

2016 has been a landmark year thus far for the hospital and health system field. Among other achievements, we recently saw modifications to the Centers for Medicare & Medicaid Services' (CMS) proposal to implement site-neutral payments for off-campus outpatient departments, the Department of Justice (DOJ) took action to stop the “mega-mergers” of four of the nation’s largest health insurers, and we were successful in challenging the unfair “two-midnight” policy, using the power of the courts to convince CMS to reverse the 0.2% payment cut for inpatient services it implemented as part of the original policy. In addition, we are working to shape the new Medicare physician payment system and bundled payment models so that providers can be aligned and better work together to ensure patients get the highest quality care at the right time, in the right place. We are helping make dramatic gains in quality and patient safety as we strive to get to zero. And we will be working with the new Administration as they transition on issues of importance to the hospital and health system field.

The American Hospital Association (AHA) is proud to be working for you. And as you transform health care delivery, we are changing to meet your needs. Below are just some of the advances we have made in the past year by working together and speaking with one voice to advocate for hospitals, health systems and the patients and communities they serve. For more, visit www.aha.org/value.

Promoting Regulatory Relief

Supporting HOPDs. AHA successfully urged CMS to provide fairer and more equitable payment to hospitals for the services they provide when implementing the Bipartisan Budget Act (BiBA) of 2015, which requires site-neutral payments be made to new off-campus hospital outpatient departments (HOPDs). As a result, the final rule appropriately recognized that the agency’s proposed policy of providing no payment to these clinics was untenable. Instead, the agency will pay new off-campus HOPDs under the physician fee schedule at newly established rates that will generally be 50 percent of the OPPS rate. CMS also modified its proposals to allow existing off-campus provider-based HOPDs to expand their services to meet the changing needs of their patients and communities without being penalized. However, AHA will continue to advocate that hospitals be able to relocate and rebuild their HOPDs so that they can provide the most up-to-date, high-quality services to their patients in locations that meet patients’ needs. The 21st Century Cures Act, which was recently signed into law by President Obama, includes exceptions from the OPPS site-neutral payments for certain off-campus HOPDs that were under construction at the time the site-neutral statutory provisions were passed in November 2015.

AHA Priorities in 21st Century Cures Act. Among other AHA priorities, the legislation includes adjustments

to the Hospital Readmissions Reduction Program to account for socioeconomic status, and reforms to the mental health system, including provisions related to mental health parity, integration with physical health services, workforce development, and privacy provisions, among others.

‘Two-midnight’ Policy Refinements. AHA helped persuade CMS to finalize several positive changes to its burdensome two-midnight policy. In addition, AHA successfully challenged through the courts CMS’s interpretation of its 0.2% payment reduction for inpatient services, convincing the agency to restore the resources that hospitals are lawfully due, restoring \$3.1 billion in unjustified cuts.

EHR Incentive Program Enhancements. At AHA’s urging, CMS finalized shortening the reporting period for 2016 to 90 days instead of a full calendar year and adding additional flexibility in Stage 3 of meaningful use. AHA also convened an advisory group on interoperability and worked with regulators to improve standards for information sharing and vendor accountability. We will continue to advocate for health IT policies that are realistic and support the information sharing needed to succeed in new models of care.

Removing Roadblocks to Hospital Realignment. The House passed the AHA-supported Standard

Mergers and Acquisitions Review Through Equal Rules (SMARTER) Act, which would remove costly and unfair regulatory roadblocks to hospital realignment. The act would align the Federal Trade Commission's (FTC) merger review with that of the DOJ by eliminating FTC's ability to use its own administrative tribunal to challenge a merger – it would have to go to court just like DOJ.

Ensuring Emergency Preparedness. CMS recently released a long-awaited final rule outlining conditions of participation in Medicare for hospitals that address disaster planning. As urged by AHA, the rule provided flexibility in how hospitals meet the conditions of participation and decided against requiring relocation of existing generators. CMS also will allow facilities within a health care system to be part of a unified preparedness program.

Providing Relief to LTCHs. The 21st Century Cures Act provides one full year of relief from the Long-term Care Hospital (LTCH) 25% Rule. The original policy arbitrarily penalized LTCH admissions based on the origin of an LTCH referral, disregarding the patient's medical necessity for LTCH services.

