HEALTHCARE LEADERSHIP COUNCIL

Reforms to Regulations that will Improve Care Delivery and Lower Costs

The Healthcare Leadership Council supports regulatory relief efforts that will improve the quality and accessibility of healthcare for all Americans. HLC members are working every day to improve the value of healthcare for consumers. In order to reach the potential we envision — a modern, high-value system that improves health outcomes and quality of life — we ask the federal government to address rules and regulations that have become ineffective. 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.

HLC urges the federal government to reduce the regulatory burden in order to:

1) Stabilize the Healthcare Marketplace and Environment
   We ask the federal government to continue efforts to stabilize the health insurance marketplace by reforming burdensome regulations that raise consumer costs. This effort should include restoring regulatory oversight to the states. It should also include reducing fees, taxes, and micromanagement of benefits and administrative requirements that result in higher costs for consumers and an inability of health plans and employers to provide health coverage that best meets the needs of individuals.

2) Transform Healthcare Through Innovation and Collaboration
   We ask the federal government to encourage, rather than discourage, innovation and collaboration to bring higher value healthcare to consumers. Efforts to reform regulations related to outdated fraud and abuse laws are a key component of driving better value for consumers. The federal government should reform regulations that inhibit the flow of information that providers, health plans, researchers, and consumers themselves need to find better ways to treat and cure disease. Finally, providers need relief from a plethora of reporting requirements that overlap and oftentimes conflict with each other. Streamlining reporting requirements to ensure that those who are in the business of healthcare are actually able to provide it to the best of their ability is what our government should encourage.

3) Ensure a Vibrant Future for Medicare Beneficiaries
   We ask the federal government to enable the modernization of the Medicare program to meet the needs of the elderly and disabled. Many of the regulations that were created decades ago during the inception of government-funded entitlement programs remain on the books. Others have been added over time, contributing to a fragmented delivery system that does not align with high quality, innovative programs in the private sector. The federal government should revise or eliminate regulations that make it difficult, if not impossible, to deliver the services and products that best meet the needs of today's and tomorrow's Medicare beneficiaries.

HLC is pleased to provide our list of regulatory relief suggestions in the accompanying chart. We look forward to working with the Trump administration in improving the quality and value of healthcare for all Americans.

Reforms to regulations that will improve care delivery and lower costs

Stabilizing the Healthcare Marketplace and Environment	
ACTION	**ADDITIONAL DESCRIPTION**
Improve communication with consumers by allowing health plans to provide more direct consumer assistance	Accelerate the development and implementation of operational solutions for seamless enrollment and consumer assistance, in order to reduce administrative costs and consumer frustration. This includes eliminating the "double redirect" between plan websites and Healthcare.gov to allow plans directly to enroll consumers and use Healthcare.gov only for verifying subsidy eligibility. It also includes ensuring that consumer calls are appropriately directed to the plans' customer service centers for all issues that can be resolved by the plans, such as claims.
Modify the ACA Section 1332 Waiver requirements by giving states more flexibility to design their programs and by allowing for expedited review and public comment periods	Modify the Affordable Care Act (ACA) Section 1332 Waiver regulations to shorten federal review timelines and provide for expedited review in some circumstances, streamline the public comment process, or give more flexibility to states to design innovative, alternative reform proposals.
Restore regulatory oversight to the states	Within the Center for Consumer Information and Insurance Oversight (CCIO)'s administrative authority, defer to the states for regulatory approval authority of nongroup products.
Lower costs by reducing the fees, taxes, and regulations that were part of the ACA and that are a burden on plans and ultimately consumers	Do not enforce taxes, such as the Health Insurance Tax (HIT), that add to the cost of premiums. Eliminate (or substantially reduce) the 3.5 percent federal exchange user fee. Revise the Medical Loss Ratio (MLR) calculation. The definition of "activities that improve healthcare quality" should include the costs of preventing fraud and abuse; agent and broker commissions should be removed from the calculation; and payroll taxes should be deducted from the premium. Reduce the number of Special Enrollment Periods (SEPs).
Support adequate risk adjustment	Establish permanent reinsurance funding for the risk adjustment program.

