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

RE: CMS-1600-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

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 revisions to payment policies under the Physician Fee Schedule (“PFS”) for calendar year (“CY”) 2014 (the “Proposed Rule”).1 SVU is a professional society comprised of over 4,600 vascular technologists, sonographers, nurses, and physicians. SVU members provide a variety of high-quality vascular ultrasound services2 to Medicare beneficiaries. Although there are aspects of the Proposed Rule we support, unfortunately, we think there are components of the Proposed Rule that will continue to contribute to inadequate Medicare reimbursement and to Medicare beneficiaries’ inability to access high quality Medicare services and providers.

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. With this in mind, SVU offers these comments to the Proposed Rule from the perspective of vascular ultrasound.

2 Such services and related codes include: 93880, 93882, 93886, 93888, 93890, 93892, 93893, 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971, 93975, 93976, 93978, 93979, 93980, 93981, 93990, and G0365.
In summary, SVU presents for CMS’ consideration the following comments to the Proposed Rule:

- **Using the Hospital Outpatient Prospective Payment System (“HOPPS”) In Developing Practice Expense (“PE”) Relative Value Units (“RVUs”):** While SVU continues to take issue with the Deficit Reduction Act of 2005 (“DRA”) requirement that certain imaging services’ PFS reimbursement be limited to the amount paid under HOPPS, SVU supports the DRA imaging cap exception to CMS’ proposal to use the HOPPS rate in developing the PE RVUs, because such imaging services are already subject to the HOPPS limit and, without the exception, the proposal would be duplicative and likely inequitable.

- **Ultrasound Equipment Recommendations:** SVU strongly believes that the vascular and ultrasound rooms should include all the items that are included in the actual room in order to accurately and fairly account and reimburse for the costs and clinical realities of the services provided in the vascular and ultrasound rooms, which unlike other rooms, captures a greater volume and a broader range of services, as well as the fact that unlike other rooms, a variety of different equipment needs to be available in the vascular and ultrasound rooms in order to adjust to varying patient habitus, among other things.

- **Codes With Proposed Changes To Ultrasound Equipment:** SVU is troubled by CMS’ proposal to change the direct PE inputs for codes 93980 and 93981 from the ultrasound room to just an ultrasound color Doppler, transducers, and vaginal probe, because, based on our years of experience, these services are typically performed in either a vascular or ultrasound room and the replacement of a room with only three equipment items does not accurately nor adequately account for the equipment costs associated with these services, which inevitably leads to further inadequate reimbursement for these sensitive, yet important services.

- **Multiple Procedure Payment Reduction (“MPPR”) Policies:** While SVU continues to be deeply concerned about the current inadequate reimbursement for vascular ultrasound services due to, in part, the current MPPR policies, SVU supports CMS’ proposal for no further expansion of the current MPPR policies.

- **Physician Quality Reporting System (“PQRS”) Measures:** SVU commends CMS on its continued commitment to ensure and improve the quality and safety of physician services through PQRS and other quality reporting programs and we support a number of the quality measures relating to ultrasound and radiation exposure as a means to promote high-quality care.

- **Ultrasound Screening for Abdominal Aortic Aneurysms (“AAA”):** SVU strongly supports the proposal to remove the time limitation and allow coverage of AAA screening for eligible beneficiaries without requiring them to receive a

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referral as part of the initial preventative physical examination ("IPPE"), because, like CMS, we agree that this proposal will help increase Medicare beneficiaries' ability to access this important preventive health service, as recommended by the United States Preventative Services Task Force ("USPSTF").

- **The Sustainable Growth Rate ("SGR"):** While SVU supports CMS’ commitment to work with Congress to reform the SGR methodology and prevent the approximate 24.4% cut to providers’ Medicare reimbursement, SVU urges CMS to consider all of its available administrative options to prevent such cuts, because such a reduction in payment, in addition to the current 2% sequester reduction, would mean that more providers would be unable to provide health care services to Medicare beneficiaries due to the grossly inadequate reimbursement rates, thereby reducing beneficiaries’ access to critical health care services.

