January 29, 2016

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Johnny Isakson
Committee on Finance
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Mark Warner
Committee on Finance
475 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Senators Wyden, Isakson and Warner:

Thank you for the opportunity to comment on the Chronic Care Work Group's (Work Group) December 2015 "Policy Options Document." The American Medical Group Association (AMGA) represents over 430 multi-specialty medical groups and integrated delivery systems that care for approximately one out of every three Americans. Given our members long history in developing chronic care management processes and programs, we believe their collective experience offers the Finance Committee (Committee) valuable insight.

We are pleased the Work Group included in its over twenty policy options several the AMGA proposed in its June 22, 2015 letter to the Committee. These include expanding telehealth services, improving primary care and behavioral health integration, allowing for copay waivers, creating additional chronic care management codes and improving risk adjustment.

Our comments are categorized by topic.

**ACO Related Policy Proposals**
The Committee proposes several Accountable Care Organization (ACO) related policy options.

AMGA supports the Committee's proposal to "clarify" an ACO's ability to provide non-reimbursed "social service or transportation services" and "remote patient monitoring" (pg. 18).
Providing this clarification is particularly important because the research evidence demonstrates beneficiaries with functional status limitations in need of long term social services supports (LTSS) account for a disproportionate amount of Medicare spending compared to Medicare beneficiaries with any number of chronic conditions but with no functional status limitations. (See, for example, Komisar and Feder, "Transforming Care for Medicare Beneficiaries with Chronic Conditions and Long-Term Care Needs: Coordinating Care Across All Services," Georgetown University, October 2011.)

The Committee proposes to waive the originating site requirement to allow for expanded use of telehealth services for at risk ACOs only (pgs. 17-18). We recommend waiving the originating site requirement for all ACOs regardless of track. There is substantial evidence via the Veterans Administration, the Indian Health Service, state Medicaid programs and commercial health plans that telehealth services reduce hospital admissions and re-admissions, hospital bed days of care, and emergency department use. More generally, telehealth services also improve timely access, quality and care coordination, patient engagement, and reduce costs. Applying this waiver to the five percent of ACOs not in Track 1 needlessly limits the benefits of this technology to a very small subgroup of ACO patients. We believe all ACO beneficiaries should benefit from this important technology.

The Committee also proposes Track 1 ACOs be allowed to choose whether its beneficiaries are assigned retrospectively or prospectively and proposes to offer ACO assigned beneficiaries the option to voluntarily elect or attest to ACO assignment. If an ACO elects prospective assignment and provides services to beneficiaries who voluntarily elect to enroll, the Committee further proposes the ACO should receive an "upfront, collective payment for all services provided to these beneficiaries" (pgs. 21-22).

AMGA and the larger ACO stakeholder community recommend all ACOs regardless of track be given the choice of prospective assignment for at least two reasons. Research by J. Michel McWilliams among others has shown year-over-year unstable assignment or patient churn is substantial at over 20 percent which compromises the ACO's ability to manage a population of patients and earn shared savings. In addition, CMS has extended prospective assignment to Next Generation and Track 3 ACO program participants, CMS should simply extend further.

Further, we do not believe Track 1 ACOs that select this option should be required to receive an "upfront collective payment." ACOs select Track 1 so they can develop the competencies necessary to assume downside financial risk. These competencies span administrative, clinical, cultural and financial issues that frequently take years to master. There is good reason why there
are fewer at risk ACOs demonstration participants today (21 in Next Generation and 9 in Pioneer) then there were in 2012 (32 in Pioneer). Offering prospective assignment, that again would allow for a more stable patient population, would accelerate the development of these competencies. Also, CMS obviously believes prospective assignment is a better method of improving patient care - which is why the agency offers it to incent at risk contracting - CMS should therefore offer the approach to all willing ACO participants.

That said, we recognize this proposal may offer some ACOs in Track 1 opportunities to innovate. Interested ACOs would be able to use the "collective payment" for a far wider array of services beyond those covered under FFS including expanded skilled nursing, home health use, telehealth, remote monitoring, home visits and the wide array of supplemental services Medicare Advantage (MA) plans offer including LTSS. Providers have criticized the ACO program because it is simply a fee for service (FFS) pay for performance program, i.e., its goal is to simply reduce spending or spending growth. Here, a "collective payment" offers ACOs the opportunity to lower delivery costs that provides a greater opportunity for savings and provider participation/program sustainability. It appears the Committee is effectively offering Track 1 ACOs the opportunity to become a Next Generation ACO since they will be able to select capitated payment beginning in 2017.

