

November 20, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Request for Information: Centers for Medicare & Medicaid Services, Innovation Center New Direction

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for information on a new direction for the Center for Medicare and Medicaid Innovation (CMMI).

Our members support the health care system moving toward the provision of more accountable, coordinated care and are redesigning delivery systems to increase value and better serve patients. They believe that programs implemented by CMMI are an important step toward determining the best methods to improve the quality of care while also reducing Medicare expenditures. Based on their experiences with these programs, certain themes have emerged that apply broadly to payment and delivery system reform. We believe that CMMI should apply these principles across all of its projects and models:

- Transparency – models should be transparently designed and shared so that participants can make fully informed decisions about participation;
- Fully integrated care – models should promote fully integrated care that considers the 'whole person,' including their behavioral and mental health;
- Balance risk vs. reward – models should balance the risk versus reward equation in a way that encourages providers to take on additional risk but does not penalize those that need additional time and experience before they are able to do so. They



should also consider the investment risk borne by providers who participate in alternative payment models (APMs) as financial risk;

- Guard against fragmentation – models should be evaluated in a holistic fashion so that they create aligned incentives across the delivery system, including consistent approaches to measuring cost and quality performance. CMMI should avoid the uncoordinated proliferation of a large number of models, which could lead to a “pile on” effect that makes it far more challenging for hospitals, health systems and post-acute care providers to focus and execute to the best of their ability;
- Barriers to clinical integration – models should waive the applicable fraud and abuse laws that inhibit care coordination to enable participating hospitals to form the financial relationships necessary to succeed;
- Barriers to care coordination – models should provide maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals. This entails waiving certain Medicare program regulations that frequently inhibit care coordination and work against participants’ efforts to ensure that care is provided in the right place at the right time;
- Timely availability of data – model participants should have readily available, timely access to data about their patient populations. CMMI should actively explore and dedicate resources to determining methods that would provide participants with more complete, timely, perhaps real-time data;
- Risk adjustment – models should include adequate risk adjustment methodologies to ensure they do not inappropriately penalize participants treating the sickest, most complicated and most vulnerable patients;
- Regulatory burden – models should seek to minimize regulatory burden to the greatest extent possible, such as those related to quality reporting requirements, as discussed in [Regulatory Overload](#), our recent report on the regulatory burden faced by hospitals, health systems and post-acute care providers;
- Partnerships – models should leverage partnerships where appropriate, such as through coordination with other federal agencies.

In addition, in our detailed comments that follow, we discuss specific concepts and models that we urge CMMI to consider as it moves forward. We believe these concepts and models will help move the health care delivery system from volume to value, and ensure that patients have access to affordable, equitable health, behavioral and social services.

Again, we thank you for your focus on this critical issue and for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Joanna Hiatt Kim, vice president of payment policy, at jkim@aha.org or (202) 626-2340.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS ON CMMI RFI

Strategies to Ensure Access in Vulnerable Communities. For millions of Americans living in vulnerable rural and urban communities, their hospital is an important, and often only, source of health care. As transformation in the hospital and health care field continues, certain communities may be at risk for losing access to health care services. As such, in 2015, the AHA's Board of Trustees created a task force to examine ways in which hospitals and health systems can help ensure access to health care services in these types of vulnerable communities. The task force considered a number of integrated, comprehensive strategies to reform health care delivery and payment. In their [report](#), they recommended nine emerging strategies that could preserve access to essential health care services (including primary care, emergency and observation, and psychiatric and substance use treatment services) in vulnerable rural and urban inner-city communities.

Some of these strategies are possible to implement under the current legal and regulatory framework, but most are not. Therefore, the AHA urges CMMI to further explore, develop and evaluate these strategies. The ultimate goal is to provide vulnerable communities and the hospitals that serve them with the flexibility necessary to choose among delivery system options that will allow them to maintain essential health care services in their community. In addition, while the task force's focus was on vulnerable communities, the strategies below have broader applicability and may serve as a roadmap for all communities as hospitals and health systems begin to redefine how they provide better, more integrated and more efficient care.

Emergency Medical Center (EMC) Strategy. The EMC strategy would allow hospitals that may be struggling, for a variety of reasons, to continue to meet the needs of their community for emergency and outpatient services, without having to provide inpatient acute care services. Specifically, EMCs would be required to provide the following services on an outpatient basis:

- Emergency services, which would be available to the public 24 hours a day, 7 days a week, 365 days a year; and
- Transportation services, either directly or through arrangements with transportation providers, that allow for the timely transfer of patients who require inpatient acute care services.

