Alliance of Specialty Medicine

Sound Policy. Quality Care.

The Honorable Max Baucus
Chairman, Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510-6200

The Honorable Orrin Hatch
Ranking Member, Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510-6200

The Honorable Dave Camp
Chairman, Ways and Means Committee
1102 Longworth Building
Washington, DC 20515

The Honorable Sander Levin
Ranking Member, Ways and Means Committee
1102 Longworth Building
Washington, DC 20515

RE: Feedback on the Senate Finance and House Ways and Means Sustainable Growth Rate (SGR) Repeal and Medicare Physician Payment Reform Discussion Draft

Dear Chairmen and Ranking Members:

The Alliance of Specialty Medicine (the Alliance) would like to thank the Senate Finance Committee and the House Ways and Means Committee for the opportunity to provide feedback on its October 31, 2013 draft legislative framework for repealing and replacing Medicare's sustainable growth rate (SGR) formula. The Alliance is a coalition of medical specialty societies representing more than 100,000 physicians and surgeons dedicated to the development of sound federal healthcare policy that fosters patient access to the highest quality specialty care.

Attached are detailed comments on each specific section of the proposal. In summary, our main concerns with the proposal include:

- Freezing physician payments for 10 years, which ignores the cost of treating patients and the resources needed to invest in quality improvement activities;
- Preserving, and even adding to, aspects of current quality reporting and value-based payment initiatives that make them irrelevant to specialty medicine, while providing little enhanced flexibility for physicians to determine which quality improvement activities are most relevant to their patient population and most appropriate for their practice;
- Applying budget neutrality across the new Value-Based Performance Payment Program, which means there will inevitably be "losers" regardless of performance.
- An Alternative Payment Model proposal that ignores the fact that the most widely tested models are most suitable for primary care physicians and present challenges in terms of specialist participation;
- Inappropriate Congressional intervention in the development of procedure codes;
- Egregious penalties for failing to participate in CMS data collection efforts; and
- Expansion of publicly reported data that are not indicative of physician quality.

Since only a discussion draft is available to review at this time, many of our outstanding concerns and questions are based on assumption and speculation. As such, it would be very helpful if the committees could clarify any misinterpretations of intent and/or share any additional details about the specific language that we can expect to see.

The Alliance again thanks the Committee for the opportunity to provide feedback and looks forward to working with you to find a permanent and meaningful solution to the flawed physician payment system. We would be happy to discuss our concerns with you or answer any other questions, and can be reached at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions
Society for Excellence in Eyecare

Alliance of Specialty Medicine Comments
Senate Finance & House Ways and Means Committee SGR Proposal

I. SGR Repeal and Annual Updates

- First and foremost, the Alliance thanks the committees for their efforts to repeal the SGR. Eliminating the SGR is essential to ensuring a stable payment system that provides Medicare beneficiaries timely access to care.
- However, the Alliance is extremely concerned about the proposal's 10-year freeze in Medicare payments to physicians. Medicare physician payments have already trailed inflation for nearly 10 years and extending this freeze for another decade will result in a cumulative gap between Medicare payments and the cost of treating patients of nearly 45%.
- We encourage you to include a 5-year period of stability following the repeal of the SGR, during which time base payments to physicians should capture the true cost of treating patients. This 5-year period can be used to support the development and testing of alternative measures, clinical improvement activities, and payment models.
- The SGR must be replaced with not only a stable, but *fair* mechanism that recognizes reasonable inflationary medical costs and ensures that physician reimbursements are based on the *actual* cost of providing care.
- Medicare updates must ensure beneficiary access to high quality care and enable physicians to make critical investments in their practice's infrastructure to support new models of care delivery that aim to improve quality and efficiency.

