701 Pennsylvania Avenue, NW, Suite 800
Washington, DC 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

June 22, 2015

Re: Chronic Care Working Group request for feedback

Dear Senators Hatch, Wyden, Isakson, and Warner:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide policy options that will improve care for Medicare beneficiaries with chronic conditions. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed's members produce the majority of the health care technology purchased annually in the United States and a significant share purchased annually around the world.

AdvaMed applauds the Committee's focus on policies that address the burden of chronic disease as our member companies develop the technologies and diagnostics that will provide the life-saving and life-enhancing treatments of the future. These technologies generate efficiencies and cost savings for the health care system, and improve the quality of patient care. Between 1980 and 2010, advanced medical technology helped cut the number of days people spent in hospitals by more than half and added five years to U.S. life expectancy while reducing fatalities from heart disease and stroke by more than half.

The Committee's focus on improving the delivery of care for patients with chronic conditions is important. As noted in the request for feedback, treatment of chronic conditions account for a majority of Medicare spending. Beneficiaries with multiple chronic conditions account for almost half of all Medicare spending.

A recent study by the Milken Institute highlights the integral role of medical technology in treating chronic disease.[1] The study examined four diseases and a limited number of technologies used to treat those diseases. It found significant increases in labor force participation and productivity directly attributable to the technologies' contribution to reducing

[1] Milken Institute: "Healthy Savings: Medical Technology and the Economic Burden of Disease." July 2014

the burden of illness. The study showed billions of dollars in expanded GDP as a result of treating these four disease states alone.

The study is attached for your review but highlighted below are the key points in the four disease areas:

- **Heart Disease** is responsible for over 600,000 deaths per year in the U.S. at an annual cost of $108.9 billion. Through appropriate use of medical technology such as pacemakers, electrocardiograms, ultrasound, and X-rays, the study found savings of over $1930 annually per person affected when compared to patients without technology.

- **Diabetes** affects over 25 million Americans at an annual cost of $245 billion. Through use of insulin pumps for treatment of people with diabetes, annual savings per person amount to over $5800 as a result of better disease management.

- **Musculoskeletal disease** costs over $950 billion per year. Through use of bone scans and joint replacement surgery for diagnosis and treatment, over $24,000 in annual per person savings can be achieved.

- **Colorectal cancer** is the third most frequently diagnosed cancer in the U.S. with costs of $8.4 billion per year. Medical technology used for early detection and prevention can generate net savings of over $150,000 annually per person.

Overall, the use of medical technologies in these four disease areas expanded U.S. GDP by $106.2 billion in 2010 and provided a net annual benefit of $23.6 billion to the economy due to the appropriate use of medical technology for prevention, early detection, disease management, and treatment. The study suggests that the medical technologies applied for the disease areas above generated economic returns that were substantially greater than their costs.

Role of alternative payment models (APMs) to improve outcomes for patients with chronic diseases

AdvaMed has been a strong supporter of alternative payment models, such as Accountable Care Organizations (ACOs) and Bundled Payment initiatives. We recognize the importance of the goals of these payment models as they seek to improve both the efficiency and quality of health care in this country and we believe that our members' technologies can play a critical role in assisting providers to achieve these goals. Our member companies do so through advances in medical devices, diagnostics, and other advanced medical technologies. These products and services improve patient care quality and many improve efficiency by reducing the lengths of stay of patients in health care facilities, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits. ACOs, in particular, with their focus on population health, are an especially promising model for managing chronic disease more effectively.

While the goals of these alternative payment models are laudable, the cost saving incentives in these programs could have the inadvertent effect of slowing medical progress and denying current and future patients access to new and better treatments if sufficient care is not taken in their design and implementation. This potential negative impact can be avoided without undercutting the goals of the new payment and delivery systems.