These comments are discussed in greater detail below. We thank you in advance for your consideration of SVU’s comments.

I. **Using HOPPS In Developing PE RVUs**

While SVU continues to take issue with the DRA’s requirement that certain imaging services’ PFS reimbursement be limited to the amount paid under HOPPS, SVU supports the DRA imaging cap exception to the proposal to use the HOPPS rate in developing the PE RVUs, because without this exception the proposal would be duplicative and inequitable. Specifically, CMS proposes to limit non-facility services’ RVUs, so that the total non-facility PFS reimbursement would not exceed the total HOPPS reimbursement for that same service (i.e., in a facility setting), except for certain services, including those services currently subject to the DRA imaging cap. While the DRA imaging cap exception to the proposal makes sense, because the proposal is essentially proposing to apply the DRA imaging reimbursement limitation to all other services, based on the fact that vascular ultrasound services have been subject to the DRA limitation for nearly seven years, we believe that we can confidently say that CMS’ perception that the HOPPS reimbursement cap is a good policy that should be applied to additional services is incorrect.

Importantly, our experience is that when a service, provided in a physician office, is reimbursed at the hospital rate, the reimbursement is grossly inadequate based on a number of factors. For instance, the proportion of costs borne by a solo or even small group physician practice to provide a service is vastly different than the proportion of costs a large health system bears in providing that exact same service due to economies of scale, market power, and purchasing volume. Also, due to the inherent differences

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between a facility and a non-facility setting, there are fundamental differences between
the way a service will be provided in a hospital versus a physician office setting, whether
that be the type of individual performing part of, or the entire service, which has real cost
implications, even if there is no clinical difference.

While these are just a few examples of the meaningful differences in costs
associated with providing the same clinical service in a facility and a non-facility setting,
they clearly demonstrate that it is not only inappropriate, but inequitable, to automatically
cap PFS services’ reimbursement at the HOPPS rate. There is a reason that Congress
established separate statutory reimbursement methodologies for hospitals and physicians\(^7\)
and we adamantly believe that CMS should honor that distinction, rather than override it
through this proposal.

With that said, should CMS choose to finalize this proposal, SVU supports the
corresponding proposed DRA imaging cap exception, because we believe that without
the exception, the proposal would be duplicative and inequitable. As noted above, CMS
is proposing to not apply this proposal to services that are already subject to the DRA
imaging cap.\(^8\) Specifically, the DRA imaging cap applies to the technical component of
services, such as x-ray, ultrasound, magnetic resonance imaging (“MRI”), computed
tomography (“CT”) and nuclear medicine, and limits this amount to the rate paid under
HOPPS.\(^9\)

In discussing the rationale behind the proposed DRA imaging cap exception,
CMS correctly acknowledges that the DRA already limits certain imaging services’ PFS
technical component reimbursement to the amount paid under HOPPS.\(^10\) Thus, for
imaging services, the DRA imaging cap effectively already does what CMS is proposing
to do - namely limiting PFS reimbursement to the amount paid under HOPPS for the
same procedure. It would, at best, be duplicative and would, at worst, be inequitable to
submit imaging services to two HOPPS caps – once in developing the PE RVUs and a
second time when determining certain imaging services’ technical component
reimbursement. Therefore, while we disagree with the overall proposal, should CMS
decide to finalize this proposal, we agree with CMS that it is absolutely necessary to
include a DRA imaging cap exception to the proposal in order to ensure that imaging
services are not repeatedly and unnecessarily subject to inappropriate reimbursement
reductions.