Reforms to regulations that will improve care delivery and lower costs

Encourage innovation and flexibility in plan design	Encourage innovative product designs that attract new consumers and offer them affordable options, as opposed to one-size-fits-all standardized benefit packages. Nonstandard plan options should be presented to shoppers in a way that is clear and does not penalize plan design.
Eliminate the employer reporting requirements of the ACA employer mandate	Immediately ease ACA employer reporting requirements by repealing the reporting requirements not essential to the calculation and payment of subsidies. Proposed revisions to IRS Form 5500, the annual reporting form for plans subject to ERISA, should be rescinded. In addition, consumer privacy should be better protected by removing social security numbers (SSNs) from IRS Forms 1094-B and 1095-B (used by entities providing minimum essential coverage to report to the IRS who they cover).
Replace the ACA multiple-language translation requirements (Section 1557) with a more efficient approach	Covered entities must present tagline notices in 15 languages spoken by individuals in their state. Excessive multiple-language "tag-line" requirements costing millions of dollars should be repealed and more efficient means of ensuring language accessibility should be developed. The Section 1557 rule should not be imposed upon specialty insurance products.

Reforms to regulations that will improve care delivery and lower costs

Transforming Healthcare Through Innovation & Collaboration	
ACTION	**ADDITIONAL DESCRIPTION**
Reform the waiver process for Anti-Kickback Statute and the Physician Self-Referral (Stark) Law rules	When the Anti-Kickback Statute (1972) and the Physician Self-Referral (Stark) Law (1988) were enacted, the healthcare system provided little or no incentive to providers to coordinate healthcare delivery. Reimbursement models based on the number of services provided rewarded volume, rather than rewarding health promotion and maintenance. As reimbursement models have evolved to become more patient-centered, the Anti-Kickback Statute, Stark Law, and their implementing regulations have become barriers to value-oriented care models that improve health outcomes and reduce costs. While these laws have been minimally modified (e.g., CMMI waivers for particular demonstration projects) in an attempt to keep pace with these changes, these modifications are piecemeal and do not apply to all value-based care models that require appropriate coordination among stakeholders. (*See HLC's February 2017 paper, "Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models")*
Align provisions on the Confidentiality of Alcohol and Drug Abuse Patient Records under 42 CFR Part 2 regulations with HIPAA	These rules duplicate the already strong privacy protections for health information under HIPAA. These provisions are not compatible with the way healthcare is currently delivered – providers and organizations need access to a patient's entire medical record, including addiction records, in order to provide safe, effective, high-quality treatment and care coordination. Regulations on substance abuse records extend far beyond the requirement in HIPAA, and compliance with two separate sets of confidentiality regulations has proven unnecessary and impedes coordinated care. The administration should fully align requirements for sharing patients' substance use records with the strong confidentiality requirements in the HIPAA regulation that allow the use and disclosure of patient information for treatment, payment, and healthcare operations. At a minimum, HHS should release guidance codifying legal protections for covered entities that act in "good faith compliance" with the final rulemaking.
Build upon provisions enacted in the 21st Century Cures Act to streamline and clarify Food and Drug Modernization Act (FDAMA) Section 114 limitations on communication of	Modifications to FDAMA Section 114 must clearly define the parameters under which healthcare economic information can be shared with providers about medical devices and drugs. It is our sincere hope that the Cures changes provide a clear path forward for manufacturer communications of healthcare economic information. We believe the phrase "payor, formulary committee or other similar entity" in section 3037 of Cures should be

healthcare economic information	interpreted as including individuals and organizations that contribute toward, advise or facilitate organizational decisions directed at improving population health, lowering healthcare costs, or improving patient experience through the availability or management of pharmaceutical treatments and programs. This should include situations such as physician-led organizations taking on risk in accountable care models. In addition, FDA's current regulatory framework will continue to pose challenges, even after Cures, for manufacturers in communicating pipeline information to payors and valuable scientific and medical information to payors, formulary committees, other similar entities and healthcare providers. To alleviate these challenges, FDA should issue regulations or guidance that will help clarify and streamline appropriate pathways for dissemination of such information by manufacturers.
Revise Telephone Consumer Protection Act ("TCPA") regulation	Ensure that the TCPA can continue to promote the consumer protections that motivated its passage while also allowing technological advances to be deployed by healthcare organizations to encourage patient engagement, increase quality, and improve outcomes. TCPA has had the unintentional and detrimental impact of impeding nonmarketing healthcare communications. As healthcare stakeholders seek to scale efforts to reach, engage, and care for patients, telephonic technologies are a critically important component. Whether it is to inform a consumer about eligibility for healthcare benefits, a pharmacy reminding a patient to refill a prescription, a primary care office sending an automated reminder for an upcoming appointment, a health plan sending a text reminder to return for an annual visit, or a hospital sending a patient a text message containing discharge instructions, telephone contact plays a vital role in patient engagement. Modern consumers expect seamless and on-demand communication by phone and text. These tools are not merely a scaling effort, but also a response to consumer demand and expectation.
HIPAA: Issue regulation changing the requirement that covered entities document receipt of a notice of privacy practices	Patients have a right to receive a notice of privacy practices under the Health Insurance Portability and Accountability Act (HIPAA). Healthcare organizations should take feasible steps to ensure that patients receive this information. However, it is excessively burdensome for health organizations to document this action every time it is taken. HHS should remove the acknowledgement requirement that adds an extra administration and document retention burden on covered entities, but does not meaningfully advance privacy interests.

