March 7, 2018

The Honorable Peter Roskam
Chairman
Subcommittee on Health
House Committee on Ways and Means
Washington, D.C. 20515

Dear Chairman Roskam:

The Healthcare Leadership Council (HLC) appreciates the Subcommittee's work on cutting red tape and reducing regulatory burden in Medicare. We share your commitment to this important issue.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Like you, HLC strongly supports the Medicare program. HLC members represent all healthcare sectors and have seen firsthand the impact of Medicare on its beneficiaries. We believe that if Congress does not act to modernize Medicare now, the program will not be able to adequately serve future generations.

Many current Medicare rules and regulations are ineffective, costly, and time consuming. HLC's thoughts on reducing these regulatory burdens to ensure access to high-quality care are outlined in the attached red tape list. Recommendations for congressional action are in section IV of the list, and a few key items are also highlighted below.

<u>Modernization of the Anti-Kickback and Stark Rules</u>
As reimbursement models have evolved to become more patient-centered, the Anti-Kickback Statute and the Stark Law have become barriers to value-oriented care models that improve health outcomes and reduce costs. While these laws have been minimally modified, the modifications are piecemeal and do not apply to all value-based

models. Congress should pass legislation that would require the Department of Health and Human Services to review and assess these laws in the context of the transformation of the healthcare system to value-based care. Congress should also grant the Office of the Inspector General and the Centers for Medicare and Medicaid Services (CMS) enhanced regulatory flexibility and rulemaking discretion to develop exceptions and safe harbors to these laws.

Access to the Patient's Entire Medical Record

The 42 CFR Part 2 regulations govern the confidentiality of alcohol and drug abuse patient records. These rules duplicate the already strong privacy protections for health information under the Health Insurance Portability and Accountability Act. In addition, the regulations are not compatible with the way healthcare is currently delivered. Especially now with the opioid abuse epidemic, healthcare providers need to have all of their patient's medical records, including those related to alcohol and substance use. Congress should pass legislation ensuring that providers have access to this information.

Coverage for Wellness Programs

Chronic disease prevention is an essential component of healthcare. Many chronic diseases are caused by modifiable health risks such as lack of physical activity, poor nutrition, and tobacco use. To avoid these problems, Medicare beneficiaries need comprehensive and evidence-based wellness programs that educate them on how to make healthy choices. Many of these programs have been implemented by employers, and to ensure that Medicare beneficiaries have access to the same opportunities, Congress should pass legislation requiring CMS to cover these programs.

Thank you again for your commitment to reducing red tape in Medicare. HLC looks forward to continuing to work with you on our shared priorities. Should you have any questions, please do not hesitate to contact Debbie Witchey at (202) 449-3435 or dwitchey@hlc.org.

Sincerely,

Mary R. Grealy
President

February 21, 2018

HEALTHCARE LEADERSHIP COUNCIL

"Red Tape" Reforms to Improve Care and Lower Costs

The Healthcare Leadership Council (HLC) supports regulatory relief efforts that will improve the quality and accessibility of healthcare for all Americans. Removing the "red tape" associated with the provision of healthcare is a critical component of ensuring that Americans have access to the high-quality healthcare they deserve. Congress and the Department of Health and Human Services (HHS) must act to reduce these burdens.

I. RED TAPE CUT: REGULATORY RELIEF ACHIEVED (✓= COMPLETED)

Action	HLC Position	Description
✓ **Promoted continuous coverage and reduced waste, fraud, and abuse.**	HHS addressed the problem of individuals, previously terminated for nonpayment or who fell within the grace period, re-enrolling in coverage without paying outstanding amounts due, by allowing issuers to collect outstanding premium payments owed for coverage within the last 12 months before allowing a consumer to enroll in new coverage with that same issuer.	Reducing waste, fraud, and abuse and promoting continuous coverage is necessary to ensure a stable marketplace.
✓ **Aligned the open enrollment period with Medicare and the private market.**	HHS is now running Open Enrollment from November 1 through December 15.	Aligning the open enrollment period for the exchanges with Medicare and the private market will encourage consumers to enroll in coverage before the end of the year and reduce the possibility of adverse selection.