EMCs also would be able to offer additional health care services to meet the needs of their community, including:

- Outpatient services, which could include primary care services, observation care, infusion services, hemodialysis, population health and telemedicine services;
- Post-acute care services, including skilled-nursing facility care, home health and hospice care; and

- Telemedicine services, which would allow EMCs to provide or maintain access to additional health care services.

The AHA urges CMMI to develop a demonstration program to test the feasibility of the EMC and its ability to ensure access to emergency services. This demonstration program should be available to current hospitals in vulnerable rural and urban communities. It should test at least three payment methodologies for services provided, including:

- Medicare outpatient prospective payment system (PPS) rates plus an additional facility payment to cover standby costs;
- a new fee schedule for EMCs; and
- rates of 110 percent of reasonable costs for EMC services.

Virtual Care Strategies. Virtual care strategies, or telehealth services, would allow hospitals to help maintain or supplement access to critical health care services in vulnerable rural and urban communities that have difficulty recruiting or retaining an adequate health care work force. Videoconferencing, remote monitoring, electronic consults and wireless communications offer a wide-range of benefits, including: immediate, around-the-clock access to physicians, specialists and other health care providers that otherwise would not be available in many communities; the ability to perform remote monitoring without requiring patients to leave their homes; less expensive and more convenient care options for patients; and improved care outcomes.

The AHA is supportive of CMMI's continued provision of telehealth waivers within its demonstrations. **However, we urge CMMI to consider a dedicated model that tests changes to coverage and reimbursement that would lead to more effective and widespread adoption of virtual care strategies.** By both lifting restrictions on the use of telehealth across risk-based payment models and conducting specific telehealth demonstrations, CMMI can evaluate its cost-effectiveness and efficacy to support expanding telehealth across all of Medicare. According to [AHA survey data](#), 65 percent of U.S. hospitals currently connect with patients and consulting practitioners at a distance through the use of video and other technology. However, there are many barriers to wide use of telehealth. Medicare coverage of telehealth services is particularly restrictive with outdated requirements that limit the areas in which telehealth is covered to only certain geographic locations, sites of service, types of technology and specific services that are covered. In order to increase patient access to services in more convenient and efficient ways and make these strategies work for vulnerable communities, CMMI should eliminate the geographic and originating site requirements, and remove restrictions on covered services and technologies.

In addition, we urge CMMI to fund additional research and studies to determine the cost-benefits of telehealth, using larger sample sizes, diverse geographies and a broader range of conditions and services. Additional research and experience from Medicare will help to deflate concerns raised by policymakers that increased access to

telehealth would lead to increased spending. Also, we believe additional research would highlight the potential benefits in quality, patient experience and efficiency that can be achieved by virtual care strategies.

Urgent Care Center (UCC) Strategy. The UCC strategy would allow hospitals that may be struggling, for a variety of reasons, to maintain an access point for urgent medical conditions that can be treated on an outpatient basis, without having to maintain emergency medical services or inpatient acute care services. UCCs assist patients with an illness or injury that does not appear to be life-threatening, but requires care within 24 hours. They also provide treatment for these conditions during days and hours that primary care physician offices are closed. Key components of UCCs include:

- No requirement for an appointment in order to see a health care provider;
- Evening and weekend hours;
- Radiology and laboratory services provided on-site; and
- Capacity to perform procedures like suturing and casting.

Beyond this, services offered by a UCC can vary widely depending on a community's needs. For example, UCCs also may function as the primary care practice or "medical home" for patients. In addition, a UCC could provide enhanced services, such as observation, home care or therapy.

While this strategy does not necessarily require federal legislative or regulatory changes to be implemented, the AHA urges CMMI to consider developing a UCC demonstration program to test different payment rates for UCCs in order to ensure access to urgent care services in vulnerable communities. We recommend that this voluntary demonstration program be available to current hospitals that convert to UCCs in vulnerable rural and urban communities. The demonstration program should test at least three payment methodologies for UCC services, including:

- Medicare physician fee schedule (PFS) rates plus an additional facility payment to cover standby costs;
- a new fee schedule for UCCs; and
- rates of 110 percent of reasonable costs for UCC services.

Social Determinants of Health Strategy. While completing its work, the task force grappled with the reality that, in vulnerable communities, even if quality care is available, social determinants often prevent individuals from being able to access health care or achieve health goals. According to the World Health Organization, these social determinants include the conditions in which people are born, grow, work, live and age and the wider set of forces and systems shaping the conditions of daily life.

While there are many ways providers could engage to help address the underlying social conditions affecting their patients, the task force identified three general paths:

- Screening and information: Providers could systematically screen patients for health-related social needs and discuss with patients the impact this may have on their health.
- Navigation: Providers could offer navigation services to assist certain patients in locating and accessing community services.
- Alignment: Providers could directly partner with community stakeholders to more closely align and help provide local services to patients.

