management Services
CMS removed "complex" from these services, there will be a separate payment for these starting in 2015. Additional public input will be requested for services' standards, a new G code was created for a 30 day billing period that must include at least 20 minutes of these services, and specialists may bill for these along with primary care providers.

Ultrasound Screening for AAA
Following many meetings with CMS and comments on barriers to AAA screening, CMS finally decided to modify this by eliminating the referral requirement as part of the Welcome to Medicare Physician Exam. his also eliminates the one-year time limit for all beneficiaries who are at risk for AAA (male-ever smokers ages 65-75 and men and women with a family history of AAA). This remains a one-time screening. These modifications are a big victory for SVS and beneficiaries.

Physician Compare Website
CMS acknowledged problems with the Physician Compare Website and will continue to make improvements. SVS has reviewed the vascular surgery information. CMS has also requested that physicians check the Provider Enrollment, Chain and Ownership System (PECOS) information since current material goes back to the physician's time of enrollment. Risk adjustment mechanisms are also being used.

Value-Based Payment Modifier (VBPM)
The Patient Protection and Affordable Care Act directs the Health and Human Services' Secretary to develop and implement a budget-neutral payment system that will use a VBPM to adjust Medicare physician fee schedule payments based on the quality and cost of care

physicians deliver to beneficiaries. The Secretary will phase in the new payment modifier over a two-year period beginning in 2015, with a two year "look-back" period to 2013. CMS is developing this program in an effort to move physician reimbursement toward a system that rewards value over volume. It is intended to provide comparative performance information to physicians to help them improve their quality and efficiency of medical care. The modifier will be applied to the Medicare paid amounts for the items and services billed under the physician fee schedule at the Taxpayer Identification Number level.

In 2015, only physician practices of 100 or more "Eligible Professionals" (EPs include physicians, physician assistants and nurse practitioners) will be affected by the modifier. CMS will use a two-step process:

- Query PECOS to identify groups of physicians with 100 or more EPs as of October 15, 2013;
- Analyze claims for services furnished during the 2013 performance year through at least February 28, 2014.

CMS will determine the Value Modifier using two categories:

- Category 1 – EPs who have self-nominated/registered for the Physician Quality Reporting System (PQRS) as a group and reported on measures or elected to have their Value Modifier calculated using the quality tier methodology based on a national benchmark, which will result in upward, downward or no payment adjustments based on performance;
- Category 2 – Groups that do not participate in PQRS will receive a negative one percent. This is in addition to the penalty for not satisfactorily reporting PQRS measures.

Thus, this creates a tiered system with "winners and losers" which SVS opposes. Payment adjustments will apply to groups of 10 or more EPs in 2016, which will affect many more vascular surgeons, and all EPs in 2017 based on successful reporting of PQRS group options or 50 percent (lowered from 70 percent) of individuals in the group successfully reporting on PQRS quality measures. Groups of EPs between 10 and 99 will only be subject to upward or neutral adjustments in 2016. A Medicare Spending per Beneficiary Measure will also be used in 2016 for groups of 10 or more. CMS will provide information on this measure to all groups in 2014 in feedback reports that will include attribution information. CMS is attributing an "episode" for an inpatient hospital service to the physician group that furnishes the plurality of Part B services.

There will be on-going refinement of this program.

Physician Quality Reporting System (PQRS)

PQRS is a pay-for-reporting program that uses a combination of incentive payments and downward payment adjustments to promote reporting of quality information by EPs. The program provides an incentive payment of .5 percent through 2014 to EPs and group practices who satisfactorily report data on quality measures for covered professional services furnished to Medicare Part B fee-for-service beneficiaries. After 2014, the payment incentive will end and a downward payment adjustment will apply to EPs who do not satisfactorily report data on quality measures for covered professional services. In addition to being the last year physicians can receive incentives, 2014 will also serve as the performance year for the 2016 downward payment adjustment of two percent.

The following are PQRS updates for 2014:

CMS finalized its proposal to lower the percentage of applicable patients a physician must report on from 80 percent to 50 percent in order to be considered a satisfactory reporter. In addition, the agency will eliminate the six-month reporting period for 2014.