Reforms to regulations that will improve care delivery and lower costs

HIPAA: Issue guidance on preparatory to research pathway under 45 CFR § 164.512(1)(ii)(b)	The "preparatory to research" pathway requires that protected health information (PHI) not be removed from the covered entity – sometimes referred to as the "on-premises" requirement. In many cases, however, the PHI is no longer on the premises of the covered entity at the outset of the activities, for example, if the records are stored at a business associate's off-site storage location or in a business associate's cloud hosting provider. HHS should issue guidance indicating that the PHI can remain on the premises where it is located at the time the preparatory to research activities are conducted.
HIPAA: Issue guidance on uses and disclosures to carry out healthcare operations	Health plans and covered entity providers want to enter into collaborative value-based pricing arrangements where health plans share information with health systems and the health systems' payment depends on the outcome of the patients. Similarly, in integrated care settings, patients do not always have a relationship with all of the providers among whom information should be coordinated to improve health outcomes. In limited, patient-serving circumstances, covered entities should have clarity that PHI may be shared under the existing payment pathway or as part of healthcare operations or through another pathway in order to establish value-based pricing models. Covered entities also need clarity that a covered entity 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 relationship (currently or previously) with both the disclosing and receiving covered entity in a value-based arrangement.
Update CMS Data Use Agreements rules to foster greater healthcare innovation	Centers for Medicare and Medicaid Services (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 data use agreement. As a result, CMS data are typically not combined with PHI in a clinical setting, though the combination of CMS data and PHI may yield benefits for care and utilization management. HHS should require the harmonization of the CMS data use agreement protections (as required by the Privacy Act of 1974 and Privacy Act regulations in 45 CFR Part 5b) with the data use agreement provisions in the HIPAA privacy rule. It would also be helpful for HHS to issue guidance on how entities may handle both PHI and CMS data in a manner that complies with HIPAA and CMS data use agreement requirements.

Reforms to regulations that will improve care delivery and lower costs

Reduce regulatory delays in updating standards for the e-prescribing market	Streamline the regulatory process for the e-prescribing SCRIPT standard. Now that this process has matured, it no longer needs the extensive CMS oversight that it had when first implemented. Improving the regulatory process will allow innovations that are approved by the standards body to reach market more quickly without unnecessary delays created by the rulemaking schedule.
Encourage and provide technical support for private sector-led efforts to develop a solution to patient identification	As the healthcare system moves toward nationwide health information exchange, the ability to identify patients with 100 percent accuracy 100 percent of the time is still lacking. Errors in patient identification foster errors when it comes to matching patients to their medical records. Ultimately, this hampers interoperability, patient treatment, and patient safety. While a congressional ban prohibits HHS from spending funds on implementing unique patient identifiers, HHS should not be precluded from supporting private sector efforts to develop a patient identification solution. 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. And, it is expected to save the healthcare system millions of dollars.
Facilitate interoperability by streamlining MIPS regulations to create a single set of outcome measures	Successful payment and delivery reform needs a high-performing, interoperable, and secure technical infrastructure. Physicians and clinicians need ample time and interoperable electronic health records (EHRs) in order to succeed. To allow more time for transition, 2018, in addition to 2017, should be treated as a transition year and the mandate to meet Stage 3-like measures under the Advancing Care Information (ACI) performance category of the Merit-Based Incentive Program (MIPS) should be removed.
Delay Stage 3 Meaningful Use requirements and use of Version 2015 CEHRT indefinitely while retaining a 90-day reporting period after 2017	The Health Information Technology for Economic and Clinical Health (HITECH) Act Meaningful Use program, now beginning its seventh year, has been very successful at helping hospitals and physicians achieve near universal adoption of EHRs. However, it has failed to deliver the level of interoperability needed to facilitate seamless information sharing among different providers and has imposed on providers a series of burdensome mandates that increase the cost of care and often do not lead to better patient outcomes. If providers are required to move