Again, we recommend that the Committee allow Track 1 ACOs the ability to select prospective assignment without an "upfront collective payment." However, the Committee could also allow Track 1 ACOs to choose prospective assignment in their second and/or third contract years for which they receive an "upfront collective payment" for all services, as the Committee states, "provided to the beneficiaries in the ACO" and for those beneficiaries that voluntarily elect. The "upfront collective payment" would be based, we imagine, on how CMS calculates the Next Generation ACO demonstration's prospective benchmark, that is using a discount formula and paid as a per member per month (PMPM) reimbursement. We further recommend that for those beneficiaries that voluntarily elect they should be required to receive all their services from the ACO unless the ACO is unable to provide services sought.

**Medicare Advantage Related Proposals**

The Committee proposes to expand the number of supplemental benefits within the MA program to improve treatment of chronic care conditions (pgs. 13-14). We support this option as well as the Committee's related proposals to allow this flexibility for all MA plans and for all chronic disease patients who would benefit from these services. Additionally, we recommend that any/all expanded supplemental benefits be offered via all Special Needs Plans (SNPs) as well. Further,
we believe an expanded list of supplemental benefits would reduce the need for beneficiaries to purchase Medigap coverage.

The Committee is considering MedPAC's March 2014 recommendation that MA plans offer the Part B hospice benefit (pgs. 8-9). AMGA recognizes this policy option presents at least four potential improvements to improve beneficiary care. Because there remains a false dichotomy between curative and palliative care, palliative care too frequently is considered beneficial for hospice patients only. If MA plans were required to provide hospice care, i.e., develop or develop further an expertise in palliative care, more hospice and non-hospice beneficiaries alike would likely receive necessary palliation. In sum, there would be more opportunity for concurrent (palliative and curative combined) care.

Including the hospice benefit would also likely improve care coordination between MA plans and providers and between providers and family caregivers (Under the hospice benefit immediate family are, along with the beneficiary, the recipients of hospice care). Since hospice care is provided under the Medicare Shared Savings Program (i.e. ACOs) it should as well be included in MA. Beneficiaries should expect there to be one, coherent Medicare program. Lastly, as MedPAC noted in its March 2014 report, this policy measure would increase "incentives for plans to use the flexibility inherent in the MA program to develop and test innovative programs aimed at improving end-of-life care and care for patients with advanced illnesses."

These points noted, we are nevertheless concerned that including the benefit in MA may produce unintended negative consequences. We are concerned including the benefit may restrict beneficiaries choice of hospice providers and MA plans may not pay hospice providers current fee for service rates. Further, MA plans may require additional authorization for beneficiaries to receive hospice services and may subject them to out of pocket expenses. The Committee should consider how to ensure these consequences are avoided.

All these reasons may worsen the fact hospice care is already selected too late by too many beneficiaries and their families for them to fully benefit. In 2013 nearly half of all Medicare hospice patients received two weeks or less of hospice care: 35 percent received less than one week; and, 14 percent received less than two weeks. We are concerned improving hospice access by adding it to the MA program will either worsen this problem or do nothing to remedy it. Finally, for profit MA plans that own hospices should not be able to financially benefit from the current hospice Medicare Conditions of Participation (CoP) requirement that volunteers contribute five percent of total patient care hours of all hospice employees and contract staff.
Since some amount of volunteer hours substitute for clinical care, this savings would constitute a financial windfall. If these unintended negative consequences were avoided, MA plans could be offered the option of including the hospice benefit.

The Committee proposes to permit MA plans to include telehealth services in their annual bid amount. The Committee is also interested in learning whether telehealth services should be limited to those currently allowed in fee for service and whether additional telehealth services should be permitted (pgs 16-17). In principle AMGA supports this proposal. We are concerned however, if MA plans are "permitted" to include telehealth services in their bid amounts this would add to the already considerable number of differences between the MA and the ACO programs. Compared to ACOs, MA plans already enjoy financial and quality measurement benchmarking, beneficiary enrollment, risk adjustment, marketing and other advantages. If MA plans are afforded the opportunity to be reimbursed for telehealth and remote monitoring services so should ACOs. Finally, the Committee should evaluate this proposal in light of the MA industry adopting telehealth use voluntarily. For example, Humana, beginning this past January 1st, is incorporating telemedicine benefits in its MA plans in 12 states, that is telemedicine is a built-in benefit included in member costs.

