

September 6, 2013

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

By Electronic Submission

RE: CMS-1601-P; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals; Proposed Rule

Dear Administrator Tavenner:

The Society for Vascular Ultrasound (“SVU”) thanks the Centers for Medicare and Medicaid Services (“CMS”) for this opportunity to comment on the proposed changes to the Hospital Outpatient Prospective Payment System (“HOPPS”) for calendar year 2014 (the “Proposed Rule”).¹ SVU is a professional society comprised of over 4,600 vascular technologists, sonographers, nurses, and physicians who provide a variety of high-quality vascular ultrasound services to Medicare beneficiaries.

Ultrasound is a critical diagnostic tool that uses sound waves to obtain images of internal anatomic structures. It offers a highly sensitive, non-invasive, and low-cost means of examining internal organs and vessels. Ultrasound utilization not only saves Medicare dollars, but also reduces the risks involved with other more expensive or invasive diagnostic imaging modalities, which may present more significant morbidity and mortality risks.

¹ 78 Fed. Reg. 43,534 (July 19, 2013).

SVU presents for CMS' consideration the following comments to the Proposed Rule:

- **Proposed Computed Tomography (“CT”), Magnetic Resonance Imaging (“MRI”), and Cardiac Catheterization Cost-to-Charge Ratios (“CCRs”) and Multiple Imaging Composite Ambulatory Payment Classification (“APC”) Changes:** SVU applauds CMS for proposing to use the distinct CCRs for CT, MRI, and cardiac catheterization services to calculate the HOPPS relative payment rates, including in the determination of the multiple imaging composite APCs rates.
- **Proposed Changes to Packaged Items and Services:** SVU is deeply troubled with CMS' proposal to package certain diagnostic tests on the bypass list with a primary service, because unlike other packaged codes, at least some of the codes on the bypass list are the primary service, and packaging such diagnostic tests is administratively infeasible due to differences in times, settings, and providers performing the services.
- **Comment Solicitation on Increased Packaging for Imaging Services:** SVU is extremely concerned by CMS' contemplation of a future proposal to package all imaging services with any associated surgical services, since imaging services are typically provided by different clinical personnel in different settings with potentially different ownership and with significant time delays between the imaging and surgical procedures.

These comments are discussed at greater length below. We thank you in advance for your consideration of SVU's comments.

I. Proposed CT, MRI and Cardiac Catheterization CCRs and Multiple Imaging Composite APC Changes

SVU strongly supports the implementation of and reliance upon separate standard cost centers for CT, MRI, and cardiac catheterization services to calculate the HOPPS relative payment rates.² SVU has supported CMS in its efforts to create separate cost centers for these services so CMS could, thereafter, create distinct CCRs to ensure fair and accurate HOPPS reimbursement rates.³ We believe that finalization of this proposal will begin to address the inaccurate Medicare payment rates caused by “aggregation bias” and “charge compression,” which, as CMS has acknowledged, results in a lower charge markup to high cost services, such as MRI and CT, and a higher charge markup to low cost services, such as ultrasound, which ultimately results in Medicare overvaluing

² 78 Fed. Reg. at 43,550.

³ See SVU's comment letters to the calendar year 2009, 2010, and 2013 HOPPS proposed rules, as well as our comments to the fiscal year 2011, 2012 and 2014 hospital inpatient prospective payment system (“HIPPS”) proposed rules.

certain items and services and undervaluing other items and services.⁴ While SVU supports this proposal, SVU believes that the Proposed Rule may have referenced the wrong Section when referring to a discussion of the impacts of calculating the proposed 2014 HOPPS relative payment rates⁵ and, thus, SVU asks for clarification from CMS on this point.

As noted above, SVU believes that CMS' proposal to calculate the calendar year 2014 outpatient relative payment weights using the distinct CT and MRI CCRs is well-reasoned, supported, and long overdue for a number of reasons. First, SVU completely agrees with CMS that there is a sufficient amount of data from the CMS 2552-10 cost reports to generate meaningful analysis of CCRs.⁶ Specifically, it is our understanding that CMS was able to calculate a valid MRI CCR for 1,853 out of 3,951 hospitals⁷ (*i.e.*, 47%), a valid CT CCR for 1,956 out of 3,951 hospitals (*i.e.*, 50%), and a valid cardiac catheterization CCR for 1,367 out of 3,951 hospitals (*i.e.*, 35%).⁸

Second, SVU concurs with CMS that the estimated changes in APC costs associated with using the new standard cost centers is consistent with RTI International's ("RTI's") conclusions and predictions outlined in its July 2008 report.⁹ The Proposed Rule's expected increase in costs range from about 17% to 30% for ultrasound related APCs and the expected decrease in costs range from approximately 24% to 38% for CT and 14% to 19% for MRI related APCs clearly and undisputedly demonstrates that RTI was correct in concluding that costs for CT and MRI were substantially overstated, while costs for x-rays, ultrasound and other imaging procedures were substantially understated when the single Diagnostic Radiology cost center was used to calculate the outpatient relative payment rates.¹⁰

As a result, SVU wholeheartedly agrees with CMS that the analytical findings support CMS' original decision to develop distinct cost centers for MRI and CT.¹¹ Moreover, SVU also does not see any reason to further delay the use of the new distinct MRI and CT CCRs in calculating the HOPPS relative payment rates.¹²

In fact, SVU adamantly believes that it would be inequitable for CMS to not use the distinct MRI and CT CCRs in setting the HOPPS rates for 2014 and would continue to perpetuate Medicare overpaying for certain HOPPS imaging services, while

⁴ 78 Fed. Reg. at 43,548.

