August 12, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-6082-NC

Dear Administrator Verma:

The Healthcare Leadership Council (HLC) appreciates the opportunity to comment on the Administration's recently released request for information (RFI) on "Reducing Administrative Burden to Put Patients Over Paperwork."

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 healthcare 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, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient centered approach.

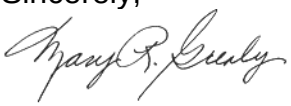
The growing number of administrative tasks imposed across the healthcare industry affecting clinicians, providers, health issuers, drug manufacturers, patients and their families add unnecessary costs to the U.S. healthcare system. Excessive administrative tasks divert time and focus from ensuring that Americans have access to the high-quality healthcare they deserve. Eliminating these unnecessary administrative burdens will decrease healthcare costs and improve patient care.

HLC member companies are working every day to improve the value of healthcare for consumers, but this mission is made more difficult by federal rules and regulations that

are ineffective, costly, and time-consuming. We applaud action already taken by the agency to reduce regulatory burden. The attached "Red Tape" Reforms to Improve Care and Lower Costs provides recommendations to assist in further reducing healthcare regulatory barriers that impede patient care and increase costs.

Thank you for the opportunity to provide comments on this RFI to reduce administrative burdens. HLC looks forward to continuing to work with you on our shared priorities. If 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

"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.

HEALTHCARE LEADERSHIP COUNCIL

I – REGULATORY RELIEF IN PROGRESS

ACTION	HLC POSITION	DESCRIPTION
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.	HHS continues its support of plans seeking to implement enhanced direct enrollment to 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).
Allowing for greater variation and flexibility in plan design.	HHS should allow greater flexibility on benefits, plan design, and actuarial value as long as the variation includes all of the 10 categories of Essential Health Benefits (EHBs).	Continuing the development and implementation of operational solutions for seamless enrollment and consumer assistance will reduce administrative costs and consumer frustration. This is a work in progress.
Revise the Medical Loss Ratio (MLR).	Allowing issuers to deduct employment taxes from the MLR will encourage greater competition in the markets. In addition, the safe harbor for quality improvement activity expenses should be 1 percent (rather than the current 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	HHS finalized the proposals outlined in the 2019 Notice of Benefit and Payment Parameters that would streamline the requirements for states to lower the MLR threshold. However, the rule prohibits issuers from deducting employment taxes from the MLR, and establishes a safe harbor for quality improvement activity expenditures for the MLR at .8 percent instead of 1 percent.

I – REGULATORY RELIEF IN PROGRESS

ACTION	HLC POSITION	DESCRIPTION
	available only to states that request it.	
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 if they have not already done so.	SEPs provide necessary access to health insurance coverage for eligible individuals with valid qualifying events. HHS has made changes in recent years to how the market approaches SEPs to better ensure individuals are truly eligible. However, even with these changes, the regulations in force do not sufficiently prevent improper use of the SEPs to access coverage outside of the open enrollment period. Additional action is needed.
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. 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.
Modernizing the Anti-Kickback Statute and Physician Self-Referral (Stark) Law rules.	**Regulatory:** HHS should issue safe harbors, exceptions, and guidance that extend and streamline the Anti-Kickback and Stark waiver process.	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 individual waivers are now permitted, these modifications are piecemeal and do not apply to all value-based care models.
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.	HHS proposed a rule that would eliminate burdens imposed by the 2016 regulation's requirement that regulated health companies distribute non-discrimination notices and "tagline" translation notices in at least 15 languages to patients and customers. These notices have cost the healthcare industry billions of dollars and data did not show that the notices have yielded the intended benefit for individuals with limited English proficiency.

I – REGULATORY RELIEF IN PROGRESS

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Reducing overlap of alternative payment models.	CMS should release clear guidance on the attribution, precedence, and reconciliation rules applied across both permanent and CMMI demonstration models.	The increasing overlap of various alternative payment models has created the need to determine a long-range plan to harmonize models. The proliferation of models and tracks within models necessitated a series of attribution, precedence, and reconciliation rules. This leads to overlap and confusion. CMS has acknowledged this as a problem but hasn't made any progress yet. More guidance is needed.
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. CMS has acknowledged this as a problem, but no progress has been made. It noted that the value to the Medicare program of the prohibition on same-day E&M visits billed by physicians in the same group and medical specialty may be diminishing.
Encouraging and providing technical support for private-sector-led efforts to develop a solution to patient identification.	**Legislative:** Congress should approve the fiscal year 2019 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 match patients to their medical records. **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 uniformly identify patients with 100 percent accuracy across care settings is still lacking. Congress, recognizing the need for accurate patient matching, asked the Government Accountability Office (GAO) to study patient matching and identify additional things ONC could do to improve matching. In February 2019, CMS proposed a rule on interoperability seeking comment on ways for ONC and CMS to facilitate private sector efforts on a workable and scalable patient matching strategy.
Aligning provisions of the Confidentiality of Alcohol and Drug Abuse Patient Records Under 42 CFR Part 2 regulation with HIPAA.	**Regulatory:** HHS should fully align requirements for sharing patients' substance use records with HIPAA. At a minimum, HHS should release guidance codifying legal protections	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 but the information must be kept separate from the patient medical record. These should be merged for the best patient care.