	to Stage 3/Version 2015 Certified Electronic Health Record Technology (CEHRT), they will not have a chance to benefit from the provisions outlined under the 21st Century Cures Act designed to improve interoperability. Stage 3 implementation should be tied to a higher state of interoperability.
Revise outdated regulations on drug manufacturer communications to facilitate 21st Century Cures implementation	21 CFR Part 99 contains 15 regulations, and the statutory authority for those regulations has expired and, thus, these rules are no longer applicable. Rather than the current final rule on intended use, FDA should adopt a policy that would prevent manufacturers from being prosecuted for mere knowledge of off-label use and clarify that it will not consider sources related to a manufacturer's knowledge in determining "intended use." This reform would ensure that physicians continue to have access to the treatments they and their patients determine best, and would prevent arbitrary punishment of companies for legitimate business operations. FDA should revise the "substantial evidence" requirement required for comparative advertising claims so as to be consistent with a truthful and nonmisleading standard. FDA should also modify its regulation to clarify that it does not limit communication of comparative data that is truthful and nonmisleading. The ability to disseminate comparative data even without two head-to-head studies would result in companies generating more comparative data about their products, and these additional data would benefit payors, providers, and patients. FDA should also adopt binding regulatory safe harbors that clearly and unambiguously exempt "scientific exchange" from FDA jurisdiction. At the same time, FDA should remove certain overly burdensome restrictions to allow manufacturers to provide physicians and other learned audiences accurate, up-to-date scientific information without fear of prosecution and, in turn, help support better treatment decisions and further medical innovation.
Reduce the regulatory burden imposed on Phase III drug trials	The cost and risk of Phase III FDA clinical drug trials typically account for 90 percent or more of a drug's development costs. An evaluation of drug development in three areas (obesity, adult-onset diabetes, and cardiovascular disease) revealed that 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 more innovation in drugs covering very rare diseases (exempt from Part III) than in drugs for conditions afflicting huge numbers of Americans.

Reforms to regulations that will improve care delivery and lower costs

Revise conflict-of-interest policies to ensure FDA is able to obtain input and advice from scientific experts	The federal government's process and criteria for evaluating conflicts of interest should be revised to allow scientific experts to provide advice to FDA through advisory committee/panel engagement. Policies should allow alternative methods of meeting the conflict-of-interest requirements to enable more timely engagement with qualified advisory panel members and hiring of employees. Current requirements can make it difficult to hire experienced staff and top scientists, especially when rules include holdings. Policies should be modified to allow recusals from participating in decisions that might affect their patents or holdings.

Ensuring a Vibrant Future for Medicare	
ACTION	**ADDITIONAL DESCRIPTION**
Reform the Center for Medicare and Medicaid Innovation (CMMI) to ensure transparency and focus on voluntary demonstration projects that serve patients	Under the ACA, CMMI was charged with implementing payment and delivery demonstrations in a targeted, patient-centered, and transparent way that accounts for the unique needs of beneficiaries. CMMI should: • Foster strong, scientifically valid testing prior to expansion. Initial CMMI experiments of new payment and delivery models should have comprehensive, methodologically sound, transparent evaluation plans and occur via appropriately scaled, time-limited tests in order to protect beneficiaries and participants from unintended or adverse consequences. Participation in model tests must be voluntary and should be structured in such a way to ensure valid results. • Respect Congress's role in making health policy changes. The legislative branch has a responsibility to oversee CMMI and must approve model expansions and related changes to Medicare and Medicaid. CMMI's important work in testing new models that improve quality or reduce costs without harming beneficiary access or healthcare outcomes should inform congressional decisions on national health policy. • Consistently provide transparency and meaningful stakeholder engagement. CMMI's process for developing, testing, and expanding models must be more open, transparent, and predictable to provide meaningful opportunities for stakeholder input, ensure safeguards for patients and providers, and improve accountability. This includes: developing new models in close consultation with affected stakeholders, maintaining complete transparency in decisionmaking and program procedures, and fully evaluating data and seeking patient and stakeholder input prior to model expansions. • Improve sharing of data from CMMI testing. Data from CMMI model tests should be made public on an ongoing basis to facilitate assessments of their impact on care quality and spending and to inform parallel efforts in the private sector. • Strengthen beneficiary safeguards. Beneficiaries must not be compelled to participate in a demonstration project and must be adequately educated about the project, as well as protected by safeguards to ensure continued access and care quality. • Collaborate with the private sector. For CMMI to have an optimal impact on improving healthcare quality and cost-efficiency, it must work collaboratively with the private sector and harness market competition and innovation. In selecting demonstration projects,