**Integrate Primary Care and Behavioral Health Proposal**

The Committee proposes generally to improve the integration of care for individuals with a chronic disease combined with a behavioral health disorder (pgs. 12-13). We particularly applaud the Committee's interest in addressing this issue. As the Committee is aware, there is substantive evidence that behavioral health problems are vastly under-diagnosed and treated. For example, it is estimated less than half of Americans with a diagnosable behavioral or mental health illness receives any specific treatment and only a third of these patients, or one in seven overall, receive treatment that could be characterized as minimally adequate. (See, for example, Jurgen Unutzer, "The Collaborative Care Model; An Approach for Integrating Physical and Mental Health Care in Medicaid Homes," Mathematica Policy Research, May 2013.) Also, it is necessary to note that many behavioral health disorders are themselves a chronic disease. In addition, frequently a "chronic" condition and a behavioral or mental health disorder are inextricably linked, that is distinguishing or treating these diagnoses as two separate or independent conditions can be or is counterproductive.

Specifically, AMGA recommends the Committee examine billing restrictions that limit or prohibit qualified non-physicians from treating beneficiaries with behavioral conditions. For example, beyond physicians, the current CCM code (99490) only allows for physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives to be reimbursed. The
Committee should consider expanding this number to include clinical psychologists, clinical social workers and medical family therapists (MedFTs). Similarly, evaluation and management codes (99201-99205, 99211-99215 and 99241-99245) do not allow for clinical psychologists and clinical social workers to be reimbursed even though these services are within their clinical expertise. Health Behavior Assessment and Intervention codes (96250-96159) are recognized at the state level. These codes ought to be uniformly available between and among states. We believe it is difficult at best to better integrate primary care and behavioral health unless or until workforce shortage or adequacy issues, that eliminating these billing restrictions would address, are remedied.

**Proposed Copay Waivers**
The Committee proposes to waive: copays under the current chronic care management (CCM) code (99490) (pgs. 23-24); and, copays related to treating chronic conditions (pgs. 25-26). AMGA believes providers should have the option to waive both copays. We agree the CCM copay is, as the Committee states, "confusing and burdensome to collect." While it is estimated 35 million Medicare beneficiaries could benefit from monthly chronic care management, providers have to date been hesitant to utilize the new CCM code. This is largely because of the qualifying criteria and burdensome paper work, the fact many physicians believe the $42 per per member per month is insufficient and the fact the CCM requires a 20 percent Part B monthly copay (or $8). It’s estimated less than 20 percent of primary care physicians have begun using the CCM code. For both copays we believe the waiver would better allow beneficiaries to seek care without having to decide presumptively whether care is essential or not, encourage more time sensitive care and/or avoid higher intensity care particularly among beneficiaries whose copays were not covered by supplemental insurance, improve patient outcomes and help reduce unstable ACO beneficiary assignment.

**Telehealth Proposals**
AMGA supports the Committee's proposal to expand the use of telehealth services by eliminating the originating site geographic restriction to improve the diagnosis of stroke (pg. 19). The Committee is aware timely diagnosis of stroke remains a significant barrier to achieving optimal outcomes particularly for minority populations especially African American men. For example, a 2010 *Journal of Hospital Medicine* article found that tPA (the thrombolytic for ischemic stroke) use in 2006 was 2.4% overall and older patients were less likely to receive tPA.

AMGA also supports the Committee's proposal to expand access to home hemodialysis therapy by allowing expanded use of telehealth services. More specifically, a dialysis beneficiary could choose to receive their monthly clinical assessment via a telehealth visit (pgs. 7-8). At home
dialysis can be appreciably expanded. As the Committee notes only a small percent of ESRD patients choose home hemodialysis. Use of telehealth would support ESRD beneficiary independence and self-management, improve patient activation and quality of life, reduce iatrogenic harm and possibly reduce spending or lower spending growth.

**Billing Code Related Proposals**
The Committee proposes to create a new high-severity chronic care management code (pgs. 11-12). There are good reasons to create this new code. For example, beneficiaries with psychiatric and/or substance abuse disorders in combination or not with other chronic conditions too typically seek care late. However, legislating this code may be unnecessary since CMS has been working on creating additional chronic care management codes (99487 and 99490). It is our understanding this new code or codes will fall under preventive services such that no copay would be required. In addition, we encourage the Committee to recommend CMS allow beneficiaries to move more easily between or among case management codes and that these codes use a comprehensive assessment tool that includes measuring beneficiaries' functional status or functional status limitations. It would be prudent as well to require CMS to evaluate the effectiveness of this new code/s such that the agency has the ability to modify or discontinue the code/s if appropriate.