The CMMI's Accountable Health Communities (AHC) Model is an excellent first step to testing whether identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries impacts health care costs and reduces health care utilization.

However, we urge CMMI to expand the scope of this program in four important ways:

- 1. Increase total funding for the program;**
- 2. Increase the number of bridge organizations;**
- 3. Expand the period for participation; and**
- 4. Remove fraud and abuse law barriers.**

In addition, the current fraud and abuse laws do not clearly allow hospitals to provide certain resources to Medicaid or Medicaid beneficiaries because they are viewed as an “inducement” that is likely to influence the selection of particular providers, practitioners or suppliers. **The AHA urges CMMI to utilize the full scope of fraud and abuse waivers allowed under the Affordable Care Act as it proceeds with the AHC model. Furthermore, we urge CMMI to work with Congress to create a patient assistance safe harbor that would enable hospitals to provide financial or in-kind assistance that promotes access to care, the ability to engage in a treatment or care plan and better overall health.**

Frontier Health System (FHS) Strategy. The task force also explored the creation of a strategy to address the unique geographic challenges faced by frontier communities, including geographic isolation, weather events, disparate road conditions or the availability of paved roads, lengthy distances and long travel times between patients and health care providers and low population density. The task force designed the FHS strategy – an accountable care organization (ACO) that provides a framework for integrated and coordinated health care in frontier communities.

The FHS would serve as a medical home for all patients in its service area, including Medicare and Medicaid beneficiaries. The FHS would include frontier health care providers that join together to provide preventive and primary care, inpatient and outpatient care, extended care and emergency services across local, secondary and tertiary settings. However, unlike traditional ACOs, the FHS also would provide:

- Transportation services, which would allow individuals to receive specialized medical care outside of their community and return to their hometown for follow-up care; and

- A full range of services, which, in addition to those mentioned above, also includes swing bed, rural health clinic, ambulance, home-based care and expanded visiting nurse services.

We urge CMMI to develop a demonstration program to test the feasibility of the FHS and its ability to ensure access to essential health care services in frontier communities. The demonstration program should have the following components:

- Aligned incentives for all providers within the FHS.
- A new payment methodology that could be a combination of different types of reimbursements, including upfront monthly payments to account for important and required investments to the FHS care coordination structure; cost-based reimbursement for health care services provided through the FHS; and pay-for-performance reimbursement or shared savings.
- A system of waivers to the current Medicare payment rules that would allow for successful implementation of the FHS (e.g. increasing the critical access hospital 25-bed limit to 35 beds; waiving the 35-mile ambulance rule; waiving telehealth restrictions and waiving the fraud and abuse laws to foster the financial relationships necessary to operate the FHS).

Indian Health Services (IHS). The task force also examined ways in which access to, and the delivery of, care could be improved for American Indian and Alaska Native Tribes that receive services from the IHS. They recommended a multi-step strategy to promote care coordination between IHS facilities and other health care providers. Doing so would increase access to, and the quality of, care provided for this vulnerable population.

While much that can be done to improve care coordination for this population may be out of the scope of CMMI, the AHA urges it to examine policy changes that may be within its purview. For example, providing technical expertise and assistance necessary for IHS to bill and collect additional reimbursement for services that may be covered by federal programs. In addition, CMMI could consider evaluating regulations that best match the needs of IHS facilities.

Global Budgets. The task force also explored global budgets as a way to ensure access to essential health care services in vulnerable rural and urban communities. They believed that global budget payment models, if appropriately structured, could provide the flexibility needed for hospitals in vulnerable communities to provide care in a manner that best fits a community's needs and circumstances. Global budgets also may provide financial certainty, potentially fair payments, and incentives to contain health care cost growth and improve quality.

CMMI is currently evaluating the effectiveness of global budgets in both Maryland and Pennsylvania. **We urge CMMI to continue these evaluations, including examining ways to optimize the effectiveness of a global budget model and providing hospitals with the necessary tools to be successful under the program.** The AHA set forth

recommendations to accomplish both of these goals in our May 2016 [comments](#) on the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on Concepts for Regional Multi-Payer Prospective Budgets.

Rural Hospital-Health Clinic Integration. Many rural hospitals have developed relationships with various types of health clinics in their communities to ensure and expand access to health care services. While this is most often seen as a relationship between a rural hospital and a Federally Qualified Health Center, the task force believed the model has the potential to be expanded to include relationships between rural hospitals and all types of health clinics, including, but not limited to, Rural Health Clinics and Community Health Clinics.