II. **Ultrasound Equipment Recommendations**

While SVU understands why CMS may have some concerns regarding the current
make-up and costs associated with the “rooms” direct PE inputs, based on the apparent
submission of inaccurate information, SVU wishes to take this opportunity to explain
why these concerns should not extend to the vascular and ultrasound rooms. Specifically,

\(^8\) 78 Fed. Reg. at 43,297.
CMS asked for comments on whether “rooms” should include: (1) all of the items that might be included in the actual room, (2) just the items typically used for every service in the room, or (3) all the items typically used in typical services furnished in the room.\textsuperscript{11}

We adamantly believe that in order to accurately and adequately reimburse for vascular ultrasound services, all vascular ultrasound services should have the vascular ultrasound room as a direct PE input and that the vascular ultrasound room PE inputs should account for all the equipment items that could be used for a vascular ultrasound procedure, or alternatively, at the very least continue to account for all items that are typically used in furnishing the services provided in the vascular ultrasound room. This proposition is supported by a number of unique clinical realities that distinguish vascular ultrasound services from other types of services that are also provided in a room.

First, the reason that the vascular and ultrasound rooms appear to “include a greater number of individual items than the ‘rooms’ for other kinds of procedures”\textsuperscript{12} is because the vascular ultrasound room was built from the premise of the type of clinical services that would be provided in the room, while other rooms appear to have been built from the premise of the specific equipment or technology that would be performing the services in the room (\textit{i.e.}, MRI room, CT room, etc). This is an important distinction, because the number of equipment items assigned to the room will inevitably vary if a room is built using the equipment as the beginning premise, compared to a room that is built using the clinical services as the beginning premise.

For instance, the positron emission tomography (“PET”) room was presumably built upon the premise of a room where the PET equipment will be housed and the associated clinical services were a secondary thought. However, the vascular ultrasound room was built on the premise of a room where vascular ultrasound services will be provided and the types of equipment that are needed to perform such services was the secondary thought. Accordingly, it is absolutely expected and necessary for the vascular ultrasound room to appear to have more items than other rooms, because the premise on which the vascular ultrasound room was built differs from the premise on which the other rooms were built.

As a consequence of this different clinical premise, there are a greater number and wider range of services provided in the vascular and ultrasound rooms, compared to the other rooms. For example, twenty-five or more distinct vascular ultrasound services are typically and routinely performed in the vascular ultrasound room,\textsuperscript{13} but there are only five specific PET services\textsuperscript{14} that would typically be performed in the PET room (\textit{i.e.}, EL009). Thus, a greater number of items and equipment will be needed for the broader range and number of services performed in the vascular and ultrasound rooms, compared to other rooms.

\textsuperscript{11} 78 Fed. Reg. at 43,298.
\textsuperscript{12} Id.
\textsuperscript{13} These codes include: 93880, 93882, 93886, 93888, 93890, 93892, 93893, 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971, 93975, 93976, 93978, 93979, 93980, 93981, 93990, and G0365.
\textsuperscript{14} These codes include: 78608, 78609, 78459, 78491, and 78492.
Second, the amount of equipment “types” needed to perform any single vascular service is greater than the number of equipment “types” needed to perform any single service provided in another room. For example, at least twenty-five vascular services typically require approximately eleven types of equipment, including: (1) an ultrasound duplex imager with vascular capabilities, (2) a vascular exam table with footboard, (3) an ergonomic sonographer chair, (4) multiple transducer types with varying frequencies, (5) a physiologic testing unit, (6) a variety of cuffs to account for varying leg sizes, (7) a printer, (8) specialized software for data collection and report generation, (9) a gel warmer, (10) a treadmill, and (11) stairs with handrails. It is our understanding that much fewer “types” of equipment are needed for a single service performed in the other rooms. For example, in the PET room, the main equipment is a GE Optima PET/CT 560 with a mobile table used to position the patient, as well as a cart, console, chairs, and computer.