Several examples of how new payment models might discourage medical progress and deny access to new and better treatments is below:

- **New treatments that are therapeutically superior but more costly may not be available.** When physicians and providers participate in ACOs and Bundled Payment initiatives they receive rewards for keeping costs down. Physician and other providers may be under pressure to limit their use of quality-improving but more costly services in efforts to achieve savings, even if the technologies are more clinically appropriate for the patient or bring more value to the health care system over the longer term. This may be a reason for physicians to be reluctant to participate in an ACO or bundled payment program.

- **New treatments that are less expensive for the health system over time, but more expensive during the <u>measurement</u> period of an ACO or bundling initiative may not be available to patients.** For example, if the cost of a treatment or therapy is higher than any savings it generates during the measurement period, the use of the device may reduce rewards to providers either in ACOs or under a bundled payment mechanism. In the long run, however, this device may improve patient outcomes and generate cost savings by decreasing the likelihood of stroke, heart attacks, or other conditions or complications.

- **The quality standards used for measurement in ACOs or bundled payments could discourage early adoption of new and better alternative treatments.** Many of the measures used by the Center for Medicare and Medicaid Services (CMS) are process measures. For example, if a patient presents at a hospital with a heart attack, percutaneous coronary intervention (PCI) is supposed to take place within 90 minutes. If a new approach is developed that may be superior to and no special exception is provided for the new, alternative treatment, the physicians or hospitals that adopt it will see their quality scores reduced and potentially suffer financial penalties. Few cutting edge physicians or leading hospitals will risk receiving a low quality label.

These negative impacts can be avoided without undercutting the goals of the new payment and delivery systems by incorporating certain technical adjustments in the programs and by adopting other patient protection measures. The basic solution to ensure Medicare beneficiaries have access to innovative treatments and services in the ACO and bundled payment programs is to provide time-limited technical adjustments within these programs. Providing an adjustment for a limited number of new treatments or services, approved by CMS after meeting certain criteria, would neither penalize nor reward participating providers. With such adjustments, potential early adopters would not be penalized when making decisions purely on medical grounds.

These adjustments would be used for a limited period of time to allow time for new treatments and diagnostics to be reflected in new benchmarks or incorporated in quality measurement to the

extent they become the standard of care. In general, CMS would make adjustments to the benchmarks and Medicare expenditures when calculating savings or losses. Where the barrier to adoption is a quality standard, quality measurement would exclude the case with the new treatment from the provider or physician quality score. That is, the new innovative treatment selected by the physician and the patient would be excluded from the numerator and the denominator in calculating the quality score. This limited period of adjustments would provide information for the development of the next round of benchmarks and patient outcomes measures.

CMS recently acknowledged the impact a higher cost innovative technology can have on providers' ability or interest in using that technology in patient care when they participate in delivery reform models, specifically in the Center for Medicare and Medicaid Innovation (CMMI) Bundled Payments for Care Improvement (BPCI) Initiative. In this instance, CMMI has decided to remove an Inpatient Prospective Payment System new technology add-on payment (NTAP), approved last year by CMS, from a BPCI project's actual spending total for an episode of care. We understand that CMMI is also considering whether to remove NTAP amounts for other approved technologies as well. This policy change will go a long way in removing disincentives providers would face in using the recently approved new technology awarded NTAP status while at the same time ensuring that Medicare beneficiaries have access to new technologies. It is a good example of how the cost reduction incentives in certain delivery models can have an enormous impact on whether beneficiaries have access to the best that American medicine has to offer.

Also of note are developments within CMMI that physicians in Pioneer ACOs have asked to be able to use a new and more effective pneumococcal pneumonia vaccine instead of an older vaccine that is specified in a process quality measure used for both the Medicare Shared Savings Program and Pioneer programs. The problem that physicians in these ACOs face is a reduction in their quality scores if they do choose to use the new vaccine, simply because this particular measure does not yet reflect a new standard of care and because no special exception is allowed for physicians to use the innovation. Patients may not be harmed by the old vaccine but they are not, at the same time, provided the benefits of the new product. This is another good example of how a technical adjustment in ACO programs can provide Medicare beneficiaries the benefits of innovations in health care without undermining the overarching goals of the program.