II. Value-Based Performance (VBP) Payment Program

<u>General</u>

- The Alliance supports positive financial incentives for higher quality and more efficient care, not penalties and withholds. The proposed ten-year freeze, paired with a budget neutral Value-Based Performance (VBP) Program, will result in cuts to many physicians starting as early as 2017 and really only represents one year of stability since payment adjustments will likely be based on 2015 performance.
- The Alliance wholeheartedly supports termination of current law incentive program payment reductions and the return of those payments to the physician payment pool.
- The Alliance also supports efforts to streamline the current approach to quality reporting rather than maintaining three distinct programs. However, we are concerned that this new structure essentially maintains current reporting program mandates while ignoring the flaws and challenges of each of these programs, which are described below. Furthermore, it would increase the regulatory burden that physicians now face by holding them accountable for clinical practice improvement activities in addition to, rather than in lieu of, existing program requirements.
- Making the VBP a budget neutral program means that there will inevitably be "losers" to finance the "winners," no matter how reasonable one's performance is (i.e. a physician could score 90 out of 100 and still be penalized). Furthermore, this proposal would extend budget neutrality in a manner that does not currently exist since the PQRS and EHR Incentive Programs are not budget neutral. Again, the Alliance supports positive financial incentives for higher quality and more efficient

care, not penalties and withholds. If the program must include winners and losers, then it should only target statistically significant outliers rather than those performing at the mean.

- The Alliance also favors providing physicians with positive incentives for reaching certain thresholds or improving upon their own personal performance versus ranking systems that arbitrarily pit physicians against each other. We favor an approach similar to that taken in the original Energy and Commerce proposal, in which a physician's composite performance score would be based on a 0-100 scale and incremental updates would be provided depending on where the physician fell on the scale. This approach avoids peer-to-peer comparisons and is based simply on a physician's attainment of certain thresholds.
- We support exempting physicians who receive a significant portion of their revenue from an advanced Alternative Payment Model (APM) from the VBP program.
- We also support exempting physicians who treat too few Medicare beneficiaries from the VBP Program. However, we request that the exemption categories be expanded to include those new to practice and those nearing retirement.

Professionals Eligible for the VBP Program

- The Alliance takes issue with the fact that the VBP program would apply to *all* physicians beginning with payment year 2017. Reforms that hold physicians accountable for value need appropriate time for proper implementation. This proposal includes no mechanisms to ensure careful and incremental implementation, nor does it differentiate between practices that are better equipped with resources and experience to fulfill performance-based reporting mandates versus those that are not.
- While we appreciate that professionals who treat few Medicare beneficiaries would be excluded from the VBP program and protected from penalties, these physicians would be left with a 10-year freeze in payments that does not keep up with the cost of providing care.

Assessment Categories

General

- It is critical that medical professional societies be able to determine the most appropriate and clinically relevant mix of quality improvement and value-based strategies.
- Due to the robustness of clinical data and the proven value of tracking practice patterns and outcomes, we support giving physicians who report to a qualified clinical data registry credit for satisfying all elements of the VBP.

Quality Measurement

- The Alliance supports preservation of PQRS measures to recognize investments made to date.
- We also support funding for measure development to address current gaps in measures, but request language that ensures that measure development is led by relevant medical specialty societies and their clinical experts; that measures are evidence-based and rely on best clinical practices; and that National Quality Forum-endorsement be recognized, but not required in order to allow for the testing of more innovative approaches to quality improvement.
- It is critical that this legislation preserve American Tax Relief Act-authorized

recognition of physician participation in a qualified registry in lieu of PQRS or other quality measure reporting.

- While outcomes measures should be incentivized, Congress must recognize that few outcomes measures currently exist due to methodological challenges and a lack of data. Funding is needed not only for measure development, but for tools, such as registries, that can assist with the collection of data and help us to better understand gaps in measurement and patient risk factors that affect outcomes. **Risk adjustment is an essential component of quality measurement, and it is very concerning that it is not mentioned anywhere in this proposal.**
- The proposal states that "professionals would be given credit for attainment and achievement of quality measures." We request clarification of this statement. As stated earlier, we caution against tournament style performance rankings that measure an individual's performance relative to others, instead of recognizing personal achievement or the attainment of certain thresholds regardless of how others perform. This is especially important since this proposal does not, like the Energy and Commerce legislation, include a mechanism through which physicians can self-identify with a peer cohort for purposes of performance assessment or any other mechanism to ensure apples-to-apples comparisons.