Furthermore, in addition to the numerous “types” of equipment that are necessary to provide a vascular ultrasound service, the number of items that are needed for each equipment “type” is unique to the vascular and ultrasound rooms and also adds to the number of items included in the rooms. Specifically, several pieces of related equipment are frequently used during a single procedure for a single patient. For example, during a venous duplex exam one-type of transducer (i.e., a C5 transducer) is used during the abdomen portion of the exam, while another type of transducer (i.e., a L9 transducer) must be used for the leg portion of the exam.

In addition, the type of transducer that is needed for an exam can vary based on patient habitus. For instance, one type of transducer (i.e., a L9 transducer) would be needed to perform an Abdominal Visceral Duplex Ultrasound (i.e., 93975 and 93976) exam if the patient weighed 120 pounds, while another type of transducer (i.e., a C5 or C2 transducer) would be required for the exact same procedure if the patient weighed 350 pounds. As both examples demonstrate, it is absolutely necessary for all these transducers to be assigned to the vascular and ultrasound rooms, because all these transducers will be needed by the provider who performs vascular ultrasound services in the vascular or ultrasound rooms to various patients throughout any given day.

This is not the case for the other rooms. For example, the same MRI machine is used regardless of patient habitus. Also, two different MRI machines are not needed to perform a single MRI service. One MRI machine usually has the capability of performing all MRI services. Thus, other rooms appear to have less items compared to the vascular and ultrasound rooms, because the other rooms do not require the high volume and broad range of equipment items that are required for the vascular and ultrasound rooms.

In conclusion, while we believe that CMS was valid in raising certain concerns in the Proposed Rule, those concerns should not expand to the vascular and ultrasound room components, as the items currently assigned to those rooms’ direct PE inputs are typically used in vascular ultrasound services and, based on the various reasons described above, it is expected that there would appear to be more items in the vascular and ultrasound rooms compared to the other rooms. We also would urge CMS to account for all items used in the vascular and ultrasound rooms, rather than only those items typically used in
these rooms, because we believe this policy would more accurately reflect and reimburse for the costs associated with providing quality vascular ultrasound services to Medicare beneficiaries in the vascular and ultrasound rooms.

III. Codes With Proposed Changes To Ultrasound Equipment

SVU is troubled by the American Medical Association’s (“AMA”) Specialty Society Relative Value Update Committee’s (“RUC’s”) recommendation, which CMS is proposing to adopt, to change 93980 and 93981’s direct PE inputs from the ultrasound room to only three pieces of equipment, namely an ultrasound color Doppler, transducers, and a vaginal probe. Based on our extensive experience providing these services, we strongly believe that the direct inputs for these codes should continue to include either the vascular or ultrasound room, because these services are typically performed in a vascular or ultrasound room. These exams are typically performed in a vascular or ultrasound room because the exam requires physiologic testing equipment, where either a plethysmographic trace or penile blood pressure is recorded, which can be accompanied by a duplex imaging study. In addition, when an exam is positive for arterial disease, a full or limited lower extremity physiologic exam may be indicated as well. Thus, to not include the vascular room as a direct PE input would be contrary to what occurs in practice and would provide for inaccurate reimbursement for these important studies.

Furthermore, this proposal appears to be in direct conflict with CMS’ current policy of assigning a direct PE “room” input for those services typically performed in a room. It also appears to be inconsistent with how every other service’s direct PE input is determined and could establish an invalid and burdensome precedent for CMS. Thus, we urge CMS to reject the AMA RUC’s recommendation and maintain the current direct PE inputs for 93980 and 93981 in order to be consistent with CMS’ current policy.

IV. MPPR Policies

As we have stated in our comments to the CY 2013, 2012, and 2011 PFS proposed rules and to the CY 2012 PFS final rule with comment period, we are deeply troubled by the implementation, as well as the historical and vast expansion of the MPPR policies. Thus, we agree with CMS that no further expansion of its MPPR policies is warranted, because we continue to believe that the current MPPR policies are inappropriate.