Court Orders HHS to Eliminate ALJ Appeals Backlog. A federal judge Dec. 5 ordered the Department of Health and Human Services (HHS) to eliminate the backlog of Medicare claims appeals pending at the administrative law judge level within four years, granting summary judgment to AHA and three member hospitals in their case challenging HHS for failing to meet statutory deadlines for processing Medicare claims appeals. The judge ordered HHS to reduce the backlog of cases 30% by Dec. 31, 2017; 60% by Dec. 31, 2018; 90% by Dec. 31, 2019; and 100% by Dec. 31, 2020; and to file status reports with the court every 90 days.

Protecting CAHs. AHA urged CMS to release new recertification guidance and checklists to state survey agency directors, allowing states to use alternative ways to document that a critical access hospital (CAH) is a necessary provider. The new guidance provides additional flexibility to state survey agencies, which is critical to helping CAHs that rightfully obtained necessary provider status prior to 2006 from losing their CAH designation.

Advancing Health System Transformation

New Care Models. AHA has worked with CMS to shape its new mandatory bundling program for hips and knees – the Comprehensive Care for Joint Replacement (CJR) model – and proposed mandatory cardiac care model. Under both the new cardiac bundled payment model and the expanded CJR model, the hospital in which the initial services are provided will be responsible for the quality and costs of care for the entire episode of care, from the time of the hospital stay through 90 days after discharge. AHA is actively monitoring both models to ensure their success and that providers are not overloaded with too many demonstrations brought on too quickly.

New Medicare Physician Payment System. The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 created a new physician payment and performance measurement system, and AHA is working with CMS to shape implementation by ensuring the regulations make sense, are aligned with other Medicare programs and do not overburden providers. We were pleased by the recent announcement that clinicians will have flexibility to decide how much data to report in 2017, as urged by AHA, and we are encouraged

that CMS is exploring a new option that would expand the available advanced alternative payment models that qualify for incentives. At the same time, the AHA remains concerned that the lack of sociodemographic adjustment to the measures used in the MIPS will unfairly disadvantage clinicians and hospitals caring for the poorest patients. Opportunities also remain to further align hospital and clinician performance measurement, and we will work with the agency to make that happen. We also are working to educate the field about these changes, regularly adding new resources for hospital and health system leaders, trustees and clinicians at www.aha.org/macra.

Protecting Patient Access to Care

Protecting Funding for Patient Care. Any time Congress struggles with a fiscal crisis, funding to protect patient care is at risk. As Congress looked for savings to fund legislation, AHA and you – our grassroots advocates – helped:

- Maintain graduate medical education funding
- Prevent harmful changes to the CAH program
- Prevent further reductions to Medicaid

In addition, AHA advocated for changes to draft House legislation on Post-Acute Care Value-Based Purchasing to promote value rather than simply focusing on cutting provider payments. Due to the concerns expressed by AHA and post-acute providers, changes continue to be made to the proposal. AHA also worked to halt proposals to loosen restrictions on physician-owned hospitals.

Fighting Escalating Drug Prices. As a member of the steering committee of the Campaign for Sustainable Rx Pricing, AHA has raised awareness with legislators, policymakers and the media of how rising prescription drug prices are putting a strain on the entire health care system. These efforts have included advertising during the primary elections, briefings on Capitol Hill for lawmakers and their staff, and media briefings. We recently unveiled a survey with the Federation of American Hospitals that demonstrated the impact the rise in the price of drugs commonly used in the inpatient setting is having on patients' and hospitals' ability to plan for the future.

Addressing the Opioid Epidemic. AHA worked to help pass several measures addressing the opioid abuse epidemic, including the Comprehensive Addiction and Recovery Act (CARA), which authorizes numerous federal grants to promote education, awareness, prevention, and treatment of opioid abuse and alternatives to incarceration. Signed into law in July, CARA incorporated numerous AHA-supported measures. AHA continues to advocate for full funding of these provisions, and partial funding was included in the continuing resolution passed in September. The 21st Century Cures Act provides \$1 billion in grants to states to help address the opioid epidemic. AHA also worked with the Centers for Disease Control and Prevention to develop and distribute a new patient education resource on prescription opioids that outlines evidence-based

information about the risks and side effects of the powerful painkillers. In addition, AHA worked to remove the Hospital Consumer Assessment of Healthcare Providers and Systems survey pain questions from the hospital value-based purchasing program scoring calculations and encouraged the development of new questions about pain management. Resources are available at www.aha.org/opioidepidemic.

