



January 25, 2018

The Honorable John R. Graham
Acting Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue, S.W., Room 415F
Washington, D.C. 20201

Sent via electronic transmission to: CompetitionRFI@hhs.gov

Dear Acting Assistant Secretary Graham:

Thank you for issuing a request for information (RFI) on promoting healthcare choice and competition across the United States. The Healthcare Leadership Council (HLC) applauds your leadership on this important issue and welcomes the opportunity to share our thoughts with you.

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, 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 supports healthcare innovation and believes that American ingenuity is critical to achieving a healthcare system that is more efficient, more effective, and of the highest quality. 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. HLC has developed the attached "red tape" list of reforms that will reduce regulatory burden and improve the quality and accessibility of healthcare. Our suggestions on revising laws, regulations, and policies to promote the development and operation of a more competitive healthcare system are also described below. Several of these solutions have been proposed by the Department of Health and Human Services (HHS), and HLC urges HHS to finalize these regulations.

Medical Loss Ratio

HLC recommends that HHS allow issuers to deduct employment taxes from the Medical Loss Ratio (MLR), implement a safe harbor for quality improvement expenditures for the MLR, and streamline the requirements for states to lower the MLR threshold. These reforms will encourage greater competition in the market between issuers.

Direct Consumer Assistance

To reduce administrative costs and consumer frustration, HHS should develop and implement solutions that promote seamless enrollment and excellent customer assistance. This should include eliminating the “double redirect” between plan websites and HealthCare.gov, allowing plans to communicate with consumers earlier in the open enrollment process, and directing consumer calls to the plans’ customer service centers for issues such as claims that can best be resolved by the plans.

Hospital Star Ratings

The star ratings and hospital readmission rates have both been publicly reported and used to penalize hospitals. This is unfair to hospitals because the star ratings and readmission measures lack appropriate adjustment for their patient population. The Centers for Medicare and Medicaid Services (CMS) should develop a system for the star ratings and readmission measures that accurately reflects hospital challenges such as the social and economic status of their patients.

Plan Design

HLC believes that HHS should encourage issuers to develop innovative, market-driven, and affordable plan choices including, but not limited to, value-based insurance design and high-deductible health plans with health savings accounts. HHS should allow for this flexibility on benefits, plan design, and actuarial value as long as the variation includes all of the 10 categories of essential health benefits. Additionally, HHS should aid consumer choice and education about the new plans by eliminating standardized plan options and by not differentially displaying plan designs.

Transparency in Payment Models

A lack of clarity in methodologies prevents model participants from accurately assessing their ongoing performance against targets. CMS should supply sufficient technical information when proposing these models, which will allow stakeholders to realistically evaluate payment impact.

Reducing the Regulatory Burden Imposed on Phase III Drug Trials

HHS should reduce the cost and risk of undertaking Phase III trials. The current system burdens pharmaceutical companies with huge and unpredictable regulatory delays; discourages small U.S. biotech companies from competing in the traditional drug market; and encourages innovation in drugs for very rare diseases that are exempt from Phase III.

Fee-for-Service Payment Regulations

Current regulations often hinder providers' ability to identify and place patients in the most appropriate setting. Additionally, providers are not able to test new, more patient-centered and streamlined clinical pathways. HHS should test new approaches to care that are free from such barriers. This will help advance solutions that improve clinical outcomes, ease family anxieties, and reduce costs and variations.

Home Care Orders

Patient choice in provider is limited by regulations that require that physicians sign home care orders. 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.

State Flexibility

Varying geographies and demographics across states make it difficult to apply one-size-fits-all policies on a national basis. HHS should give states additional flexibility through the Section 1332 waivers. By shortening the application and review process for these waivers, HHS will help states to implement new plan choices that will increase consumer choice and access.

Risk Adjustment

HHS must continue to build on recent improvements to its risk adjustment program. Market stability mechanisms such as risk adjustment help ensure that issuers have equal incentive to enroll all individuals, regardless of their health status. A broad cross section of consumers with different health risks stabilizes the market and makes coverage more affordable for all.

Anti-Kickback and Stark Modernization

As reimbursement models have evolved to become more patient-centered, the Anti-Kickback Statute and the Stark Law have become barriers to value-based 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 modes. HHS should issue safe harbors, exceptions, and guidance that extend and streamline the waiver process for all stakeholders.

Sharing of Economic and Scientific Information

Restrictions on the sharing of economic and clinical information by manufacturers restricts payers and providers from having information that could be valuable to projecting a drug's impact on patients. This information is especially important when considering "breakthrough" drugs that may offer significant health benefits for patients and reduce costs in the long term. The Food and Drug Administration (FDA) should issue regulations or guidance to further clarify and streamline appropriate pathways for dissemination of scientific and medical information by manufacturers.

Patient Identification

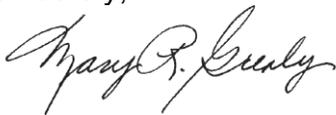
Ensuring correct patient identification is especially important as health information increasingly flows among unaffiliated providers and as patients access and share their data. Correct patient identification is the first step in protecting and securing identities and mitigating fraud, and it will also reduce costs. HHS should work with private-sector leaders on the development of a patient matching solution.

Telehealth Services

Telehealth can make the delivery of healthcare more efficient, effective, and patient-centric. It has also been shown to improve healthcare access and quality. However, Medicare only approves new telehealth services on a case-by-case basis, which limits the technology's adoption. CMS should lift current restrictions on telehealth.

Thank you again for your work at HHS. HLC looks forward to continuing to collaborate with you on our shared goal of promoting choice and competition. Should you have any questions, please do not hesitate to contact Debbie Witchev at (202) 449-3435.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mary R. Grealy".

Mary R. Grealy
President