Use of telehealth and remote monitoring technology

Telehealth and remote monitoring technologies are generally recognized as fundamental tools for improving the efficiency and quality of health care but out-of-date and inappropriate coverage and reimbursement restrictions under Medicare limit their ability to do so. Medicare's fee-for-service program does include a separate benefit category called telehealth services, but coverage is restricted both by site of service where beneficiaries may receive care and by the geographic area where they reside. Specifically—

- Telehealth services can be provided only in rural areas (and certain rural census tracks in urban areas) and must involve an interactive audio and video telecommunications system that permits real-time communication between the provider and the beneficiary;

- Current law limits covered services to those provided by professionals specifically enumerated in sections of Medicare law that include physicians, nurse practitioners, physician assistants, clinical psychologists, etc. They do not include services provided by physical therapists, occupational therapists, speech audiologists, etc.;
- The law also limits coverage to a list of services specified in law and regulation, when those services are provided through "distant sites" where the physician receiving payment under the physician fee schedule for a covered service is located and "originating sites" where the beneficiary is located. Originating sites are limited to specified settings—physician offices and certain facilities and clinics—and do not include the beneficiary's home.

The Medicare telehealth benefit also is restrictive as it does not include services such as remote monitoring that already have been proven to improve the clinical and economic outcomes of certain high-cost, chronically ill Medicare patients. To the extent that any payment is made for these services under Medicare, it is only through a very limited number of physician services paid under the physician fee schedule which is not designed to adequately reflect the multidisciplinary teams involved in caring for patients with chronic diseases or compensate providers for the delivery of care using many emerging telehealth technologies.

AdvaMed believes that ACOs and the bundled payment programs, with their emphasis on care coordination and improvements in the efficiency and quality of care, provide the right incentives for providers to invest in and to use telehealth technologies. However, benchmarks and actual spending for individual ACO and bundled payment programs are based on fee-for-service payments for covered Medicare services. To the extent telehealth and remote monitoring services are not covered by Medicare, benchmarks will never be able to reflect spending for the services because Medicare does not recognize them for payment. As a result, an ACO or bundled payment program deciding to provide expanded telehealth services or remote monitoring services will have to weigh these new costs not recognized in a benchmark against the promise of savings in other areas, or to cover the costs through their shared savings. Despite the proven benefits of many telehealth technologies, the upfront investment and ongoing implementation costs of telehealth creates a disincentive to use these technologies amidst rising cost pressures and restricted budgets.

AdvaMed has proposed a solution to address these barriers to coverage and payment for telehealth and remote monitoring services under the Medicare program by amending the Innovation Center's authority in Section 1115(A) to require that the Center, through delivery reform models implemented by the Center, provide coverage and payment for expanded telehealth and remote monitoring services. Under this proposal, the Center would test where these services assist providers in achieving delivery reform program goals and result in Parts A and B savings without reducing quality or improved quality and reduced program spending. Covered services would be required to enhance coordination and collaboration in care delivery and reduce utilization of other covered Parts A and B services. They would also be targeted on persons with chronic or other conditions. At a minimum, the Innovation Center would be required to test expanded coverage in ACO and bundled payment initiatives, and would be authorized to test expanded services in other relevant initiatives as well. Expanded services would be covered during a 5-year period beginning not later than January 1, 2017, and evaluated

for whether they reduce Parts A and B spending and maintain or improve quality of care. Coverage beyond 5 years would be continued only for those services found to meet savings and quality requirements. These same services would also be required to be covered under Medicare's fee-for-service program. In order to take into account the need to limit new spending under any telehealth proposal, our proposal has a number of "dials" that can be turned up or down. The outlines of our proposal described below serve as a starting point for considering how an actual proposal could be structured.