I. RED TAPE CUT: REGULATORY RELIEF ACHIEVED (✓= COMPLETED)		
Action	***HLC Position***	***Description***
✓ **Facilitated interoperability by streamlining regulations under the Advancing Care Information (ACI) performance category of the Merit-Based Incentive Payments System (MIPS).**	In the Quality Payment Program rule, HHS provided additional flexibility for reporting outcomes.	Successful payment and delivery reform needs a high-performing, interoperable, and secure technical infrastructure. Physicians and clinicians require ample time and interoperable electronic health records (EHRs) in order to succeed. The additional flexibility HHS has given for reporting outcomes under the ACI performance category will assist with this.
✓ **Delayed Stage 3 Meaningful Use requirements and retained use of Version 2015 and a 90-day reporting period.**	HHS retained Version 2015 and the 90-day reporting period in the Medicare Access and CHIP Reauthorization Act (MACRA) Quality Payment Rule.	In October 2016, the Centers for Medicare and Medicaid Services (CMS) released the final rule implementing the MACRA. The Final Rule set forth the guidelines for participation in Medicare's Quality Payment Program (QPP). In that rule, CMS stated that eligible clinicians participating in MIPS would be expected to use EHR technology certified to the 2015 edition. HLC members believed the timeline for requiring all eligible clinicians to use EHR technology certified to the 2015 edition was not realistically attainable for many clinicians, even with a 90-day EHR reporting period in 2018. HLC applauds CMS for not requiring eligible clinicians to use EHR technology certified to the 2015 edition. HLC also applauds CMS for delaying implementation of Stage 3 of the Meaningful Use program and Stage-3 like measures in the MIPS program in 2017.

II. SCISSORING IN PROCESS: RULE CHANGES REQUIRING FINAL ACTION

Action	*HLC Position*	*Description*
Revising the Medical Loss Ratio (MLR).	HHS should finalize the proposals outlined in the 2019 Notice of Benefit and Payment Parameters that would allow issuers to deduct employment taxes from the MLR, implement a safe harbor for quality improvement activity expenditures for the MLR, and streamline the requirements for states to lower the MLR threshold.	Allowing issuers to deduct employment taxes from the MLR will encourage greater competition in the markets. However, the safe harbor for quality improvement activity expenses should be 1 percent (rather than the proposed rule's threshold of 0.8 percent). Additionally, states should be given the flexibility to lower the MLR threshold to stabilize the individual market. While the 80 percent threshold may be appropriate in some states, in others having a lower MLR rate may have competitive benefits. HHS should make the streamlined process available only to states that request it.
Improving communication with consumers by allowing health plans to provide more direct consumer assistance.	HHS should continue the development and implementation of operational solutions for seamless enrollment and consumer assistance, which will reduce administrative costs and consumer frustration.	CMS should proceed with plans to implement enhanced direct enrollment for the 2019 plan year, which will eliminate the "double redirect" between plan websites and HealthCare.gov. This will allow plans to enroll consumers directly and use HealthCare.gov only for verifying subsidy eligibility. In addition, states should take measures to ensure their consumer calls are appropriately directed to the plans' customer service centers for all issues that can be resolved by plans (such as claims).

II. SCISSORING IN PROCESS: RULE CHANGES REQUIRING FINAL ACTION

Action	*HLC Position*	*Description*
Streamlining regulations creating electronic clinical quality measures (ECQMs) for providers, and harmonizing remaining quality measures across federal programs.	CMS should reduce the number of measures and the length of the reporting period and harmonize measures across programs.	While improvements in quality and patient safety are critical, the ever-increasing number of conflicting and overlapping measures in CMS programs takes time and resources away from what matters most – improving care. Vendors and providers have invested significant time and resources to revise certified EHRs to meet CMS ECQM requirements, without a clear benefit to patient care. Moreover, CMS has acknowledged that the electronic test submissions by hospitals and physicians do not accurately measure the quality of care. CMS should shorten the number of ECQMs from eight to four and the length of the reporting period from a full year to 90 days. CMS also needs to publish guidance on how the ECQM data will be compared to existing chart-abstracted measures.
Revising hospital star ratings and readmission measures to reflect differences in patient populations.	CMS should use the feedback it is collecting on the star ratings for hospitals and work closely with experts in the private sector to develop a system that appropriately reflects health system challenges such as the social and economic status of the system's consumers. CMS should do the same for hospital readmission measures.	The star ratings published on the CMS website are inaccurate and misleading for consumers. Similarly, the hospital readmission rates and other outcome measures have been publicly reported and used to penalize hospitals. This is unfair to hospitals because both the star ratings and the readmission measures lack appropriate adjustment for the population being served.