The Committee is also proposing to create a one-time visit code that recognizes the additional time required to consult with beneficiaries whom have received a diagnosis of a "serious or life-threatening illness" such as Alzheimers and dementia (pgs. 24-25). AMGA is generally supportive of this proposal, however, with concerns. We believe it is difficult to create a discrete list of "diseases that would be considered serious or life-threatening," "determining whether the nature of certain illnesses is more conducive to dedicated, covered planning visits upon diagnosis" and "whether a planning visit should have different required elements for each illness." If the Committee chooses to pursue this option further the best approach may be to begin with a limited number of prevalent, serious and eventually fatal disease conditions and to evaluate to what extent physician's are effective in consulting with these patients. We believe the Committee should exercise caution here since the 1980s SUPPORT study (that produce over 1,000 publications) proved that even after training clinicians in providing end of life counseling or "support" they had no impact on improving the quality of end of life care.

**Quality Measures Proposal**
The Committee is proposing to require that CMS develop measures that focus on health care outcomes for chronic disease. The Committee is specifically interested in measures concerning patient and family engagement, communication, care planning, patient-reported measures, shared
decision making, care coordination, end of life care, Alzheimer's and dementia and community measures in areas such as obesity, diabetes and smoking prevalence. The Committee may also recommend the Government Accountability Office (GAO) conduct a study to identify community-level measures related to chronic care management (pgs. 22-23).

Problems with Medicare's quality measure development are well recognized. For example, MedPAC in 2014 stated CMS's "current quality measurement approach has gone off the track." There's consensus agreement quality measures generally need to be less process-based, fewer in number, less burdensome and instead be more aligned or harmonized between and among programs, patient-centered and outcome focused.

Consider for example the Medicare ACO quality measure set. Of the 34 ACO quality measures, none meet the best definition for a health care quality measure: outcomes achieved over dollars spent. In addition, none of the 34 measure care quality or cost, that is defined as the full cycle of care. The ACO quality set largely measures instead inputs, i.e., care coordination/patient safety, preventive health, aspects of evidence-based care for at-risk populations, and patient experience of care. This problem is not unique to the ACO program. It is estimated only one out of over 70 Healthcare Effectiveness Data and Information Set (HEDIS) measures could be described as an outcome measure. Better quality care typically results in lower costs when fully accounted for which explains why quality is typically considered cost effective.

Here, however, there is no correlation between ACO quality and ACO financial performance. In the 2014 performance year, out of the 60 ACOs that earned quality scores at or above 90 percent only 22 earned shared savings. One is left to question whether Medicare's current measure sets are self-defeating in that they sacrifice or crowd out innovation or efforts to develop more effective care in order to achieve near term cost containment. It is worth noting as well compared to MA measures, ACO quality measures are more in number and only somewhat related. How CMS scores quality measure performance between the MA and ACO programs is distinctly different. Under MA, high performance plans receive a higher benchmark, allowed to keep a larger share of any rebate, and five star plans enjoy considerable marketing advantages. None of this is true for high quality performing ACOs.

Generally, AMGA is supportive of the Committee's interests in requiring CMS to develop measures that focus on health care outcomes. The agency should develop outcomes over cost measures or at least outcome and cost measures independently. We would welcome efforts to design outcome measures that in part measure care delivery results defined as all services that in
combination or jointly determine results for a defined patient population, that is a population with similar needs and over the full cycle of care (or annually).

Measures should also be sensitive to the health circumstances relevant to patients and adjust for risk. More specifically, we have three comments. We believe quality measurement reporting should be at the group level as in MA. Among other reasons this approach encourages team work and care coordination. Second, we believe providers be given the opportunity to develop self-reported quality measurement systems, for example, as developed in California. Providers would then have the option to report their self-reported measures (that are independently audited) or report via national reporting mechanisms such as Group Practice Reporting Option (GPRO). This would in part encourage measurement ownership and enable providers to receive far more timely performance feedback. Third, we believe providers should be scored and rewarded based on the higher of two scores: quality performance attainment; or, quality performance improvement. This approach would in part level the playing field between providers in wealthier communities versus those in poorer communities.

While we encourage the Committee to redirect CMS's measure development efforts through legislation, we note that CMS last month published a quality measure development plan (MDP). Since MACRA requires CMS to develop measures in five domains including care coordination and patient and caregiver experience, it is our hope CMS via MACRA's quality measurement mandates will be responsive to the Committee's concerns regarding the development of chronic care outcome measures.