Key components of AdvaMed's proposal are as follows:

- **Covered Services:** Covered services under this expanded telehealth benefit would be required to assist providers in the coordination of care, enhance collaboration among providers to improve the efficiency and quality of care, reduce hospital admissions and readmissions, reduce or replace physician office visits, reduce utilization of skilled nursing facility services, or allow beneficiaries to remain in the community or return to the community more quickly than they would in the absence of services. Services would also be targeted at persons with the following conditions (chronic care conditions and conditions used in the Hospital Readmissions Reduction Program): chronic hypertension, ischemic heart diseases, chronic obstructive pulmonary disease, heart failure, heart attack, arthritis, diabetes, chronic kidney disease, depression, atrial fibrillation, cancer, asthma, stroke, total hip and knee replacement procedures, Parkinson's disease, and such other conditions or diseases determined by the Secretary to be appropriate for testing improvements in efficiency and quality of care.

- **Telehealth/Remote Monitoring Technologies to be Tested.** Covered services would be provided through the following technologies: bi-directional audio/video technologies; physiologic and behavioral monitoring technologies; engagement prompt technologies; remote monitoring technologies, including remote device management (for remotely interrogating or programing a device, e.g. pacemaker or CRTD, outside the specialist's office); store and forward technologies; point-of-care testing technologies, and such other technologies as the Secretary may specify.

- **Practitioner's Authorized to Provide Covered Services.** As currently required by Medicare statute, covered services would be furnished by eligible physicians, as defined in Section 1861(r)—Medicare's definition of physician—and other practitioners as defined in Section 1842(b)(18)(C)—Medicare's definition that includes physician assistants, nurse practitioners, etc.

- **Payment for Services.** As determined by the Secretary and to the extent appropriate for the particular delivery model in which services are tested, payment for expanded telehealth/remote monitoring services would be made according to existing fee schedule amounts for telehealth/remote monitoring services, a new fee schedule established by the Secretary for covered services, and/or risk-sharing payment methodologies that will ensure savings from covered services. Payments should reflect equipment and staffing costs associated with implementation of the telehealth program.

- **Period for Testing and Evaluation.** The Innovation Center would be required to test expanded services during a 5-year period beginning not later than January 1, 2017. After 3 years of coverage of expanded services during which time data on expanded telehealth/remote monitoring services are collected, the Innovation Center would be required to begin evaluation, through an independent evaluator, of expanded services for their assisting delivery reform models in achieving Parts A and B savings or increasing those savings and for maintaining or improving quality of care. As part of its design for testing and evaluating expanded services, the Innovation Center would be required to compare beneficiaries in delivery reform models with access to expanded services with beneficiaries in delivery reform models without access to these services. In determining whether expanded coverage of services resulted in reduced Medicare Parts A and B spending, the Secretary would be required to take into account costs and savings across the continuum of care for an episode of care and condition involved.

- **Continued Coverage after 5 years.** Upon findings of the independent evaluator that specific telehealth/remote monitoring services resulted in Parts A and B savings without reducing quality or improved quality and reduced program spending, the Secretary would be required to continue to be covered and paid for in delivery reform models beyond the 5-year period of testing and evaluation with certification by the Chief Actuary that such expansion would reduce Medicare program spending.

- **Application to Medicare's Fee-for-Service Telehealth Benefit.** Upon a decision by the Secretary that specific telehealth/remote monitoring services in delivery reform models resulted in Parts A and B savings without reducing quality or improved quality in delivery reform models, the Secretary would be required to cover and pay for such services under Medicare's fee-for-service program with certification by the Chief Actuary that such expansion would reduce Medicare program spending.

AdvaMed welcomes the opportunity to provide feedback to the working group on chronic care. We would be pleased to answer any questions regarding these comments. Please contact Duane Wright (dwright@advamed.org) or Riley Swinehart (rswinehart@advamed.org) if we can be of further assistance. We look forward to collaborating with you as this discussion evolves. AdvaMed will continue to follow the working group's deliberations with interest and be prepared to offer additional constructive input.

Sincerely,

JC Scott
Senior Executive Vice President and Director, Government Affairs
The Advanced Medical Technology Association