For individual participation: CMS finalized its plan to increase the number of measures that must be reported from three to nine measures for incentive purposes. The measures must cover at least three of the National Quality Strategy (NQS) domains.

CMS will no longer recognize the reporting of one measure or one measures group or the election of administrative claims reporting conducted by CMS as viable reporting options for ***avoiding*** **a PQRS penalty**. However, physicians may report on ONLY three measures for 50 percent of their applicable patients to avoid the 2016 PQRS penalty.

PQRS **measures groups** will only be reportable through a registry starting in 2014.

For **group practices** reporting through the Group Practice Reporting Option (GPRO), CMS did not finalize its proposal to eliminate the GPRO web interface option for practices comprised of 25-99 EPs. Practices comprised of 25-99 EPs may satisfy PQRS reporting in 2014 through the GPRO web-interface.

CMS did finalize its proposal to allow groups of 25 or more EPs to count reporting of **Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CGCAHPS)** survey measures towards meeting the criteria for satisfactory reporting for 2014 PQRS incentives and avoiding the 2016 PQRS penalties. If a practice of 25-99 EPs chooses to report CGCAHPS to earn an incentive, it will need to report all CGCAHPS survey measures via a certified vendor, AND report at least six measures covering at least two of the NQS domains using a qualified registry, direct Electronic Health Records (EHR) product, EHR data submission vendor, or GPRO web interface reporting mechanisms. Unfortunately, CMS will only bear the cost of administering the CGCAHPS survey for group practices of 100 or more EPs registered to utilize the GPRO web interface for PQRS reporting.

Finally, for **group practices reporting individual measures via registry**, CMS finalized its proposal to increase the number of measures that must be reported from three to nine measures and proposes a 50 percent threshold instead of an 80 percent threshold, which it also finalized for the individual satisfactory reporting criteria for the 2014 PQRS incentive.

Summary of Final PQRS Measures: For 2014, CMS is adding 57 new individual measures and two measures groups to fill existing measure gaps and plans to retire many claims-based measures to encourage reporting via registry and EHR-based reporting mechanisms. Therefore, PQRS will contain a total of 287 measures and 25 measures groups in 2014.

SVS-Owned Measures: Below is a list of the measures owned and maintained by SVS that are available for reporting through the PQRS system. Please note, this is not a comprehensive list of

available PQRS measures an EP can use to report. A full list of measures for the 2014 reporting year is available on the CMS PQRS website.

Measure #172: Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula

- Percentage of patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 3,4 or 5) or End Stage Renal Disease (ESRD) requiring hemodialysis

Measure #257: Statin Therapy at Discharge after Lower Extremity Bypass (LEB)

- Percentage of patients 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge

Measure #258: Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Without Major Complications (discharged to home by post-operative day #7)

- Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7)

Measure #259: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Without Major Complications (discharged to home by post-operative day #2):

- Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication

Measure #260 Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, Without Major Complications (discharged to home by post-operative day #2)

- Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2

Measure #344 Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (discharged to home by post-operative day #2)

- Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2

Measure #345 Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS)

- Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital

Measure #346 Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA)

- Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital

Measure #347 Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital

- Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital

PQRS Reporting via Satisfactory Participation in a Qualified Clinical Data Registry: The American Taxpayer Relief Act of 2012 allows EPs to be treated as satisfactorily submitting data on quality measures for covered professional services if the EP satisfactorily participates in a qualified clinical data registry. Under this clinical data registry option, EPs report the data on quality measures used by the qualified clinical data registry, including non-PQRS measures. EPs may report measures on all patients, regardless of whether or not they are Medicare Part B fee-for-service patients. For the 2014 PQRS incentive, EPs participating in qualified clinical data registries may meet the criteria for satisfactory participation by reporting to the qualified clinical data registry at least nine measures covering at least three of the NQS domains, and report each measure for at least 50 percent of the EP's applicable patients. At least one of the measures must be an outcomes measure. For the 2016 PQRS payment adjustment, EPs participating in qualified clinical data registries need only report three measures covering one NQS domain for at least 50 percent of the EP's applicable patients.