⁵ 78 Fed. Reg. at 43,550.

⁶ 78 Fed. Reg. at 43,549.

⁷ See 78 Fed. Reg. at 43,583.

⁸ 78 Fed. Reg. at 43,549.

⁹ *Id.*; see also RTI International, Refining Cost to Charge Ratios for Calculating APC and MS-DRG Relative Payment Weights (July 2008), available at <http://www.rti.org/reports/cms/> (last visited Aug. 13, 2013) (hereinafter "RTI Report").

¹⁰ 78 Fed. Reg. at 43,549; RTI Report at p. 113.

¹¹ 78 Fed. Reg. at 43,550.

¹² *Id.*

underpaying for other HOPPS imaging services, which, implicates Medicare's reimbursement under the Physician Fee Schedule, due to the Deficit Reduction Act of 2005's ("DRA's") mandate that certain imaging services' reimbursement be capped at the HOPPS rate.¹³ Furthermore, we believe that failure to use the distinct MRI and CT CCRs in setting the HOPPS rates for 2014, now that CMS clearly has the valid data to do so, could be a violation of the Administrative Procedure Act ("APA"),¹⁴ as well as various Congressional and Executive mandates and policies aimed at promoting accurate and equitable reimbursement for health care items and services.¹⁵

SVU members have been struggling for too many years to provide high-quality vascular ultrasound services to Medicare beneficiaries at grossly inaccurate and low reimbursement rates. Now that CMS finally has the evidence, data and ability to revise and accurately reimburse for vascular ultrasound services, SVU believes CMS must do so immediately in order to preserve Medicare beneficiaries' access to quality vascular ultrasound services.

II. Proposed Changes to Packaged Items and Services

SVU is deeply troubled with CMS' proposal to package certain diagnostic tests on the bypass list when they are integral, ancillary, supportive, dependent, or adjunctive to a "primary service."¹⁶ In attempting to explain this proposal, the Proposed Rule states that a "dependent service" refers to "codes that represent services typically ancillary and supportive to a primary diagnostic or therapeutic modality."¹⁷ A "primary service," on the other hand, under the Proposal Rule, refers to "codes that represent the primary therapeutic or diagnostic modality into which [CMS] package[s] payment for the dependent service."¹⁸ While we appreciate CMS' efforts to improve hospital efficiency, we strongly believe that this proposal is inappropriate for several reasons.

First of all, many of the services that SVU members provide, which could be potentially impacted by this proposal,¹⁹ are always the primary service, because they are services that represent the primary "diagnostic modality" for a particular patient and condition. For example, a venous duplex ultrasound is recognized as the primary diagnostic test of choice for patients who present with symptoms of deep venous thrombosis. If positive, treatment is initiated based solely on the venous duplex results, with no further diagnostic testing required. In other words, the diagnostic service is primary to any subsequent intervention, and determines whether that invention occurs or

¹³ DRA. Pub. L. No. 109-171. § 5102(b), 120 Stat. 4, 5102 (2005) (codified at 42 U.S.C. § 1395w-4(b)(4)).

¹⁴ 5 U.S.C. § 553.

¹⁵ See e.g., The Affordable Care Act ("ACA"), § 1003, adding § 2794 to 42 U.S.C. §§ 300gg-91 et seq.; ACA § 3102, amending 42 U.S.C. § 1395w-4(e); and 78 Fed. Reg. at 43,555.

¹⁶ 78 Fed. Reg. 43,574.

¹⁷ 78 Fed. Reg. at 43,569.

¹⁸ *Id.*

¹⁹ Such services and related codes include: 93880, 93882, 93886, 93888, 93925, 93926, 93930, 93931, 93970, 93971, 93975, 93976, 93978, 93979, 93990, and G0365.

does not occur. The diagnostic service does not occur at the same time and as ancillary part of the intervention, such as the use of a fluroscope in an interventional radiology service.

Thus, SVU adamantly believes that packaging of certain diagnostic tests on the bypass list is inappropriate, because such services satisfy the Proposed Rule's "primary service" definition and not the Proposed Rule's "dependent service" definition. Initially, SVU believed that CMS agreed that certain diagnostic services on the bypass list were "primary services" and needed to be removed from the bypass list, as the Proposed Rule indicates in Table 1. Specifically, Table 1 proposes to remove several codes that SVU members typically perform from the bypass list.²⁰

However, the Proposed Rule explains that the "list of codes proposed for *removal* from the bypass list includes those codes that *would* be affected by the 2014 [HOPPS] proposed packaging policy."²¹ Since it is not clear to us how codes that are being proposed to be removed from the bypass list would then still be subject to the proposal to package diagnostic services on the bypass list, we ask for clarification from CMS on this point.