EHR Meaningful Use

- The Alliance supports provisions to prevent duplicative reporting and appreciates that the proposal would recognize professionals who report quality measures through certified EHR systems as satisfying the meaningful use clinical quality measure (CQM) component. However, we remind the committees that CQMs are only one component of the EHR Incentive Program and that the program's remaining objectives and all-or-nothing scoring approach make it largely irrelevant and challenging for specialists by assuming that every measure is absolutely appropriate and of equal value to every practice situation (see additional comments below).
- To realize the full potential of EHRs, requirements of the current program need to be less prescriptive to allow physicians to be creative in applying the technology to their unique clinical workflows and patient needs. The program's timeline also must be more gradual to allow vendors to keep up with certification requirements and to allow physicians more time to learn how to incorporate system functionalities into practice and use them in a meaningful manner that improves patient care, ensures patient safety, and improves workflows. We remind the committees that there is currently not a single system that has been certified for the full set of Stage 2 MU requirements, which is set to start in 2014.
- We also recommend that Congress recognize physicians who participate in qualified clinical registries as having met the meaningful use criteria. Participation in a clinical registry requires that physicians (1) capture relevant patient data, the ONC's goal of stage 1 meaningful use; (2) exchange data with the registry and across settings, the goal of stage 2 meaningful use; and (3) engage in quality improvement activities, the goal of stage 3 meaningful use. Therefore, physicians who participate in a qualified clinical data registry should be deemed by CMS as having satisfied the requirements of the meaningful use program.

Resource Use Measurement

- The Alliance also appreciates language to ensure that current resource use metrics and methodologies are enhanced, including the development of more specific

episodes of care. We request specific language to ensure that resource use measures not be used for accountability purposes until more specific episodes are defined and until risk adjustment and attribution methodologies are refined enough to produce accurate and reliable results.

- All-cost and per capita resource use metrics used under the current VBM should no longer be used since they inappropriately hold individual's accountable for decisions outside of their control. CMS has also indicated that the current set are less than ideal and are being used only as a stopgap measure to satisfy a legislative mandate until more appropriate metrics are developed. If total per capita costs measures are maintained, they should at least be expanded to include payments under Part A, Part B, *and* Part D drug expenses, which are currently not accounted for. If Part D costs are not considered when calculating total beneficiary costs, physicians who prescribe Part B drugs will appear to have significantly higher resource use over their peers who are prescribing Part D drugs for the same condition. This is a major concern for specialty physicians who treat patients that rely on pharmacotherapy to manage a specific condition and who are faced with a choice between Part B and D drugs. To date, risk adjustment has been unable to address this issue to a degree that limits adverse effects on clinical decision-making and patient choice.
- We request specific language to ensure that that both quality and cost measures used under the VBP program are properly risk adjusted prior to being used for accountability purposes. Sec. 3007 of the Affordable Care Act, which authorizes the Value-Based Payment Modifier, states that quality measures *"shall be risk adjusted as determined appropriate by the Secretary,"* and that costs shall be evaluated under a mechanism that *"eliminate[s] the effect of geographic adjustments in payment rates and take[s] into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions) and other factors determined appropriate by the Secretary."*

Clinical Practice Improvement Activities

- It is critical that the categories used to define Clinical Practice Improvement Activities not limit a physician's flexibility to choose activities that are most relevant and meaningful to his/her practice. Additional activities relevant to specialty medicine may include reporting to a clinical data registry, participating in Maintenance of Certification, serving on-call for a hospital's emergency department, and/or consulting specialty society-developed Appropriate Use Criteria or evidence-based clinical practice guidelines when making clinical treatment decisions.
- We request language that gives professional societies the authority to identify relevant clinical quality improvement activities that make the most sense for their members, such as that which was included in the Energy and Commerce legislation: *"…the term 'clinical practice improvement activity' means an activity that the appropriate fee schedule provider societies and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved health outcomes."*
- It is unclear how this category would be measured if everyone is doing different things. The Alliance supports giving physicians full credit for this category for attesting to engagement in a clinical practice improvement activity that meets broad principles.