Yet, despite this collaboration, rural hospitals and health clinics are required to meet separate and distinct regulatory requirements. In addition, each is paid under its own reimbursement structure, which has its own set of standards and expectations. **We urge CMMI to remain cognizant of these relationships as it evaluates regulations or policies that affect rural hospitals or clinics, and to promote policies that foster cooperation and collaboration amongst these providers.**

Expanded Opportunities for Participation in Advanced Alternative Payment Models (APMs). Nearly one year into implementation, the Quality Payment Program (QPP) continues to have a significant impact not only on physicians and others clinicians, but also on the hospitals and health systems with whom they partner to deliver care. There remains strong interest from the field in participating in advanced APMs to support new models of care, and to qualify for the bonus payment and exemption from the QPP's Merit-based Incentive Payment System (MIPS). However, opportunities to access the advanced APM track remain significantly constrained. In the calendar year 2018 QPP final rule, CMS estimates that as few as 10 percent of eligible clinicians will qualify for the advanced APM track in 2018.

The single biggest driver of the limited access to the advanced APM track is CMS's policy decision to allow only those APMs with downside financial risk to "count" towards the advanced APM track. **For this reason, the AHA continues to urge CMS to expand its definition of financial risk to include the investment risk borne by providers who participate in APMs and to develop a method to capture and quantify such risk.** This approach would enable many of the CMMI models in which significant resources already have been invested to qualify for advanced APM incentive payments. Furthermore, it would appropriately recognize the significant up-front investment that must be made by providers who develop and implement APMs. Indeed, providers who participate in APMs invest significant time, energy and resources to develop the clinical and operational infrastructures necessary to better manage patient care. For example, an AHA analysis estimated start-up costs of \$11.6 million for a small ACO and \$26.1 million for a medium ACO.

Clinicians participating in shared savings-only models are working hard to transform care delivery; under CMS's policy, their significant investments and efforts are not sufficiently recognized. Regardless of whether an APM entails downside risk, providers must acquire and deploy infrastructure and enhance their knowledge base in areas, such as data analytics, care management and care redesign. Further, one metric for APM success – meeting financial targets – may require providers to reduce utilization of certain services, such as emergency department visits and hospitalizations through earlier interventions and supportive services to meet patient needs. However, this reduced utilization may result in lower revenues. Providers participating in APMs accept the risk that they will invest resources to build infrastructure and potentially see reduced revenues from decreased utilization, in exchange for the potential reward of providing care that better meets the needs of their patients and communities and generates shared savings. This risk is the same even in those models that do not require the provider to repay Medicare if actual spending exceeds projected spending.

In addition, restricting the advanced APM track to models with downside risk may inhibit the movement towards APMs. If physicians and other clinicians cannot engage with existing shared-savings only model participants – which have a head start on building infrastructure and engaging in care redesign – they instead must start from scratch. While we acknowledge CMS's interest in encouraging providers to move toward accepting increased risk, such an interest must be balanced with the reality that providers are starting at different points and will have different learning curves. CMS should define financial risk in a way that provides a path for physicians and other clinicians who are interested in participating in risk-bearing models – particularly those who are exploring such models for the first time – rather than serving as a barrier to entry.

However, if CMS is intent on retaining its downside risk qualification criteria, then the AHA recommends the agency consider how to adapt its existing CMMI models to meet the advanced APM track's qualification criteria. The agency recently used this approach to develop Medicare Shared Savings Program (MSSP) Track 1+, which provides a more gradual glide path to downside financial risk for current Track 1 MSSP participants than either Track 2 or 3. CMS should consider a similar approach for models 2, 3 and 4 of the Bundled Payments for Care Improvement (BPCI) program, which entail downside risk, but do not meet the quality measurement and electronic health record (EHR) use criteria for advanced APMs. CMS should examine whether it can identify quality measures that would be appropriate for pay-for-performance, and develop an EHR attestation process similar to what it developed for the Comprehensive Care for Joint Replacement model.

Greater Regulatory Relief for APM Participants. AHA continues to call for greater regulatory relief for all providers participating in APMs. The waiver of certain Medicare program regulations is essential so that hospitals, health systems and post-acute care (PAC) providers may coordinate care and ensure that it is provided in the right place at the right time. Participants should have maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals. Providing such waivers is also commensurate with the level of risk and

accountability that CMS is asking participants to assume in its APMs as it shifts the burden of risk further away from the Medicare program onto providers. Specifically, we urge CMMI to routinely waive:

- hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services;
- the skilled nursing facility three-day rule;
- the home health homebound rule;
- the inpatient rehabilitation facility (IRF) ‘60% Rule;’
- the IRF ‘Three-hour Rule;’ and
- the long-term care hospital ‘25% Rule.’