With that being said, for purposes of our comments, we presume that these specific codes that SVU members typically perform will remain on the bypass list. As a result, these codes could be subject to the proposal to package diagnostic tests on the bypass list with other primary services.

Also, since the Proposed Rule did not provide any explanation or examples of when certain diagnostic codes on the bypass list²² will fail to satisfy the "primary service" definition, and apparently meet the "dependent service" definition, which is contrary to SVU members' every-day clinical practices, SVU feels the Proposed Rule fails to give SVU and other stakeholders adequate notice and opportunity to comment on this proposal. As such, finalization of this proposal without adequate notice and opportunity to comment would be in violation of the requirements under the APA.²³

Furthermore, SVU is very concerned that CMS did not account for the administrative infeasibility of packaging certain diagnostic tests on the bypass list with another primary service based on the clinical realities. Specifically, diagnostic tests on the bypass list performed by SVU members²⁴ can lead to numerous outcomes, including: (1) insignificant findings, (2) significant findings, but either due to clinical guidelines and/or patient choice, no further services are provided to the patient, or (3) significant

²⁰ 78 Fed. Reg. 43,547.

²¹ 78 Fed. Reg. at 43,546 (emphasis added).

²² Namely: 93880, 93882, 93886, 93888, 93925, 93926, 93930, 93931, 93970, 93971, 93975, 93976, 93978, 93979, 93990, and G0365.

²³ 5 U.S.C. § 553.

²⁴ Namely: 93880, 93882, 93886, 93888, 93925, 93926, 93930, 93931, 93970, 93971, 93975, 93976, 93978, 93979, 93990, and G0365.

findings, and due to clinical guidelines and/or patient choice, additional services are provided to the patient in an attempt to remediate the significant findings discovered during the primary diagnostic service. As we understand it, the proposal would only apply in the third scenario, in which CMS would package payment for the diagnostic test on the bypass list that resulted in significant findings and led to additional services being provided to the patient in an attempt to correct or mitigate such significant findings. We ask that CMS confirm our understanding, as it is not entirely clear to us how the proposal would actually apply and be administratively implemented.

Assuming that our understanding of the proposal is correct and it would only apply in the third scenario described above, the primary diagnostic services listed on the bypass list are almost never performed by the same clinical personnel who will be providing the subsequent services that attempt to remediate the significant findings found as a result of the diagnostic test. It is also often the case that the clinical personnel performing the primary diagnostic test on the bypass list works for a different entity or provides the service in a different setting than the clinical personnel who performs the subsequent remedial service(s). Furthermore, there is often a significant time delay between the time that a SVU member performs a primary diagnostic test on the bypass list, which results in significant findings, and the subsequent service(s) provided to the patient in an attempt to remediate those findings. As a result, SVU believes that these differences in clinical personnel, setting of care, ownership, and time would make it administratively infeasible and inequitable for CMS to package diagnostic tests on the bypass list with some other “primary service”.

For the above reasons, we urge CMS not to finalize the proposal to package certain diagnostic tests on the bypass list with a “primary service”. Consequently, we further strongly disagree with CMS’ related, proposed regulatory changes at 42 C.F.R. § 419.2(b)²⁵ and similarly, we recommend that CMS not finalize this proposal as well.

III. Comment Solicitation on Packaging Imaging Services With Surgical Services

SVU appreciates the opportunity to address CMS’ contemplation of a future proposal to conditionally package all imaging services with any associated surgical procedure.²⁶ However, for similar reasons discussed above, we are very concerned by CMS’ contemplation, particularly with respect to the administrative feasibility based on the realities of current clinical practice.

As noted above, in the instances when a diagnostic imaging service results in significant findings that leads to surgery, it is almost always the case, particularly with respect to surgery, that the diagnostic imaging service is performed by a different clinical personnel than the personnel performing the surgery. Furthermore, the diagnostic imaging service will likely always be performed in a different setting, which also may be

²⁵ 78 Fed. Reg. at 43,575.

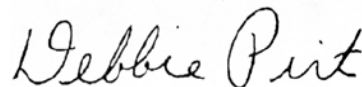
²⁶ *Id.*

owned by a different entity than the setting and ownership of where the surgery is done. Finally, there is often a significant time delay between when a diagnostic imaging service is performed and when the corrective surgery is performed. Consequently, any one of these differences calls into question the administrative feasibility and fairness of packaging all imaging services with any associated surgical service's reimbursement. Furthermore, when looking at these differences in combination with one another, SVU believes that packaging all imaging services with any associated surgical service would be administratively infeasible and inequitable. As such, we urge CMS to no longer contemplate this possible proposal.

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We thank you for your consideration of these comments to the Proposed Rule. We look forward to continuing to work with CMS to improve the health of Medicare beneficiaries.

Respectfully submitted,



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