The MPPR policies dramatically reduce the payments for both the professional component and technical component of multiple imaging services that are furnished to the same patient in the same session by a provider (or providers within the same group practice). SVU believes that CMS’ imaging MPPR policies are wildly inappropriate for two reasons. First, the authority that CMS has cited in the past to support its MPPR

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17 78 Fed. Reg. at 43,408.
policies does not give CMS authority to implement multiple service reductions, but instead merely allows CMS to modify the reimbursement for “codes”.\footnote{42 U.S.C. § 1395w-4(c)(2)(K).} Importantly, CMS’ MPPR policies are not modifications to specific codes, but are instead dramatic policies that reduce payments for a range of services.

Congress did in fact give CMS limited authority to implement multiple service reductions in another part of the Social Security Act ("SSA").\footnote{42 U.S.C. § 1395w-4(b)(4).} However, Congress did not intend to provide the authority that CMS claims under the “misevaluation” clause, because the codes are not “misvalued”. Specifically, CMS does not question the codes’ valuation, but instead, is concerned that payment across multiple procedures is not accurate. Thus, this is clearly not a case of “misvalued” codes.

Secondly, imaging service providers have been subject to successive and devastating cuts to imaging services’ reimbursement, in part through significant expansions of the MPPR. Because of these cuts, CMS is clearly at risk of fundamentally undermining beneficiary access to these critical, low-cost services. Therefore, we support CMS’ decision not to expand the MPPR policies and urge CMS to not expand the policies in future rulemaking.

V.  

\textbf{PQRS Measures}

SVU applauds CMS on its continued commitment to ensure and improve the quality and safety of physician services through PQRS and other quality reporting programs and appreciates CMS’ efforts to align various programs, reporting systems, and quality measures.\footnote{78 Fed. Reg. at 43,356.} Specifically, SVU supports the adoption of the following proposed PQRS Core Measures for reporting in 2014 and beyond, because such measures will promote high-quality care, which will ultimately benefit beneficiaries.

- TBD: Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation.
- TBD: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) who Die while in Hospital.
- TBD: Rate of postoperative stroke or death in Asymptomatic Patients undergoing Carotid Endarterectomy (CEA).
- TBD: Rate of postoperative stroke or death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS).
- TBD: Rate of Major Complications (Discharged to Home by Post-Operative Day #2) Carotid Artery Stenting (CAS) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2).
- TBD/256: Surveillance after Endovascular Abdominal Aortic Aneurysm Coordination Repair (EVAR).
Also, SVU agrees with CMS’ proposal to revise the “Proposed Ischemic Vascular Disease (IVD) Measures Group”\(^{23}\) and the “Proposed Cardiovascular Prevention Measures Group”\(^{24}\) to include additional quality measures. Specifically, certain providers may report based on a group of measures, or using individual measures, but if they report based on a group, they must report on all the measures within the group.\(^{25}\) Since both of the groups above involve services provided by SVU’s members, we are thrilled that our providers can have an additional opportunity to be rewarded for providing high-quality imaging services.

SVU is also strongly in support of CMS’ proposed inclusion of quality measures that address the need for radiation dose tracking, because we are deeply concerned about excessive and/or unnecessary patient exposure to radiation. Such excessive and/or unnecessary radiation exposure may occur when a provider fails to consider certain circumstances, such as recent tests performed by other providers. Therefore, we are hopeful that the addition of radiation dose tracking measures will be a first step in reducing unnecessary radiation exposure to Medicare beneficiaries. These measures include the following:

- TBD: Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description.
- TBD: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies.
- TBD: Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry.
- TBD: Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes.
- TBD: Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive.

Additionally, SVU supports CMS’ creation of a measures group called “Optimizing Patient Exposure to Ionizing Radiation”.\(^{26}\) SVU fears that too many patients are unnecessarily exposed and/or overexposed to radiation. We are hopeful that this radiation dose tracking group will help to alert providers and beneficiaries of the radiation risks. Therefore, SVU strongly supports the above additions to the PQRS since

\(^{24}\) 78 Fed, Reg. at 43,466.
\(^{26}\) Id.
we are hopeful that such changes will incentivize providers to engage in the highest-quality of care, leading to the delivery of cost-effective and safe health care services to Medicare beneficiaries.