The application of these and similar fee-for-service (FFS) regulations in an episode-payment scenario clouds the findings on the efficacy of that model, thereby limiting the potential for lessons learned through the model and its usefulness if, in the future, applied to a broader population of patients and providers. Further, such relief could grow the number PAC providers that engage in an APM. The testing of APMs in an environment free from artificial barriers to care coordination across settings will improve clinical outcomes and reduce overall costs and variation.

Supplemental Services Models. We urge CMMI to consider creating models that allow entities such as ACOs and Medicare Advantage plans to provide beneficiaries with certain services that are not covered by FFS Medicare, such as transportation, social services and remote patient monitoring services. Alternatively, CMS could modify the existing program rules to allow this. Under such a supplemental services model, eligible entities could propose and be funded to provide integrated medical and social service interventions. In developing this model, CMMI not only would need to waive rules related to which services are eligible for reimbursement, but also permit plans and providers to provide unique benefits to different groups of beneficiaries based on their specific needs.

Many social, economic and demographic factors contribute to an individual’s health status, and patients may not fully benefit from medical interventions if they do not have safe and stable housing, transportation to care, assistance with activities of daily living, or adequate nutrition and physical exercise. These factors often cannot be addressed by medical services alone, yet can have a negative impact on health outcomes, patient experience of care and total cost of care. Allowing entities to provide these services would increase their ability to best address the needs of the population they are managing. As it currently stands, hospitals and health systems are prohibited from offering supplemental services by the civil monetary penalty (CMP) restrictions on patient incentives that could influence Medicare beneficiaries to seek services from a particular provider (existing ACO models include a waiver of the beneficiary inducement CMP, but it is limited to certain circumstances only).

ACO Cost-sharing Waiver. We also urge CMMI to consider modifying the existing ACO models to allow the programs to waive beneficiary cost-sharing for items and services that treat a chronic condition or prevent the progression of a chronic disease. Doing so could help remove a financial barrier that may discourage beneficiaries with chronic conditions from seeking needed care, which, ultimately, can lead to increased costs and poor health outcomes. Further, this policy may provide ACOs with a tool to encourage beneficiaries to seek care from ACO providers.

Expanded Data Sharing with PAC Providers. We encourage CMS to share with all PAC providers the data needed to engage in local efforts to improve the quality and cost of care for Medicare beneficiaries. Market-level, patient-specific data on utilization and outcomes would meaningfully advance PAC efforts to partner with other care providers in the community to improve care coordination. Absent such data, PAC providers may have less input in the appropriate design and implementation of APMs. We believe that CMMI has the capacity to do this given the regular data feeds sent to BPCI participants, which contain patient-level data on utilized services, providers of care, and expenditures during an episode. On a related note, currently, some of the PAC quality reporting programs are only furnishing quality measure feedback in an aggregate and annual basis, which greatly hinders the transition of these data into actionable improvements in care and processes. Rather, providers need patient-level data delivered in a timely fashion to improve patient care and efficiency. At a minimum, we urge CMMI to share with PAC providers the same level of quality data detail shared with general acute-care hospitals.

Advanced Illness Management Models. AHA encourages CMMI to test new models that support advance illness management. In particular, models that bring curative and palliative care providers together in an interdisciplinary approach are needed to address the otherwise fragmented care for patients with serious health issues. The Coalition to Transform Advanced Care (C-TAC) presented a model to the Physician-Focused Payment Model Technical Advisory Committee that includes an advanced care model package of care delivery services that is patient-centered and incorporates interdisciplinary teams that can function across inpatient, outpatient and home settings. Such an approach would coordinate care across settings to support advanced illness management. Moreover, it would prevent avoidable hospitalization while engaging the patient and their family in care delivered based on their wishes. This innovative approach would enable insight on interventions specifically designed to offer coordinated care to improve quality for a highly vulnerable population.

New Technology Models. The AHA encourages CMMI to prioritize models that specifically test new technology approaches. Doing so would allow CMS to learn about the benefits of certain technology functionality before it is required for use under the meaningful use program and the advancing care information (ACI) category of MIPS. As discussed above, it also would provide greater understanding of the benefits of telehealth to support greater coverage of telehealth in the entire Medicare program. Models that incorporate technology also are consistent with Congressional intent.