II. SCISSORING IN PROCESS: RULE CHANGES REQUIRING FINAL ACTION		
Action	***HLC Position***	***Description***
Allowing for greater variation and flexibility in plan design.	In addition to allowing issuers greater variation in actuarial value, HHS should consider other ways to ensure the creation of new and innovative plan designs. HHS also should follow through on its proposals in the 2019 Notice of Benefit and Payment Parameters to seek feedback from issuers on how current regulations and policies may be modified to facilitate access to innovative market-driven strategies, including value-based insurance design and high-deductible health plan-health savings account arrangements.	HHS should allow greater flexibility on benefits, plan design, and actuarial value as long as long as the variation includes all of the 10 categories of Essential Health Benefits (EHBs).
Reducing fraud and abuse associated with the Special Enrollment Periods (SEPs).	In addition to requiring verification for the SEPs, HHS should further reduce the number of SEPs and expand continuous coverage requirements for SEPs. HHS should also require state-based marketplaces (SBMs) to implement preenrollment SEP verification.	Abuse of the SEPs worsens the risk pool and results in higher premiums. By tightening restrictions on use of the SEPs, HHS can help to minimize potential abuses and ensure that only beneficiaries who are eligible for a SEP use one to enroll in coverage outside of open enrollment.

II. SCISSORING IN PROCESS: RULE CHANGES REQUIRING FINAL ACTION		
Action	***HLC Position***	***Description***
Restore regulatory oversight of health insurance to the states.	HHS should defer to states for regulatory approval authority of products and rates in the individual and small-group markets.	States, which are the traditional regulators of health insurance, know best how to meet their residents' health insurance needs. HHS should defer to states for regulatory approval. This includes finalizing proposals in the 2019 Notice of Benefit and Payment Parameters to defer to states regarding qualified health plan (QHP) certification in the following additional areas: accreditation requirements, reviews of compliance plans, minimum geographic area of the plan's service area, and quality improvement strategy reporting. However, states should not be given flexibility to reduce payment transfers, since this would reduce the effectiveness of the risk adjustment program and create incentives for issuers to engage in practices that would result in risk segmentation. Additionally, states should not be allowed to add benefits under the EHB benchmark process without paying for the costs for those mandates.
Recognize Medicare Advantage (MA) as an advanced alternative payment model.	CMS should move forward with the demonstration discussed in the final rule for Year 2 of the Quality Payment Program.	The demonstration would allow physicians that participate in value-based arrangements with MA plans to see the same payment benefits as physicians participating in one of the CMS designated Advanced Alternative Payment Models.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Streamlining the employer reporting requirements of the Affordable Care Act (ACA) employer mandate.	The Department of Treasury and the Internal Revenue Service (IRS) should issue a replacement rule that streamlines reporting requirements for employers providing minimum essential coverage (MEC).	The IRS should streamline the taxpayer identification number (TIN) solicitation. The IRS should also streamline the process for resolving inconsistencies by allowing the issuer, with enrollee permission, to contact his or her employer to obtain correct names, Social Security numbers, and other identifying information. Additionally, the IRS should create a system for alternative coverage verification to replace Form 1095, reduce the required frequency of solicitation efforts for Social Security numbers, and eliminate the need to collect the Social Security numbers of spouses and dependents.
Pursue policies that encourage workplace wellness and condition management programs.	HHS should allow meaningful incentives for employees that participate in these programs and reduce administrative burden for employers that offer them.	Workplace wellness programs can help improve health by giving employees access to comprehensive and evidence-based programs that educate them on how to make healthy choices.
Encouraging innovation and flexibility in plan design.	Elimination of standardized plan options and their differential display will encourage innovative product design as opposed to one-size-fits-all standardized benefit packages.	As proposed in the 2019 Notice of Benefit and Payment Parameters, HHS should not establish standardized plans, differentially display plan designs, or require agents, brokers, and issuers to differentially display plan designs.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Enhance the Medicare Plan Finder.	The Plan Finder tool should be improved so that it allows for better comparison of MA and FFS plans.	The Medicare Plan Finder allows Medicare beneficiaries to compare MA and Part D options where they reside, but the site remains difficult for beneficiaries and family members to navigate.
Require beneficiaries to actively choose between MA and FFS at initial enrollment.	HHS should not auto-enroll beneficiaries in FFS.	When first enrolling in Medicare, individuals are currently not required to make an active choice between FFS and MA. Instead, they are auto-enrolled into FFS. CMS should require them to make an active selection into FFS or MA.
Ensuring transparency in payment models.	CMS should supply sufficient technical information when proposing new payment models to allow stakeholders realistically to evaluate payment impact. A lack of clarity in methodologies prevents CMS and Center for Medicare and Medicaid Innovation (CMMI) model participants from accurately assessing their ongoing performance against targets once they have joined programs because they are not able to replicate CMS calculations.	When data are extensive, or calculations are complex, data and examples should be made available online simultaneously with proposed models. CMS should also allow organizations to apply for a national file to calculate not only individual participant performance, but also national factors.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Reducing overlap of alternative payment models.	Increasing overlap of various alternative payment models has created the need to determine a long-range plan to harmonize various models. The proliferation of models and tracks within models necessitated a series of attribution, precedence, and reconciliation rules. Yet few efforts have been made by CMS to rationalize the universe of these programs, which leads to overlap and confusion.	CMS should release clear guidance on the attribution, precedence, and reconciliation rules applied across both permanent and CMMI models.
Reforming the Telephone Consumer Protection Act (TCPA) regulations.	HHS should work with the Federal Communications Commission (FCC) to ensure that the TCPA allows healthcare providers and plans to use telephone technology to remind consumers to fill a prescription, attend an upcoming appointment, or follow other instructions.	HHS must work with the FCC to ensure that the TCPA continues to promote the consumer protections that motivated its passage while also allowing for the appropriate use of technology. Modern consumers expect to be able to use their phones to obtain health information and communicate with their providers.