VI. Ultrasound Screening for AAA

SVU strongly supports the proposal to remove the one-year time limitation and allow coverage of AAA screening for eligible beneficiaries without requiring them to receive a referral as part of the IPPE for a number of reasons. Currently, beneficiaries can only receive AAA screening if they receive a referral for the screening during the IPPE. However, the IPPE must occur within the first year of becoming eligible for Medicare Part B. Thus, the IPPE referral requirement places an unnecessary and burdensome time restriction on receiving AAA screenings. First, we agree that the Secretary has the requisite authority, under Section 4105 of the Affordable Care Act (“ACA”), to modify the coverage of specified preventative services, such as AAA screening, because the USPSTF has recommended one-time AAA screening for certain patients without a time limit.

Furthermore, CMS acknowledges that many beneficiaries may have been unable to obtain this critical preventative service for a variety of reasons. For instance, a beneficiary could have had their IPPE in July of 2005, but Medicare did not cover AAA screening until 2007. Thus, under the current policy, this beneficiary was effectively excluded from receiving Medicare coverage for AAA screening, even if it was clinically appropriate. In addition, some beneficiaries simply may not have had an IPPE when they were eligible and, thus, lost the opportunity to receive AAA screening. We agree with CMS that these are a few examples of how the current policy effectively acted as a barrier to Medicare beneficiaries obtaining access to AAA screening, which has been found to reduce AAA-specific mortality. Thus, SVU adamantly supports CMS’ proposal to remove the IPPE referral requirement for AAA screening and allow all Medicare beneficiaries that meet the specified risk profile, one-time coverage of an AAA screening examination, because we believe it will save lives and help reduce Medicare’s costs associated with caring for those individuals that did not get this important preventive service.

28 42 C.F.R. § 410.19.
29 42 U.S.C. § 1395m(n).
VII. The SGR

SVU urges CMS to do what it can to fix the pending 24.4% cut to physician payments scheduled to take effect January 1, 2014 through the SGR unless Congress intervenes. As we have noted before in our comments to the CY 2013 PFS rule, a long-term solution to the current SGR methodology is absolutely necessary to ensure that meaningful access to necessary health care services is not impeded. While Congress has made efforts to prevent the cuts in both the House and the Senate prior to the August recess,\textsuperscript{32} without a solution enacted yet, we urge CMS to work towards a permanent fix. In the event that Congress does not act, we urge CMS to develop a comprehensive set of proposed fixes to the repeated threat of across the board cuts to physician payments, and to do so, as quickly as possible.

Such action by CMS is even more critical than in the past, due to the 2% sequestration reduction that is currently applied to PFS services.\textsuperscript{33} Thus, should Congress not act to prevent the SGR cuts, the total reduction in PFS reimbursement will be 24.4% plus the 2% sequester, which means a total cut of 26.4%. Such a cut is unprecedented and would absolutely have a profound affect on beneficiary access to critical health care services, because many providers would unlikely be able to continue to provide quality health care services to beneficiaries if providers were required to take more than a quarter reduction to their reimbursement. We therefore urge CMS to develop administrative options, in the event that Congress does not act before January 1, 2014. Otherwise, the limitations on access to health care for beneficiaries is certain to be disastrous.

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\textsuperscript{32} See Medicare Patient Access and Quality Improvement Act of 2013, H.R. 2810 (passed by the House Energy and Commerce Committee on July 31, 2013).

\textsuperscript{33} 2 U.S.C. § 901a(8).
SVU would be happy to provide additional information on any or all of the aforementioned issues. We look forward to continuing to work with CMS to improve the health of Medicare beneficiaries, and we thank you in advance for your thoughtful consideration of our comments.

Respectfully submitted,

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