Specifically, the AHA encourages CMMI to test new technology approaches currently embedded in Stage 3 of meaningful use and the ACI category of MIPS *before* making them regulatory requirements for all health care providers. In particular, Stage 3 and the ACI category currently include significant use of patient-generated data and use of application programming interfaces (APIs) to connect the app of a patient's choice to a health care provider's electronic medical record. These technologies are still in a development stage, and have not been widely tested. A CMMI model that specifically incorporated these items would allow the agency, providers, and consumers to better understand how these technologies are best used, and how they contribute to improved health outcomes.

CMS also could greatly decrease administrative burden by removing these requirements from regulation. A demonstration permitting the use of the technologies will reveal their true benefits for patients and providers and would spur their adoption where the technology used makes the most sense and is reasonable and necessary, without heavy-handed regulatory action. In our Sept. 11 outpatient PPS comment letter to CMS, we [recommended](#) canceling Stage 3 of meaningful use, given the significant regulatory burdens of the program. The AHA's Regulatory Overload [report](#) found that an average-sized hospital (161 beds) spends nearly \$760,000 annually to meet only the administrative requirements of meaningful use and invests \$411,000 in related upgrades to systems during the year. These resources are better spent on deploying technology that truly improves care, rather than reporting on prescriptive requirements about the use of technology.

Prescription Drug Models. The price of prescription drugs has increased significantly over the past several years – from six-digit launch prices for some new specialty drugs to significant annual increases on all types of drugs, including older generics that are widely used. These price increases are troublesome. They not only threaten patient access to drug therapies, but also challenge providers' abilities to provide the highest quality of care. Drug costs also are a major factor in the rising cost of health care coverage.

Hospitals bear a heavy financial burden when the cost of drugs increase, and they must make tough choices about how to allocate scarce resources. A study by NORC at the University of Chicago last year found that inpatient drug spending increased on a per admission basis by 38.7 percent from 2013 to 2015.¹ One AHA member hospital put the challenge starkly: the annual price increases for just four common drugs, which ranged between 479 and 1,261 percent, cost the same amount as the salaries of 55 full-time nurses. Managing these skyrocketing cost increases forces difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs, especially when these price increases are not linked to new therapies or improved outcomes for patients.

¹ NORC at the University of Chicago, "Trends in Hospital Inpatient Drug Costs: Issues and Challenges," October 11, 2016. Accessed at: <http://www.aha.org/content/16/aha-fah-rx-report.pdf>

The AHA encourages CMS to test new ways of paying for drugs that advances innovation while simultaneously preserving or enhancing the quality of care for those individuals who receive Medicare benefits. We particularly support the development of value-based payment (VBP) models for drugs. While significant strides have been made in developing VBP models for hospitals and physicians, little work has been done on drug purchasing models.

CMMI should advance the development and implementation of such arrangements for drugs purchased under all parts of Medicare, as well as make such models available to the states and commercial payers. Because little work has been done in this area to-date, we recommend that CMS undertake a public, multi-stakeholder process to develop potential VBP models for drugs. This process should begin with an initial meeting between CMS and a broad group of stakeholders to discuss the scope of potential demonstration projects (e.g., limited to Parts B or D, condition-specific, etc.) and potential VBP models for consideration. Subsequently, CMS should issue a request for information for more details on specific proposals. Based on this information, CMS should follow the standard regulatory process for proposing, modifying and finalizing VBP models for testing. Drug purchasers, including hospitals, could use these CMS-developed models in negotiations with manufacturers for other populations as well.

Examples of potential VBP models include:

Medicare-negotiated Rates. We urge CMMI to implement a model that identifies a subset of drugs for which CMS would negotiate directly with manufacturers on pricing. That pricing would then be made available to all Part D sponsors for incorporation into their benchmark rates. In other words, drug manufacturers would be required to contract with insurers at the negotiated rate. CMS could evaluate whether such a negotiation strategy reduced drug prices beyond what private insurers can today achieve, as well as whether such an approach results in other savings or costs to the system.

Indications-based Pricing. CMMI also should consider models to test indications-based pricing, which varies the payment for a drug based on its clinical effectiveness for the different indications for which it has been approved. Such models could spur important work to determine the clinical effectiveness of particular drugs for their various indications. They also could entail CMS developing a cross walk for each drug to the various indications for which payment will vary, and enabling hospital information systems to operationalize the coding that would be needed to correctly implement indications-based pricing.

Risk-sharing Agreements Based on Outcomes. CMMI should consider models that implement voluntary outcomes-based risk-sharing contracts with drug manufacturers to link price adjustments for a drug to patient health outcome goals. Under such an arrangement, the outcome-based agreements would tie the final price of a drug to results achieved by specific patients. Manufacturers would agree to provide rebates, refunds or price adjustments if the product does not meet targeted outcomes.