Amending the Airline Deregulation Act.	The Airline Deregulation Act needs to be amended so states can prevent air ambulance providers from demanding exorbitant prices from patients.	The federal Airline Deregulation Act appears to prevent states from acting to protect their citizens from egregious practices by air ambulance companies. The lack of state oversight for these companies is a growing source of unnecessary healthcare costs that can drive up premiums. Due to the restrictions imposed by federal law, several states have struggled to implement policies to protect consumers from air ambulance company bills.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Eliminating the excessive multiple language "tag-line" (Section 1557) requirements for health plan products.	HHS should narrow the rule that requires issuers to present tagline notices (notifications that indicate information is available in alternative languages) in 15 languages.	The scope of the Section 1557 rule should be narrowed only to affect entities that directly receive federal funding. The Section 1557 rule should not be imposed upon specialty insurance products.
Allowing issuers greater flexibility with regards to communicating with enrollees.	HHS should allow issuers greater flexibility with respect to the content/format of notices of renewal and discontinuation, as well as summaries of benefits and coverage. HHS should also allow issuers to communicate with enrollees earlier in the open-enrollment process.	Issuers know how to communicate with their enrollees in efficient and easy-to-understand ways. In addition, by allowing issuers to communicate with enrollees earlier in the process, enrollees will have additional time to consider their options for open enrollment.
Eliminating the Health Insurance Portability and Accountability Act (HIPAA) acknowledgement requirement.	HHS should eliminate the requirement that a healthcare organization document patient receipt of the privacy notice.	Patients have the right to receive notice of their privacy rights under HIPAA, and healthcare organizations should ensure that patients receive this information. However, it is excessively burdensome for healthcare organizations to have to document this action each time it is taken.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Allowing protected health information (PHI) to remain where it is located at the initiation of a research project.	HHS should issue guidance to allow remote access to PHI as part of the preparatory-to-research pathway.	The preparatory-to-research pathway under HIPAA allows researchers to review PHI in connection with activities to prepare for research. HIPAA does not permit researchers to remove PHI from the premises of the covered entity that houses the PHI. The 21st Century Cures Act did not adequately address remote access of PHI by researchers who are reviewing information that is outsourced to another location (e.g. "cloud-based"). It is becoming more common for covered entities, such as hospitals, to outsource medical records storage, digital or otherwise.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Allowing health plans and providers to share PHI as part of value-based arrangements.	HHS should issue guidance on the uses and disclosures of PHI for value-based arrangements.	Collaborative value-based pricing arrangements, where health plans share information with health systems and providers and payment depends on patient outcomes, can improve patient health and reduce costs. In limited, patient-serving circumstances, covered entities should have clarity that PHI may be shared under the existing payment pathway, as part of healthcare operations, or through another pathway necessary to establish value-based pricing models. Covered entities should also have clarity that they may disclose PHI to another covered entity for healthcare operations activities even if the individual who is the subject of the PHI does not have a current or previous relationship with both the disclosing and receiving covered entity.
Updating data use agreements between CMS and HIPAA.	HHS should require the harmonization of the CMS data use agreement protections with the data use agreement provisions of HIPAA and issue guidance on this subject.	The combination of CMS data and PHI may yield benefits for care and utilization management. However, CMS data use agreements do not permit the use of data for purposes other than those that support the user's study, research, or project referenced in the agreement. As a result, CMS data is typically not combined with PHI in a clinical setting. HHS should require the harmonization of the data use agreements to ensure that these data are shared.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Reducing regulatory delays in updating standards for the e-prescribing market.	HHS should streamline the regulatory processes for the e-prescribing SCRIPT standard.	Now that the SCRIPT standard has matured, it no longer needs the extensive CMS oversight it had when it was first implemented. Improving the regulatory process will allow innovations that are approved by the standards body to reach the market more quickly.
Reducing the regulatory burden imposed on Phase III drug trials.	HHS should reduce the cost and risk of undertaking these trials.	The Phase III system burdens pharmaceutical companies with huge and unpredictable regulatory delays; discourages small U.S. biotech companies from competing in the traditional drug market; and perversely encourages innovation in drugs for very rare diseases that are exempt from Phase III.
Revising conflict-of-interest policies to ensure that the Food and Drug Administration (FDA) is able to obtain input and advice from scientific experts.	HHS should modify its policies to allow experienced scientists to serve on advisory panels and be hired for staff positions while also requiring their recusal from decisions that might affect their patents or holdings.	The federal government's process and criteria for evaluating conflicts of interest should be revised to allow scientific experts to provide advice to the FDA through advisory committee/panel engagement. The federal government should institute policies that allow alternative methods of meeting the conflict of interest requirement to enable more timely engagement with qualified experts. This would also facilitate the speedy hiring of employees by the FDA.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Reforming fee-for-service (FFS) payment regulations that impede the redesign of episodes of care across provider settings in new outcome-driven payment models.	HHS should test new approaches in an environment free from artificial barriers to care coordination such as the Inpatient Rehabilitation Facility 60 Percent Rule and the home health homebound rule.	Current regulations often hinder providers' ability to identify and place patients in the most clinically appropriate setting. They also inhibit providers' ability to test new, more patient-centered and streamlined clinical pathways. Testing new approaches without these barriers will more effectively advance solutions that will improve clinical outcomes for patients, ease anxiety of families, and reduce costs and variation.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Simplifying and improving the MA star ratings program.	HHS should work with industry to develop a plan for improving the MA stars ratings and align them with other measures.	CMS should develop a strategic plan on star ratings that includes defined goals for the ratings system, creates a framework for inclusion and retirement of the measures, and addresses a permanent adjustment for the social determinants of health. CMS should ensure that the program is simplified, accurately reflects plan performance, and places the most emphasis on measures that plans can influence. This system should emphasize outcomes measures that focus on improvements in beneficiaries' health. CMS should concentrate on data-informed measures with objective clinical relevance, rather than survey-based measures. There needs to alignment between the MA stars ratings and the measures used in the FFS program. This would allow for better comparison of programs and reduce reporting measures for providers. CMS should apply all modifications on a prospective basis and finalize measures and their methodology prior to the start of the measurement period to give stakeholders adequate notice. CMS should reinstate the four-star thresholds for selected measures on transparency, as well as plans' and providers' quality programs.