**Risk Adjustment/HCC Proposal**

The Committee is considering a wide array of changes to the Hierarchical Condition Categories (HCC) risk adjustment model including factoring in the total number of disease conditions, effects of behavioral/mental health conditions, costs associated with dual eligibility, the use of more than one year of data and factoring in functional status limitations. The Committee is also interested in how to improve reporting regarding functional status and how changes should be differentially applied to different payment models such as MA and ACOs (pg. 20). AMGA is on record in support of improving risk scores for continuously enrolled ACO beneficiaries. More generally, AMGA supports MedPAC's June 2014 recommendation that the Medicare program align or "synchronize" FFS, ACO and MA rules concerning risk adjustment along with spending benchmarks and quality measurement. (See Chapter 1, "Synchronizing Medicare Policy Across Payment Models," MedPAC's June 2014 Report to the Congress.) Also, per our noting the Komisar and Feder study under "ACO Related Policy Proposals" above, we strongly support the Committee's interest in including functional status limitations since Medicare spends on average
three times more for beneficiaries with chronic conditions and functional status limitations as beneficiaries with any number of chronic conditions and no functional status limitations.

**Proposal to Expand Prediabetes Education and Expand Digital Coaching**

AMGA supports the Committee's proposal to cover evidence-based lifestyle intervention training to beneficiaries with prediabetes and allow entities that are currently not providers under the Medicare statute to deliver self-management training under limited physician supervision (pgs. 26-27). It is estimated approximately one in four Medicare beneficiaries fit the definition of prediabetic. CMMI is already conducting a demonstration on this intervention, however, outcomes are not yet known.

The Committee's proposal "expanding access to digital coaching" (pgs. 27-28) compliments the prediabetes education proposal since it would expand "medically-related information and education tools" that would help beneficiaries "in the self-management of their own health." We support this latter, again related, proposal but believe the Committee should include requiring an on-going evaluation of the expanded use of Medicare.gov, "Medicare and You" and any and all additional tools used to provide prediabetes self-management support education.

**Proposal to Expand CMMI Transparency**

The Committee proposes to require CMS to follow formal rule making procedures for all Centers for Medicare and Medicaid Innovation (CMMI) demonstrations that would "affect a significant amount of Medicare spending, providers or beneficiaries" or "require CMMI to issue notice and comment rulemaking for all mandatory models and at least a 30 day public comment period for all other innovation models" (pgs. 28-29). AMGA agrees for all demonstrations requiring mandatory participation CMMI be required to undertake formal rulemaking as required by the Administrative Procedures Act. For new, non-mandatory demonstrations, we believe CMS should be allowed to use its discretion how the agency seeks public comment. Thirdly, CMS should be required to offer a 30 day public comment period for any proposed changes that would impact an ongoing demonstration. AMGA believes the Committee needs to balance the benefits of transparency against rapid cycle innovation.

**Proposed Studies Regarding Same Day Drug Prescribing and Obesity Drugs**

AMGA supports the Committee's proposals to study the feasibility of dispensing multiple prescriptions on the same day in order to improve beneficiary medication adherence since it aligns with previous Medication Therapy Management (MTM) statutory efforts (pg. 29).

AMGA also supports the Committee's proposal to study the use and impact of obesity drugs in Medicare and non-Medicare populations (pg. 30). Obesity, now defined as an "epidemic," poses
a significant public health threat since 38 percent of American adults are obese (or have a BMI greater than or equal to 30). There is research literature demonstrating related drug treatment effectiveness. For example, a systematic review funded by the National Institutes of Health (NIH) (published in 2012 in Health Technology Assessment) concluded all three pharmacological interventions studied were effective. Our understanding is CMS does not cover these drugs because the agency argues they are subject to an exclusion for medicines used to treat anorexia, weight loss or weight gain. If the Congress wants to better ensure the Medicare program covers this class of drugs, it should pass appropriate legislation. In addition, if the Congress is serious about addressing the $200 billion in obesity-related medical costs, Members should address the underlying causes of the obesity "epidemic."

Thank you for offering AMGA an opportunity to comment. We sincerely appreciate the Committee's focus on improving care for our most vulnerable citizens. We look forward to working with the Committee to further develop and implement policy options that support Medicare beneficiaries. If you have any questions please do not hesitate to contact David Introcaso, Senior Director for Regulatory and Public Policy, at dintrocaso@amga.org.

Sincerely,

Donald W. Fisher
President and CEO