Under such a model, drug manufacturers and providers would agree upon appropriate outcomes that can be tracked and achieved within a reasonably short period of time. In addition, hospital information systems would need to be able to readily provide the data to demonstrate whether the chosen outcome has been achieved. Finally, the outcome would need to be able to be linked directly to the drug therapy.

Discounting or Eliminating Patient Cost-sharing. **The AHA also supports exploration of models that reduce or eliminate patient cost-sharing for high-value drugs.** Linking the level of cost-sharing to the effectiveness of a drug regimen supports greater compliance with treatment plans and, therefore, could help decrease unnecessary utilization across the health care system, such as unplanned emergency department visits and hospitalizations. The collection and use of comparative effectiveness data to support the determination of the value of drugs and appropriate levels of beneficiary cost-sharing would be extremely beneficial. However, we recognize that the federal government does not have the processes or infrastructure in place at this time to systematically and comprehensively collect and evaluate such data, and we encourage CMMI to pursue the development of such an evidence base in collaboration with Patient-Centered Outcomes Research Institute, the Food and Drug Administration, the National Institutes of Health and emerging public-private initiatives.

Feedback on Prescribing Patterns and Online Decision Support Tools. **We encourage CMMI to explore the development and use of clinical decision support tools that provide prescribers with evidence-based and timely information to help them select the most clinically effective drugs for their patients and to promote safe prescribing.** The AHA also supports the development and use of provider report cards to enable providers to compare their performance with their peers at the local, state and national levels. Similar tools already in use in some hospitals and health systems have been effective in changing clinicians' practice patterns to better align with evidence-based developments and best practices.

Expansion of the Value-based Insurance Design (VBID) Model. VBID holds tremendous promise for helping patients make the best care choices to manage and improve their health. VBID uses cost-sharing incentives, as well as other tools, to guide patients towards the highest value care. CMS is currently testing VBID models through the Medicare Advantage program in seven states and is expanding it to several more in 2018. **We encourage CMS to further expand the model to make it available to Medicare Advantage plans in all states on a voluntary basis.**

Medicaid Innovation Models. State governments, through both regulatory and waiver authority, have long used their Medicaid programs as a platform to explore payment and delivery innovations. The following recommendations build on that history to test innovations through the Medicaid program.

Behavioral Health Medicaid Models. The growth in Medicaid managed care calls for a thorough review of the regulatory barriers that interfere with care coordination across

settings, particularly for behavioral health. **We urge CMMI to consider testing innovative models that prohibit the carve out of behavioral health services from Medicaid managed care benefits.** States currently have the option to carve out certain services, particularly behavioral health services, from Medicaid managed care benefits. Such carve-out arrangements create barriers to the integration of behavioral health and physical health care and inhibit the sharing of information across care settings. The inability of behavioral health and medical care providers to share information and coordinate care can have a significant impact on millions of patients; about half of the Medicaid disabled population have been diagnosed with a mental illness.

In addition, CMMI should explore delivery innovations that could be made under 1115 Waiver authority to eliminate or restrict the scope of the Institutions for Mental Disease (IMD) exclusion to improve access to care and help reduce costs. The IMD exclusion prohibits federal Medicaid reimbursement for inpatient care provided to individuals between the ages of 21 and 64 in IMDs such as private freestanding psychiatric hospitals with more than 16 beds. CMS recently issued guidance to states regarding the use of 1115 waiver authority and the IMD exclusion to treat substance use disorder including opioid abuse. CMMI could explore how providers and state could collaborate on various treatment protocols including providing treatment in inpatient and community-based settings.

Social Determinants of Health Medicaid Models. A recent Robert Wood Johnson Foundation issue brief on Medicaid and social determinants of health found that states do not typically account for social determinants in their payment models.² It described payment approaches by two states – Massachusetts and Minnesota. Massachusetts developed a payment adjustment for social risk factors such as poverty, education, employment, family status and housing. Minnesota is examining its Medicaid population to identify the key social determinants of health that are predictive of poor health outcomes or health disparities. **CMMI should consider helping states and providers develop their own state-specific payment methodologies to address social determinants of health.**

Housing stability is often cited as one of the key social risk factors in poor health outcomes. The city of Philadelphia and Arizona's Maricopa County are two examples where regions have looked at ways to address homelessness and behavioral health through Medicaid managed care.³ In addition, the state of Maryland, through its 1115 waiver, is exploring ways to pay housing related costs to address homelessness and behavioral health. CMS's Medicaid Innovator Accelerator Program (IAP) also is looking at ways to encourage state Medicaid programs to collaborate with state housing programs through partnerships. **We urge CMMI to support the IAP effort and explore how to integrate providers of mental and behavioral health into these approaches. In addition, CMMI should explore partnerships with providers and other regional stakeholders on a sub-state level to focus on housing and homelessness.**