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Eliminating the Long-Term Care Hospital (LTCH) 25% Rule.	HHS should eliminate this rule and instead rely on the site-neutral payment policy.	The LTCH 25% Rule reduces overall payments to LTCHs by applying a penalty to selected admissions exceeding a certain threshold, even if the patient meets LTCH medical necessity guidelines. With the implementation of site-neutral payments for LTCHs in October 2015, the LTCH 25% Rule has become outdated, excessive, and unnecessary. Given the magnitude of the LTCH site-neutral payment cut – a 54% reduction, on average, to one of two current cases – CMS should rescind the 25% Rule and instead rely on the site-neutral payment policy.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Ensuring that the implementation of home health agency (HHA) rules meets the needs of consumers and does not penalize providers caring for medically fragile patients.	CMS should delay and improve the Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies (CMS-3819-P) before implementing changes to the program.	Certain CMS Outcome and Assessment Information Set (OASIS) measures may be inappropriate for analyzing care provided by private duty nurses to medically fragile or chronic patients whose improvement is not expected or sometimes even possible. Another challenge is that in many areas, including rural ones, it can be particularly difficult to staff nurses and other home health professionals on an ongoing, uninterrupted basis, which can unfortunately result in temporary reductions in staff availability at certain times. In many cases, without a clear allowance for an HHA to discharge a patient to other providers when staffing availability changes, HHAs may be reluctant to take on new cases for patients whose homes are far away from the HHA's service area. To help ensure better patient access to home health professionals, CMS should establish clearly defined reasons for appropriate HHA discharges in the Medicare and Medicaid Conditions of Participation. CMS should also ensure that patients' healthcare needs are not compromised as a result of a transition of care among providers.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Minimizing CMS overregulation that undermines private sector accreditation standards.	HHS should not require that private sector bodies rewrite their standards or alter their survey processes to conform to those used by CMS.	HHS's insistence on requiring private sector bodies to rewrite or alter their survey processes limits private-sector innovation that encourages greater attention to safety and quality.
Increasing transparency and improving risk adjustment in MA.	CMS should increase transparency around updates to risk adjustment in MA and move to a more clinically accurate model that supports care provided to all beneficiaries, including the chronically ill.	CMS should institute a payment (similar to that in FFS) for chronic care management. Instead, CMS has eliminated or continues to exclude risk adjustment payment for the care management of chronically ill MA beneficiaries. CMS should increase transparency and move to a more clinically accurate model that ensures equitable payment is provided to MA plans for chronic care management, assessment, and care planning activities.
Clarifying the add-on payment programs for new technology.	CMS should provide clear guidance on what new technology should be considered under the New Medical Services and New Technologies (NTAP) add-on payments and transitional pass-throughs.	CMS should structure the NTAP add-on payments and transitional pass-throughs to encourage the use of new and innovative technology.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Expediting the assignment of Healthcare Common Procedure Coding System (HCPCS) codes for Medicare products and technologies.	CMS should assign new HCPCS codes on a quarterly rather than an annual basis.	When HCPCS codes are assigned on an annual basis, new drugs and technologies introduced after January 1 are paid using a "miscellaneous code." Because these codes are not specific to a single drug or technology, they must be processed manually. This leads to delays and uncertainty among providers, and it occasionally negatively affects patient access.
Revising Evaluation and Management (E&M) guidelines.	HHS should revise E&M guidelines to allow multiple physician visits to group practice providers on the same day.	Current Medicare payment policies that allow one E&M visit per physician specialty per date of service are a disincentive for greater physician collaboration and consultation. This policy inadvertently discriminates against team-based destination medical practices. Patients come to these clinics for treatment of highly complex conditions that require collaboration among multiple specialists and subspecialists.
Streamlining E&M documentation guidelines.	CMS should simplify its documentation requirements and consider adopting the E&M codes in the American Medical Association's current procedural terminology (CPT) manual.	Medicare's requirement that physicians document long histories, review of symptoms, social histories, and physical exams on each patient visit is overly burdensome. The American Medical Association's CPT manual, which is already in use by commercial insurers, would simplify the documentation process.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Modifying the Advance Beneficiary Notice of Noncoverage (ABN).	CMS should modify the ABN requirement to allow for electronic communication.	Compliance with the CMS ABN face-to-face requirement poses unnecessary challenges. Allowing electronic communication would cut red tape and relieve regulatory burden.
Requiring all federal agencies to adopt common research terms and conditions.	HHS should harmonize administrative paperwork requirements across all federal agencies to save time and research resources.	The inconsistency of different federal agencies using different research terms and conditions under the Uniform Guidance increases administrative burden as institutions are forced to comply with an array of different terms and conditions across multiple agencies.
Harmonizing the National Institutes of Health (NIH) Genomic Data Sharing Policy with the HHS definition of human subjects.	HHS should ensure that agencies employ the same definition of human subjects.	The NIH Genomic Data Sharing Policy's treatment of deidentified data as human subjects data results in significant administrative work for institutions and researchers. Using this definition of human subject requires Institutional Review Board (IRB) review and certification, including for data collected prior to the implementation of the policy and study-specific informed consent. This contrasts with the Common Rule definition of human subject that does not apply to research with nonidentified biospecimens.
Eliminating the requirement that physicians sign home care orders.	HHS should allow nurse practitioners and other advanced practice providers to meet the face-to-face encounter requirement for ordering home care.	Nurse practitioners and other advanced practice providers are an important part of the healthcare team and should be able to certify that patients need home care.