Performance Assessment

- As stated above, if a value-based payment methodology is implemented, we encourage the Committees to adopt an approach similar to that taken in the original Energy and Commerce Committee proposal, in which a physician's composite performance score would be based on a 0-100 scale and incremental updates would be provided depending on where the physician fell on the scale.
- In terms of calculating the composite score, we recommend that greater weight be given to clinical practice improvement activities (proposed to be weighted at 15%) since this is where physicians have the most flexibility to choose what is most relevant to their practice. Less weight should be given to EHR Meaningful Use (currently weighted at 25%) due to the inflexible nature of the program and the persistent unavailability of relevant, certified products. Less weight also should be given to resource use (currently weighted at 30%) until better metrics and methodologies are developed that result in more accurate assessments.
- We support group-level performance analyses, as well as allowing facility-based professionals to have their quality assessment determined by the performance of their affiliated hospital or facility so long as these professionals are given the choice to decide what is most appropriate.
- We appreciate recognition of group-level reporting to a clinical data registry so long as individual reporting is also preserved.
- The Alliance requests language similar to the Energy and Commerce legislation to ensure that the performance period ends as close as possible to the beginning of the year for which an adjustment is applied.
  "*PERFORMANCE PERIOD.—Not later than [___] there shall be established a period, with respect to a year, to assess performance on quality measures and clinical practice improvement activities. Each such performance period shall occur prior to the beginning of the year and shall occur as close to the beginning of the year as is practical*."

Performance Pool Funding

- Again, we are highly concerned that the budget neutral nature of this program could result in significant and arbitrary cuts to physicians**.**

Feedback for Performance Improvement

- The Alliance requests language similar to the Energy and Commerce legislation, which strives to provide feedback to physicians in as real time as possible. It states: *"ONGOING FEEDBACK.—Under the update incentive program there shall be provided, as real time as possible, but at least quarterly, to each fee schedule provider feedback—(i) on the performance of such provider with respect to quality measures and clinical practice improvement activities…(ii) to assess the progress of such provider under the update incentive program with respect to a performance period for a year."*
- The Alliance also recommends that confidential feedback be provided to physicians for at least a year *prior* to holding physicians accountable for performance.

III. Encouraging Alternative Payment Model Participation

- While we appreciate that the Secretary would be encouraged to test APMs relevant to specialists and those that align with private and state-based payer initiatives, we request stronger language to ensure that physicians have the flexibility to choose a

model that is most relevant and meaningful to their practice and patient population, including one that is based on the fee-for-service system, even if it is not part of the set of payment and delivery models being tested through the Center for Medicare and Medicaid Innovation (CMMI). Rules regarding participation in certain current CMMI models remain unclear and carry potential risks that make them inappropriate for specialty medicine. One of the most concerning issues is physician exclusivity to one ACO. CMS has clarified that it is requiring exclusivity whenever any physician in an ACO-affiliated group, regardless of specialty, provides any of the relevant evaluation and management services, even if none of those services were used to attribute patients to the ACO. Because CMS applies exclusivity at the level of the TIN, even if one member of the practice meets the exclusivity requirement, all physicians billing under the same TIN must also be exclusive. Other concerns include unintended intra-ACO gatekeeper scenarios that may limit patient access to specialty care and the potential for shared savings to be distributed disproportionately among primary care and specialty physicians. These issues-- in particular, the exclusivity issue-- must be fixed before tying a significant portion of physician reimbursement to participation in an APM. Other models, such as the Medical Home, may be available to specialists, but are often of little relevance and rarely used by specialists. The Alliance wants to make sure that these are not the only models that would be deemed appropriate for the APM. The rules need to be flexible enough to encourage the testing of a range of innovative and unique models while ensuring minimum standards such as the inclusion of a quality component.