² https://www.healthmanagement.com/wp-content/uploads/SHVS_SocialDeterminants_HMA_July2017.pdf

³ <https://www.kff.org/report-section/linking-medicare-and-supportive-housing-issue-brief/>

Additional Medicaid Payment Innovations. State Medicaid programs are exploring a variety of value-based provider payment arrangements. Some of these initiatives are supported by CMMI and CMS's State Innovation Models initiative or SIM grants. These payment innovations include patient-centered care, bundled episodes of care, home health and accountable care organizations. States have looked to these innovations to improve care coordination, health outcomes and improve programmatic efficiencies. However, many researchers and policy makers have noted that while states are exploring payment innovations at a rapid rate, there is virtually no evaluation of their effectiveness. **To help disseminate the learning from the payment initiatives, we urge CMMI to consider funding such comprehensive evaluations.**

Program Integrity Models. Hospitals take seriously their obligation to properly bill for the services they provide to Medicare beneficiaries and are committed to working with CMS to ensure the accuracy of Medicare payments. They acknowledge the importance of the role of audits in oversight of the Medicare program; however, there is a heavy regulatory burden associated with these audits. Our recent [report](#) on the regulatory burden faced by hospitals, health systems and post-acute care providers showed that an average-sized hospital with 161 beds incurs over \$340,000 in costs each year related to program integrity. A large part of this is due to the excessive erroneous denials made by Medicare Recovery Audit Contractors (RACs), which have forced hospitals to shoulder the [significant burden](#) of pursuing appeals in order to receive payment for the medically necessary services they provide to Medicare beneficiaries. The contingency payment structure of the RAC program and the resulting volume of inappropriate claim denials are putting significant strain on the appeals process. Hospitals are experiencing wait times of close to three years for their appeals to be heard by an Administrative Law Judge (ALJ), let alone for receiving a decision. This is significant because it is at the third level of appeal, in a hearing before an ALJ, that hospitals are afforded their first opportunity to present testimony based on clinical factors that are critical to accurate decisions in denial of complex hospital claims and receive a review of all evidence by an objective party (that is, a reviewer who is not a Medicare contractor).

With these challenges in mind, we urge CMMI to consider ways in which it could test alternative structures, models and oversight of the RAC program. The following actions would address challenges created by the RAC program, including by reducing the excessive, unnecessary regulatory burden it imposes on patients and providers:

- **Move RACs to a “Targeted Probe and Educate” model, as has been done for the Medicare Administrative Contractors.** CMS has stated that similar Probe and Educate models have shown favorable results in terms of decreasing the number of claim errors after providers received education. Including RACs in such a model would lead to more favorable results as well as a decrease regulatory burden.
- **Remove the perverse financial incentives that encourage RACs to deny claims.** The current contingency fee structure is one-sided in that RACs can deny claims

with impunity. Instead, RACs should be paid similarly to other Medicare contractors, such as through a cost-based contract.

- **Spur performance improvement among the RACs by reducing payments to RACs with a high rate of overturned denials at any and all levels of appeal.** Hospitals bear the significant cost of appealing inappropriate RAC denials, while RACs are not penalized for inappropriately denying claims when those overturns occur at the ALJ (third) level of appeal. This reform would curb overzealous RACs and create a level playing field for both RACs and providers in addressing incorrect payments.
- **Codify in regulation the limitation of RACs to considering only the medical documentation available at the time the admission decision was made in determining whether an inpatient stay was medically necessary.** While CMS has stated that this is its policy, we continue to have concerns that RACs second-guess physicians' judgment based on the outcome rather than the facts the physician had at the time of treatment. CMS also could require that a physician approve all complex review denials.
- **Delay the collection of alleged overpayments and accrual of associated interest.** As noted above, hospitals are experiencing wait times of close to three years for their appeals to be heard by an ALJ. Given that this is the first level of appeal at which the reviewer is not a Medicare contractor, delaying collections until after an ALJ decision would reduce the burden hospitals experience as a result of having substantial amounts of funds tied up in the appeals system as a result of the RACs' inappropriate claim denials.

Finally, we urge CMMI to consider ways in which to improve the education of all of its program integrity providers, RACs included. Stricter oversight is necessary to ensure consistent application of policies in contractor determinations. The agency could, for example, analyze data on overturned denials and provide additional, uniform education to contractors on payment policies related to the most common overturns. It could also ensure that it provides all Medicare contractors with the same guidance and education on new/modified CMS regulations and guidance.