III. RED TAPE INTACT: HHS ACTION REQUIRED		
Action	***HLC Position***	***Description***
Creating comprehensive guidance depositories to facilitate compliance and reduce complexity.	CMS should create a single depository for each program/provider type, and that depository should be continuously updated.	Creating a single depository would be very helpful in reducing administrative time and ensuring greater compliance. Currently, Medicare rules are found in a wide array of sites, including manuals, opinions, rulings, alerts, and national and local coverage determinations. Providers conduct significant and time-consuming research to ensure all relevant rules, guidelines, and policies are being taken into account. But despite their efforts, there is no assurance from CMS that all relevant guidelines have been located, or that the found guidance represents the latest changes. A single, updated depository would reduce these burdens.

IV. RED TAPE INTACT: HHS, CONGRESSIONAL ACTIONS REQUIRED		
Action	***HLC Position***	***Description***
Giving states flexibility through Section 1332 waivers.	**Legislative:** Congress should pass legislation that would make it easier for states to apply for the waivers. **Regulatory:** HHS should build upon its Section 1332 waiver checklist by further shortening the application process and review.	State flexibility is critical to achieving a healthcare system that is more efficient, more effective, and of the highest quality. Varying geographies and demographics across states make it difficult to apply one-size-fits-all policies on a national basis. To increase consumer choice and ensure their access to affordable health insurance, states need to be given flexibility through the Section 1332 waivers to implement their health insurance proposals.
Reducing the taxes and fees that were part of the ACA.	**Legislative:** Congress should pass legislation to permanently repeal the health insurance tax (HIT), the medical device tax, and the tax on brand-name prescription drugs. **Regulatory:** HHS should not enforce these taxes.	These burdensome taxes and fees raise health insurance premiums, harm job creation, deter the medical innovation needed to save and improve patients' lives, and inhibit economic growth.