- This provision should also take into account participation in multiple arrangements if a physician chooses.
- The requirement that the APM include two-sided financial risk is restrictive and, depending on interpretation, could exclude important models currently being tested, such as bundled payments. This language should be clarified so that it more broadly reflects accountability for certain (unspecified) losses when a target (again, unspecified) is not reached.

IV. Encouraging Care Coordination for Individuals with Complex Chronic Care Needs

- Congress should not get involved in the development of procedure codes for physician services. Processes to develop billing and reimbursement codes are well established and already consider input from public and private stakeholders in an open and transparent forum.
- Codes to describe care coordination services are already being vetted though the aforementioned process and the Secretary has already noted its intent to carry this forward using its existing authority.
- This provision states that codes could be billed by specialty physician practices that meet certain criteria, but it is unlikely many specialty physicians would meet the criteria that is later set forth by the Secretary given the criteria that has already been proposed through rulemaking.

V. Ensuring Accurate Valuation of Services Under the Physician Fee Schedule

<u>GAO Study of RUC Processes</u>

- We are concerned that this provision may result in the replacement of the AMA RUC, as CMS would take over the RUCs function and contribution to developing RVUs, including the administration of "RUC surveys." Specialty medicine does not support

eliminating the RUC, whose processes have evolved to address concerns raised by the primary care community, including greater granularity, more accurate valuation, greater transparency, and greater engagement by all physician stakeholders. In fact, the RUC has changed its processes to enhance primary care representation and ensure that the samples are statistically valid in number.

- This provision also fails to recognize that CMS has addressed several of these issues through its ongoing work on the potentially misvalued code initiative, as well as through its new authority to validate RVUs through study. CMS contractors, RAND and Urban Institute, are conducting this work.

Ensuring that Global Payment for Work Component of Surgical Procedures Accurately Reflects Visits Following Surgery

- The data collected by the RUC is based on the typical patient, which is an appropriate and practical methodology that should continue.
- Global surgery is a form of bundled payment, and the data collected to date supports the level of care built into the global surgical codes. If global surgery payments are targeted in the manner proposed under this proposal, surgeons/specialists could face very similar challenges when it comes to developing other bundled, episode-based payments moving forward.
- The global surgical package for surgical services is already subject to potential review through RUC and CMS processes, thereby making this provision unnecessary.

Penalties for Failure to Respond to CMS "RUC-like" Surveys

- The steep 10% penalty proposed is unreasonable, unacceptable, and places a significant administrative and financial burden on physician practices. Completing surveys is timely and expensive, and without technical assistance, can be challenging. This activity should be voluntary, compensated, and offer technical assistance, but never punitive.
- Data obtained in a coercive manner, either through payment or penalty, is likely to be tainted in a way that purely voluntarily provided data is not. The Council of American Survey Research Organizations (CASRO), which represents more than 300 companies and market research operations in the United States and abroad, has stated in their code of ethical conduct that respondents should be voluntary.
- It is not clear whether physicians who inaccurately complete the survey would be subject to the penalty or if they would be subject to the False Claims Act if they mistakenly or unknowingly provided inaccurate data.
- It also is not clear whether surveys will be the only mechanism by which CMS would collect data. It has been said that time-motion studies could be carried out. It is our understanding that CMS is already using its statutory authority to carry out similar activities through its contracts with RAND and Urban Institute. It is not clear if these activities will continue under this proposal. Regardless, any effort should include an element of technical assistance, whether it is for completion of surveys or participation in a time-motion study.
- "Eligible professionals" are not defined. It is not clear who, besides physicians, would be surveyed. Physicians who most frequently provide the service being valued should determine physician "work."
- While we appreciate efforts to reduce the regulatory burden on smaller practices via an exemption, we are concerned that the result of such data collection efforts will be flawed. Small practices are differentially efficient when compared to their larger

counterparts. This could result in the misvaluation of services due to a biased sample. Moreover, with some medical specialties, the vast majority of providers will be in small practices, and, therefore, eliminated from the survey effort altogether. This proposal risks misvaluing services by using a biased and possibility discriminatory sample, as well as basing data on a limited, non-representative sample.