	priority should be given to partnerships involving providers, payors, and other private sector entities throughout the healthcare continuum. CMMI models should support private sector organizations' efforts to advance healthcare value, rather than impeding such efforts by picking winners and losers in the market.
Reform payment regulations that CMS or Congress established for use in fee-for-service (FFS) reimbursement, but that impede the redesign of episodes of care across provider settings in new outcome-driven payment models	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 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, will more effectively advance solutions that improve clinical outcomes for patients, ease anxiety of families, and reduce overall costs and variation.
Streamline regulations creating quality measures for providers, and harmonize remaining quality measures across federal programs	Improvements in quality and patient safety are critical, but the ever-increasing number of conflicting, overlapping measures in CMS programs takes time and resources away from what matters most – improving care. Most recent measure additions to the inpatient quality reporting (IQR) and outpatient quality reporting (OQR) programs do not focus on the most important opportunities to improve care. Vendors and providers have invested significant time and resources to revise certified EHRs to meet CMS electronic clinical quality measure requirements for 2016, with no clear benefit to patient care. Moreover, CMS acknowledges that the electronic test submissions by hospitals and physicians do not accurately measure the quality of care provided. Despite these facts, CMS regulations double the electronic clinical quality measure reporting requirements for hospitals in 2017, without an expectation that the data generated by EHRs will be accurate. CMS should reduce the number of electronic clinical quality measures from eight to four and the length of the reporting period from a full year to 90 days for the IQR program and Meaningful Use until electronic Clinical Quality Measures (eCQMs) mature. (CMS also needs to publish guidance on how eCQMs data will be compared to existing chart-abstracted measures, audit plans, and address technical specifications of measures themselves, which are constantly changing, thus requiring vendors to upgrade their products and clinicians to upgrade systems/workflows, etc.)

Reforms to regulations that will improve care delivery and lower costs

Work with industry to revise hospital star ratings and readmission measures to reflect differences in patient populations	CMS published a set of flawed hospital star ratings on its website. The ratings were broadly criticized by quality experts and Congress as being inaccurate and misleading to consumers seeking to know which hospitals were more likely to provide safer, higher quality care. By working closely with experts in the private sector, a system that appropriately reflects health system challenges – such as the social and economic status of consumers – can create a more accurate system. Hospital readmission measures and other outcome measures have been publicly reported and used to penalize poor performance. However, because they lack appropriate adjustment for the impact of the community population being served and other factors, those hospitals serving certain communities sustain larger penalties.
Collaborate with industry to improve the Medicare Advantage Star Ratings Program	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 measures, and addresses a permanent adjustment for social determinants of health. CMS should ensure the program is simplified, accurately reflects plan performance, and places the most emphasis on measures that health plans can influence. The star ratings system should emphasize outcomes measures that focus on improvements in beneficiaries' health. In particular, we suggest that CMS focus on data-informed measures with objective clinical relevance over survey-based measures. Proposed changes to star ratings should use annual and formal notice-and-comment rulemaking. CMS also should apply all modifications on a prospective basis and finalize measures and their methodology prior to the start of the measurement period in order to give stakeholders adequate notice. It should reinstate the four-star thresholds for selected measures supporting transparency, as well as plans' and providers' quality programs.
Modernize Medicare coverage to include telehealth services	Adequate coverage and payment for telehealth services remain major obstacles for providers seeking to improve patient care. Medicare, in particular, lags far behind other payors due to its restrictive statutes and regulations. For example, CMS approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only a small percentage of services when they are delivered via telehealth. CMS should lift current restrictions on telemedicine, including patient location restrictions, communication technology restrictions, and coverage