IV. RED TAPE INTACT: HHS, CONGRESSIONAL ACTIONS REQUIRED		
Action	***HLC Position***	***Description***
Supporting market stability mechanisms.	**Legislative:** Congress should establish a reinsurance program for the individual market with predictable, reliable, and broad-based funding. Given the repeal of the individual mandate, alternative mechanisms should be enacted to promote continuous coverage. **Regulatory:** HHS should continue to build on recent improvements to the risk adjustment program without making changes that would undermine the integrity and accuracy of the program.	Market stability mechanisms such as risk adjustment help ensure that issuers have equal incentive to enroll all individuals. Given the skewed distribution of healthcare spending – especially in the individual market – reinsurance is necessary to help spread the costs of covering high-risk individuals. By reducing claims costs, reinsurance reduces premiums for all individual market consumers and encourages enrollment of a broad crosssection of health risks. Sufficient incentives must be in place to encourage healthy individuals to purchase and maintain coverage. Broad participation is required to ensure that the risk pool is functioning as intended, with healthy individuals balancing higher risk participants.
Fund Cost-Sharing Reduction (CSR) subsidies.	**Legislative:** Congress should pass legislation that funds CSR subsidies and the risk corridor program for 2017 and beyond. **Regulatory:** HHS and the Trump administration should fund CSR subsidies for 2017 and beyond.	CSR subsidies play a pivotal role in ensuring access to healthcare services for very low-income enrollees, helping these individuals better afford their copays, deductibles, and other out-of-pocket costs.

IV. RED TAPE INTACT: HHS, CONGRESSIONAL ACTIONS REQUIRED		
Action	***HLC Position***	***Description***
Modernizing the Anti-Kickback Statute and Physician Self-Referral (Stark) Law rules.	**Legislative:** Congress should pass legislation that would require HHS to review and assess these laws in the context of the transformation of the healthcare system to value-based care. Congress should also grant the Office of the Inspector General (OIG) and CMS enhanced regulatory flexibility/rulemaking discretion to develop exceptions and safe harbors to the Anti-Kickback Statute and Stark Law.	As reimbursement models have evolved to become more patient-centered, the Anti-Kickback Statute and the Stark Law have become barriers to value-oriented care models that improve health outcomes and reduce costs. While these laws have been minimally modified, these modifications are piecemeal and do not apply to all value-based care models.
	Regulatory: HHS should issue safe harbors, exceptions, and guidance that extend and streamline the Anti-Kickback and Stark waiver process.	
Aligning provisions of the Confidentiality of Alcohol and Drug Abuse Patient Records Under 42 CFR Part 2 regulation with HIPAA.	**Legislative:** Congress should pass legislation ensuring providers are able to provide safe, effective, and high-quality care coordination by ensuring that they have access to all of a patients' records (including those relating to substance abuse).	The 42 CFR Part 2 regulations govern the confidentiality of alcohol and drug abuse patient records. These rules duplicate the already strong privacy protections for health information under HIPAA. In addition, 42 CFR Part 2 is not compatible with the way healthcare is currently delivered and the need for providers to have access to the patient's entire medical record.
	Regulatory: HHS should fully align requirements for sharing patient's substance use records with HIPAA. At a minimum, HHS should release guidance codifying legal protections for covered entities that act in "good faith compliance" with final rulemaking.	