Enhancing Patient Care. AHA worked with the House Energy and Commerce Committee to approve the Title VIII Nursing Workforce Reauthorization Act (H.R. 2713), which would reauthorize the Health Resources and Services Administration's nursing workforce development programs through fiscal year 2020 and update the programs to reflect current nursing roles and practices.

The House also approved the Protecting Patient Access to Emergency Medications Act (H.R. 4365), also supported by AHA, which would clarify that medications governed by the Controlled Substances Act may be administered by Emergency Medical Services (EMS) practitioners pursuant to a standing order issued by a physician medical director of an EMS agency.

Supporting Medical Innovation. The 21st Century Cures Act is primarily designed to advance the development of medical treatments and cures through investments in research and updates to how new therapies are developed and approved. The major components of the legislation fund new initiatives at the National Institutes of Health (NIH) and the FDA. Specifically, it authorizes \$4.8 billion for the NIH to fund new initiatives around precision medicine, cancer, neuroscience, and regenerative medicine. The bill also provides \$500 million over 10 years to the FDA to facilitate the development of new drugs and devices, as well as modernizing clinical trials and the development of evidence.

Protecting Access in Rural Settings. The 21st Century Cures Act includes prohibitions on enforcement of the "direct supervision" regulations for 2016 for outpatient therapeutic services provided in critical access hospitals and certain small, rural hospitals. In addition, the legislation extends the Rural Community Hospital Demonstration Program for five years.

Sustaining and Expanding Gains in Health Coverage

Protecting Patients from Insurer Consolidation. At the urging of AHA and others, DOJ took action to stop the mergers of four of the five largest health insurers. AHA has worked to ensure that the proposed acquisitions received the highest level of scrutiny from regulators and Congress. We provided analysis to DOJ and testified before Congress numerous times, introducing into the record concrete reasoning why the acquisitions would decrease competition and hurt the marketplace. We also worked with state associations to urge their state attorneys general and insurance commissioners to carefully scrutinize these proposed mergers and the impact they would have on their respective states.

Expanding Access to Medicaid. AHA continues to support state hospital associations in non-expansion

states to make the case for Medicaid expansion. Montana and Louisiana expanded their Medicaid programs in 2016.

Maintaining Viable Health Insurance Marketplaces.

The Health Insurance Marketplaces authorized by the Affordable Care Act have not yet stabilized, threatening access to coverage for millions of Americans. AHA has proactively promoted policy and operational changes to CMS that would encourage robust consumer and plan participation. The agency has advanced several of our recommendations, including refinements to the risk adjustment model and a number of changes to the special enrollment periods, including a pilot to test a pre-enrollment verification process.

Enhancing Quality and Patient Safety

Providing Consumers with Meaningful Quality Information. AHA continues to promote a streamlined approach to quality measurement through the implementation of the recommendations in the National Academy of Medicine's recent "Vital Signs" report and is leading efforts to define measures that matter. We are collaborating with other national hospital associations to get to a smaller number of measures that have a real opportunity to drive quality and safety forward for patients.

Ensuring Medical Device Safety. As urged by AHA, the national standards body for the development and maintenance of electronic data interchange standards voted on a solution for reporting the new unique device identifier (UDI) on health care claims that will allow tracking of medical devices for safety reasons, while minimizing disruptions to automated claims processing. The technical solution meets AHA's operational concerns as well as the objectives of the FDA and CMS.

Combating Deadly Synthetic Drugs. The House passed the AHA-supported Synthetic Drug Control Act (H.R. 3537), helping to fight against the devastating health consequences and increased mortality that these drugs have caused. The new legislation would give the Drug Enforcement Administration authority to stop the distribution, sale and use of additional synthetic drugs by classifying them as Schedule I controlled substances.