Target for Misvalued Services

- The Alliance opposes the 1% target, which it believes is arbitrary as well as unrealistic given that more than $76 billion of the $87 billion in physician expenditures have been reviewed as part of the existing misvalued code initiative. Any savings generated through a review of RVUs should be redistributed within the MPFS, regardless of how small.

VI. Recognizing Appropriate Use Criteria

- The Alliance supports efforts to encourage physicians to consult Appropriate Use Criteria, as well as more robust evidence-based clinical practice guidelines. However, we believe that AUCs and other practice guidelines should be used for educational purposes only and not tied to payment penalties or restrictions in care.
- If penalties must be imposed, we request that they focus only on outliers. Since the true goal of AUCs is to educate physicians and spur higher quality care, these individuals should first be given the opportunity to undergo educational training and improve upon their practice patterns. If deficiencies continue despite training, a financial penalty may be appropriate.
- Only AUCs developed by medical professional societies should be used under such a program.
- Physicians should have the freedom to choose which society's AUCs it would like to use, especially in cases where there are competing recommendations.
- We remind the committees that not all specialties have developed AUCs. Furthermore, many specialties believe that evidence-based clinical practice guidelines are far superior to AUCs, and have focused on developing guidelines rather than AUCs. The Alliance supports federal investments in registries and other data collection tools to help collect the data that will assist multiple specialties to develop AUCs or other practice guidelines or parameters, as well as investments in technologies that allow these to be accessed and used meaningfully at the site of care when making clinical treatment decisions.
- The Alliance believes that this program should be limited to Advanced Diagnostic Imaging Services, which already have been subject to a demonstration project involving implementation of the AUC and for which private payers already commonly require the use of AUCs. We urge the Committees to add language to ensure that additional areas of clinical focus can only be added after inappropriate utilization has been widely documented and the clinical topics have been fully considered via public notice and comment period.
- As stated earlier, we request that consultation of AUCs and/or practice guidelines be recognized as a Clinical Quality Improvement Activity under the VBP.
- The Alliance objects to any form of prior authorization on the grounds that this is a major departure from precedent for the Medicare program.

VII. Expanding the Use of Medicare Data for Performance Improvement

- The Alliance strongly opposes allowing qualified entities to provide or sell data analyses to health insurers and employers since they may use it in a black box manner for financial or business decisions unrelated to quality.
- We do support requiring the Secretary to make data available to qualified clinical data registries to support quality improvement activities.
- The Secretary of HHS also should work with qualified clinical data registries to ensure access to demographic data, including Social Security death files, which are critical for tracking outcomes yet often inaccessible to registry hosts.

VIII. Transparency of Physician Medicare Data

- This provision ignores current challenges with public reporting. While consumers have a right to informed decision-making, transparency is only valuable if it is meaningful and relevant. If not, it can actually cause greater harm and confusion.
- Utilization and payment data are not indicative of a physician's quality or efficiency and may create further confusion and inaccurate assumptions among consumers.
- There is still little evidence that consumers value or to what extent they even use publicly reported data regarding physician quality and costs.

IX. Additional Concerns Not Addressed in Proposal

The Alliance also would like to see the following provisions included in any SGR replacement package:

- Legal protections for physicians who follow clinical practice guidelines and quality improvement program requirements. At the very least, the rule of construction contained in the Energy and Commerce Committee's bill should be included. This states: "*RULE OF CONSTRUCTION REGARDING HEALTH CARE PROVIDER STANDARDS OF CARE.—(1) IN GENERAL.—The development, recognition, or implementation of any guideline or other standard under any Federal healthcare provision shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim.*"
- Repeal of the Independent Payment Advisory Board (IPAB); and
- Allowing for voluntary private contracting between physicians and Medicare beneficiaries.