	restrictions (known as 1834m restrictions). HHS should also eliminate originating site restrictions for telehealth to allow Medicare Advantage plans more flexibility in providing basic telehealth services to individuals in both urban and rural areas and allow for increased innovation in MA delivery systems. Currently, MA plans must use their rebate dollars to pay for these services as a supplemental benefit for their members.
Eliminate Long-term Care Hospital (LTCH) "25 % Rule" and instead rely on the site-neutral payment policy	With the implementation of site-neutral payments for LTCHs, which began in October 2015 (as mandated by the Bipartisan Budget Act of 2013), the LTCH "25 Percent Rule" has become outdated, excessive, and unnecessary. The purpose of the 25 Percent Rule is to reduce overall payments to LTCHs by applying a penalty to selected admissions exceeding a specified threshold, even if the patient meets LTCH medical necessity guidelines. Given the magnitude of the LTCH site-neutral payment cut – a 54 percent reduction, on average, to one out of two current cases – CMS should rescind the 25 Percent Rule and instead rely on the site-neutral payment policy to bring transformative change to the LTCH field.
Ensure that implementation of home health agency rules meets the needs of consumers and does not penalize those providers caring for medically fragile patients	We support CMS's efforts better to monitor care quality in home health agencies (HHA), but have concerns about measures that are focused on functional improvement assessments for patients. Certain CMS Outcome and Assessment Set (OASIS) measures may be inappropriate for analyzing care provided by private duty nurses to patients where improvement is not expected or sometimes even possible. In rural areas, it can be particularly difficult to staff nurses and other home health professionals on an ongoing, uninterrupted basis, which unfortunately can 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 in distant locations from the HHA's predominant service area. To help ensure better patient access to home health professionals, CMS should establish additional, clearly defined reasons for appropriate HHA discharges in the Medicare and Medicaid Conditions of Participation (CoPs) for home health agencies. CMS should also ensure that patients' healthcare needs are not compromised as a result of any transition of care among providers.

	CMS should delay and improve Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies (CMS-3819-P) to resolve these challenges before implementing changes to the program.
Minimize CMS overregulation that undermines private sector accreditation standards	HHS has the authority to determine that private sector accrediting bodies' standards and survey processes are equivalent to or better than the CoPs for Medicare and the survey processes that HHS uses to review compliance with the CoPs. When HHS determines that the private sector's accreditation is at least equal to or superior to its own, it can decide that the accrediting body's accreditation determination is sufficient to allow a hospital or other healthcare facility to participate in Medicare. Recently, HHS has insisted that private sector bodies, such as the Joint Commission, rewrite their standards or alter their survey processes to conform to those used by CMS itself because HHS claims it has no other way to determine if the standards and processes are "at least as good" as its own standards. This limits private-sector innovation that encourages greater attention to safety and quality.
Address gaps in patient access to care by allowing providers to share treatment space	Many hospitals share treatment space with other providers in order to offer a broader range of medical services and better meet patient needs. In rural areas, hospitals may lease space to visiting specialists from out of town several days per month. Recently, CMS issued several very restrictive interpretations of the shared space rules, such as disallowing visiting specialist arrangements because the spaces for the specialists are not completely separate from the hospital and do not provide independent entrance and waiting areas. Overly prescriptive interpretations of the sharing or "co-location" rules can create patient access or quality of care problems and subvert broader goals to provide more coordinated and patient-centered care at lower cost.
Increase transparency and improve risk adjustment in Medicare Advantage	CMS should increase transparency around updates to risk adjustment in Medicare Advantage, and move to a more clinically accurate model that supports care provided to all beneficiaries, including the chronically ill. Recent Medicare FFS physician payment rules provide for a new service and resulting payment for chronic care management (CCM). However, no companion payment exists in MA to

	support chronic care management. Instead, CMS has eliminated or continues to exclude risk adjustment payments for the care management of some chronically ill MA beneficiaries (e.g., chronic kidney disease, dementia). CMS should ensure equitable payment is provided to MA plans for CCM and assessment and care planning activities, as it is for FFS.
Clarify 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-through, and structure these programs to encourage the use of new technologies having the potential to improve patient outcomes.
Expedite the assignment of new HCPCS codes for Medicare products and technologies	With limited exceptions, CMS assigns new Healthcare Common Procedure Coding System (HCPCS) codes on an annual basis every January 1. As a result, 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, leading to delays and uncertainty among providers, and occasionally negatively affecting patients’ access. To address this issue, CMS should assign new HCPCS codes on a quarterly rather than annual basis.