I – REGULATORY RELIEF IN PROGRESS

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	for covered entities that act in "good faith compliance" with final rulemaking.	SAMHSA is working on changes to the confidentiality of alcohol and drug abuse patient records, to remove barriers to coordinated care and permit additional sharing of information among providers and 42 CFR Part 2 programs assisting patients with substance use disorders.
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.	In the Inpatient Prospective Payment System proposed rule for fiscal year 2020, CMS sets out several proposals to revise policies related to new technology add-on payments and increase payment rates.
Allowing health plans and providers to share protected health information (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 patient information with health systems and providers and payment depends on patient outcomes, can improve patient health and reduce costs. In 2018, the HHS Office for Civil Rights issued an RFI on HIPAA seeking comment on ways in which HIPAA may be reformed to support the transformation to value-based healthcare.
Eliminating the Health Insurance Portability and Accountability Act (HIPAA) Notice of Privacy Practice acknowledgement requirement.	HHS should eliminate the requirement that a healthcare organization document patient receipt of the Notice of Privacy Practice.	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. Additionally, in 2018, the HHS Office for Civil Rights issued an RFI on HIPAA that proposes to eliminate or modify this requirement.
Amending the Airline Deregulation Act.	The Airline Deregulation Act needs to be amended to reduce high out-of-network charges to patients.	Members of both the U.S. House and Senate are drafting bipartisan legislation to amend the Airline Deregulation Act to allow states to regulate air ambulances in a very limited way to protect consumers from excessive out-of-network charges.
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 recently released final policy and payment updates to the Medicare Advantage (MA) and Part D programs through the 2020 Rate Announcement and Call Letter. CMS finalized the Alternative Payment Condition Count model with additional Hierarchical Condition Categories (HCC) for pressure ulcers and dementia. The model will count the number of conditions a beneficiary may have that are in the risk adjustment model and adjust as the number increases. CMSwill blend 50

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		percent of the risk score using the 2017 CMS-HCC model and 50 percent of the risk score calculated with the Alternative Payment Condition Count (APCC) model. More accuracy is needed in the risk adjustment model. CMS should add conditions to the risk adjustment model that reflect social determinants of health.
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.
Require beneficiaries to actively choose between MA and FFS at initial enrollment.	HHS should not auto-enroll beneficiaries in FFS, and instead require beneficiaries to choose either MA or 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	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.

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	performance against targets once they have joined programs because they are not able to replicate CMS calculations.	
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 and health plans.
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.
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 under HIPAA.	HIPAA does not permit researchers to remove PHI from the premises of the covered entity. Remote access of PHI by researchers reviewing information that is outsourced to another location (e.g. “cloud-based”) is becoming more common. In 2018, the HHS Office for Civil Rights issued an RFI on HIPAA that seeks to modify provisions that do not meaningfully contribute to the protection of the privacy or security of individuals' protected health information.
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.

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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.
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 quicker hiring of employees by the FDA.
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 for families, and reduce costs and variation.
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 has actively focused on making the star ratings program more predictable, releasing CY 2020 Medicare Advantage and Part D Flexibility Final Rule, finalizing enhancements to the cut point methodology for non-CAHPS measures intended to improve stability and predictability of star rating. Mean sampling will be added to address data outliers, and guardrails to ensure cut points do not increase or decrease by more than 5 percent from one year to the next.
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

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		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.
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.
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.
Creating comprehensive guidance depositories to facilitate compliance and reduce complexity.	CMS should create a single depository of Medicare rules 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 considered. But despite their efforts, there is no assurance from CMS that all relevant guidelines have been located, or that the guidance found represents the latest changes. A single, updated depository would reduce these burdens.
Revising hospital star ratings and readmission measures to reflect differences in patient populations.	CMS should use the feedback it collects 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.	CMS updated consumer resources for comparing hospital quality in February 2019 on the Hospital Compare and Medicare's data websites. However, the information continues to be inaccurate and misleading for consumers. Both the star ratings and the readmission measures lack appropriate adjustment for the population being served. Similarly, the hospital readmission rates and other outcome measures have been publicly reported and used to penalize hospitals up to 3 percent of base inpatient PPS payments. This is unfair to hospitals because both the star ratings and the readmission measures lack appropriate adjustment for the population being served.

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		Recently, AHA released an overview of the FY 2020 IPPS proposed rule. In the proposed rule, CMS estimates that readmissions penalties across all eligible hospitals will total $550 million in FY 2020. Overall, CMS is taking steps to work with industry to address concerns, but issues still persist.
Streamline reporting specifications for quality measures related to controlling high blood pressure among Medicare programs.	CMS should streamline the quality measure reporting specifications for controlling high blood pressure to allow remote readings that integrate directly into a patient's electronic medical record to count toward required blood pressure measurements in the Medicare Shared Savings Program.	The National Committee for Quality Assurance (NCQA) incorporated telehealth into the measure specifications for controlling high blood pressure in the 2019 Healthcare Effectiveness Data and Information Set; however, these specifications were not updated in a similar way for the Quality Payment Program. Providers who participate in the Medicare Shared Savings Program cannot count remote blood pressure monitoring measurements that transmit readings directly into a patient's electronic health record toward the required measurement for controlling high-blood pressure.
Reducing the taxes and fees that were part of the ACA.	**Regulatory:** IRS 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.
Supporting market stability mechanisms.	**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.	**Regulatory:** HHS should permanently fund CSR subsidies.	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.

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Modernizing Medicaid Best Price Report regulations to support value-based arrangements.	**Regulatory:** CMS should waive the Medicaid Best Price rule in all value-based demonstrations.	Under current CMS rules, CMS must require drug makers 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.
Providing Medicare coverage for wellness programs.	**Regulatory:** CMS should implement regulations allowing for wellness programs and conduct demonstration projects on such 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.
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.