IV. RED TAPE INTACT: HHS, CONGRESSIONAL ACTIONS REQUIRED		
Action	***HLC Position***	***Description***
Streamlining and clarifying the parameters under which manufacturers can communicate economic and scientific information.	**Legislative:** Congress should pass legislation allowing broader communication of this information by manufacturers. **Regulatory:** HHS should build upon provisions of the 21st Century Cures Act that provide a path forward for economic communication by manufacturers. Additionally, the FDA should issue regulations or guidance that help clarify and streamline appropriate pathways for dissemination of scientific and medical information by manufacturers.	Restrictions on the sharing of economic and clinical information by manufacturers restricts payers and providers from having the kind of information that could be valuable in projecting a drug's impact on patients. This information is particularly important when considering "breakthrough" drugs that may offer significant health benefits for patients and reduce costs in the long term.
Encouraging and providing technical support for private-sector-led efforts to develop a solution to patient identification.	**Legislative:** Congress should approve the fiscal year 2018 Labor, Health and Human Services, and Education Appropriations Bill that includes language directing the Office of the National Coordinator for Health Information Technology to engage with stakeholders on private-sector-led initiatives to accurately identify patients. **Regulatory:** HHS should work with private-sector leaders on the development of a patient identification solution.	As the healthcare system moves toward nationwide health information exchange, the ability to identify patients with 100 percent accuracy is still lacking. Errors in patient identification lead to errors when it comes to matching patients to their medical records. This hampers interoperability, patient treatment, and patient safety. Addressing this problem is especially important as health information increasingly flows among unaffiliated providers in order to coordinate care and as patients increasingly gain access to and share their own data. Ensuring correct patient identification is the first step toward effectively protecting and securing identities and mitigating fraud. It is also expected to save costs.

IV. RED TAPE INTACT: HHS, CONGRESSIONAL ACTIONS REQUIRED		
Action	***HLC Position***	***Description***
Modernizing Medicaid Best Price Report regulations to support value-based arrangements.	**Legislative:** Congress should pass legislation that exempts Medicaid Best Price requirements in value-based arrangements. **Regulatory:** CMS should waive the Medicaid Best Price rule in all value-based demonstrations.	Under current CMS rules, CMS must require drugmakers to offer the Medicaid program the lowest price they negotiate with any other buyer. If a value-based contracting arrangement establishes the Best Price under the Medicaid Drug Rebate Program, it can create significant financial liability for the manufacturer. Furthermore, these rules are highly technical, and areas of ambiguity exist where government guidance does not explicitly address certain situations. The use of reasonable assumptions is critical to addressing value-based arrangements that involve areas of ambiguity. Updated guidance on the use of these assumptions could help to enable increased use of value-based arrangements.

IV. RED TAPE INTACT: HHS, CONGRESSIONAL ACTIONS REQUIRED		
Action	***HLC Position***	***Description***
Modernizing Medicare coverage to include telehealth services.	**Legislative:** Congress should revise the statutory restrictions on telehealth originating sites to allow the provision of telehealth services in different environments, including the patient's home, long-term care facilities, and mobile and community-based settings. Congress should also pass legislation allowing telehealth in MA, and for patients with stroke or receiving home dialysis.	Telehealth can make the delivery of healthcare more efficient, effective, and patient-centric. Telehealth services have been shown to improve healthcare access and quality. They help to meet patient demand and deliver care to patients who cannot be seen in person. However, adequate coverage and payment for telehealth services remain major obstacles. Medicare lags far behind other payers and approves new telehealth services only on a case-by-case basis.
	Regulatory: CMS should lift current restrictions on telehealth. CMS should interpret the use of telehealth as a mode of delivering the basic healthcare benefits covered under FFS, which will expand the ability of MA plans to cover such services.	
Providing Medicare coverage for wellness programs.	**Legislative:** Congress should pass legislation enabling Medicare to undertake programs similar to employee wellness programs.	Chronic disease prevention is an essential component of healthcare. Many chronic diseases are caused by modifiable health risks such as lack of physical activity, poor nutrition, and tobacco use. To avoid these risks, Medicare beneficiaries need access to comprehensive and evidence-based wellness programs. Many of these programs have been implemented by employers, and retirees covered by Medicare should have access to similar programs, as well.
	Regulatory: CMS should implement regulations allowing for wellness programs and conduct demonstration projects on such programs.	