This option can only be utilized by EPs who are using a registry that has qualified, under the requirements and standards set forth by CMS, to become a Qualified Clinical Data Registry. In the 2014 reporting year, not all registries will qualify. An EP should check with his/her registry before assuming use of this reporting option.

Reporting PQRS Measures as a Group Practice Under GPRO

Some changes to certain criteria for satisfactory reporting, as well as adopting new criteria, for group practices for purposes of the 2014 PQRS incentive and 2016 PQRS payment adjustment were made, including the following:

- Adopting a new reporting mechanism, the certified survey vendor reporting mechanism, under which a group comprised of 25 or more EPs reporting CGCAHPS survey measures in conjunction with other PQRS reporting mechanisms.
- Aligning the reporting criteria for group practices reporting individual measures via registry with the individual EP reporting criteria for the 2014 PQRS incentive and 2016 PQRS payment adjustment.
- Because CMS adopted its proposal to eliminate the reporting of a measures group via claims-based reporting, the only way to report a measures' group in 2014 will be through a registry.

Given the alignment of certain criteria, in some cases, the same criteria for satisfactory reporting under the GPRO, apply for purposes of the 2014 PQRS incentive and the 2016 PQRS payment adjustment (group practices that meet such criteria would earn the 2014 PQRS incentive and also avoid the downward payment adjustment that applies in 2016). Please note that group practices that are participating in the PQRS as an Accountable Care Organization under the Medicare Shared Savings Program must meet the requirements outlined for the Medicare Shared Savings Program for purposes of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

EHR Incentive Program – CMS is establishing an option for EPs to submit clinical quality measure (CQM) information using qualified clinical data registries (as defined for PQRS) for purposes of meeting the CQM reporting component of Meaningful Use for the Medicare EHR Incentive Program beginning in 2014. Among other requirements for this reporting option, EPs would need to use certified EHR technology, as required under the Medicare EHR Incentive Program, and report on CQMs that were included in the EHR Incentive Program Stage 2 final rule.

CMS also finalized its proposal for EPs who seek to report CQMs under the Medicare EHR Incentive Program to require the use of the most recent version of the electronic specifications for the clinical quality measures and have certified EHR technology (CEHRT) that is tested and certified to the most recent version of the electronic specifications for the clinical quality measures. EPs who do not wish to report clinical quality measures electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) would be allowed to report clinical quality measure data to CMS by attestation for the Medicare EHR Incentive Program.

Medicare Coverage of Items and Services in the FDA Investigational Device Exemption Clinical Studies – Revision of Medicare Coverage

Investigational Device Exemption (IDE) Clinical Studies are designed to generate clinical data on safety and/or effectiveness of a clinical device. FDA approval to conduct an IDE does not currently guarantee coverage of costs and services by CMS for either Category A or Category B medical devices.

CMS proposed criteria to ensure studies of Category A and B devices conform to "appropriate scientific and ethical standards". CMS proposed centralizing the approval process for CMS coverage of these studies and automatically granting coverage for IDE studies that conform to 13 trial standards AND possess the following two characteristics: a pivotal study with a superiority study design.

SVS agreed with the concept of the 13 trial standards and a centralized review for approval or denial of reimbursement for IDE studies, but expressed concerns regarding the governance of this process. In the Final Rule, CMS agreed to a review timeframe of approximately 30 days but did not clarify who will comprise the reviewing body or what the pre-submission process will be.

SVS had expressed significant concern about the two characteristics required to ensure CMS approval: the study be a pivotal study and the study have a superiority design. CMS was responsive to the comments submitted by SVS and key stakeholders and has removed these two requirements and has also removed the proposed definitions of pivotal and superiority studies. In addition, by eliminating the need for superiority study design, another proposed requirement (that a Category A or B IDE study must include an active control group) has been eliminated.

The timeline for implementation of these changes in CMS coverage for IDE Clinical Studies has been rolled back to January 1, 2015. SVS is pleased with the CMS response to our

recommendations and will continue to monitor proposed changes critical to SVS members who perform IDE studies.