

August 25, 2017

The Honorable Pat Tiberi
Chairman
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Tiberi:

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 provide input to the Subcommittee on its Provider Statutory and Regulatory Relief Initiative.

The Subcommittee's initiative aims to identify opportunities to reduce legislative and regulatory burdens on Medicare providers, thus improving the efficiency and quality of the Medicare program for seniors and individuals with disabilities. Indeed, the regulatory burden faced by hospitals is substantial and unsustainable. As one small example of the volume of recent regulatory activity, in 2016, the Centers for Medicare & Medicaid Services and other agencies of the Department of Health and Human Services released 49 rules pertaining to hospitals and health systems, comprising almost 24,000 pages of text. In addition to the sheer volume, the scope of changes required by the new regulations is beginning to outstrip the field's ability to absorb them. Moreover, this does not include the increasing use of sub-regulatory guidance (FAQs, blogs, etc.) to implement new administrative policies.

Hospitals recently have been granted some important regulatory relief, such as the implementation of a 12-month moratorium on the outdated long-term care hospital 25% Rule, as well as a 90-day reporting period and flexibility in the use of technology for the meaningful use program for fiscal year 2018. Yet, more work remains to be done. To that end, the AHA is currently assembling a report that will catalogue the full sweep of regulatory requirements in a way that provides a holistic view of the combined burden imposed on hospitals and health systems; we anticipate issuing this report in the fall.



The Honorable Pat Tiberi

August 25, 2017

Page 2 of 19

In the attached document, we have laid out actions that Congress could take to immediately reduce the regulatory burden on hospitals, health systems and the patients that we serve. They range from cancelling Stage 3 of the meaningful use program, to postponing and re-evaluating post-acute care quality measurement requirements, to permanently prohibiting the enforcement of direct supervision requirements.

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 Erik Rasmussen, vice president of legislative affairs, at erasmussen@aha.org or (202) 626-2981.

Sincerely,

/s/

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

Enclosure

AMERICAN HOSPITAL ASSOCIATION (AHA) DETAILED COMMENTS ON REGULATORY RELIEF FOR MEDICARE PROVIDERS

There are numerous duplicative and excessive rules and requirements on America's hospitals and health systems. The AHA suggests the following actions to immediately reduce burdens on hospitals and patients.

Create Anti-Kickback Safe Harbor for Clinical Integration Arrangements. Hospitals and other providers are now more accountable than ever for financial and patient outcomes across the entire spectrum of care. This collective accountability requires hospitals, physicians and other providers to work together in new ways. They must be able to financially align themselves with shared incentives, shared resources, seamless technology and pooled information. However, current laws impede innovation. The principal obstacle to innovation is an overly complex legal framework grounded in the increasingly outdated fee-for-service payment structure. Hospitals and physicians cannot partner on innovative programs unless the arrangement meets highly technical requirements of both an exception under the Stark Law and safe harbor under the Anti-Kickback Law. However, the core requirements of existing laws are not in sync with collaborative models that reward value and outcomes.

We urge Congress to create an Anti-Kickback safe harbor for clinical integration arrangements that establishes the basic accountabilities for the use of incentive payment or shared savings programs among hospitals, physicians and other providers and allows for the sharing of expertise in cybersecurity:

- **Transparency:** Documentation of the use of incentives or other assistance is required and must be available to the Department of Health and Human Services (HHS) on request.
- **Recognizable improvement processes:** Any performance standards that providers use to govern their collaboration (e.g., required care protocols, metrics used to award performance bonuses) must be consistent with accepted medical standards and reasonably fit for the purpose of improving patient care.
- **Monitoring:** Performance under integration arrangements must be internally reviewed to guard against adverse effects and documentation disclosed to HHS upon request.

The safe harbor should not try to supplant, duplicate or recreate existing quality improvement processes or the mechanisms for monitoring quality of care in hospitals. Currently, there is both internal and external oversight. State licensing agencies and accrediting organizations have an ongoing role. Medicare Quality Improvement Organizations continuously review the quality of care for beneficiaries. Other Medicare program oversight includes the hospital inpatient and outpatient quality reporting programs, readmissions program and value-based purchasing program.

The safe harbor would cover arrangements established for one or more of these purposes:

- *Promoting accountability for the quality, cost and overall care for patients;*
- *Managing and coordinating care for patients; or*
- *Encouraging investment in infrastructure (e.g., ensuring the security of information systems and information exchange) and redesigned care processes for high-quality and efficient care delivery for patients.*

The safe harbor would protect remuneration, including any program start-up or support contribution, in cash or in-kind.

Remove Compensation from the Stark Law. Hospitals cannot succeed in their efforts to coordinate care, participate in new payment models, and maintain secure information exchange with community partners because of outdated regulations, such as the Anti-Kickback Statute and the “Stark” law.

We urge Congress to remove the compensation prohibitions under Stark – returning the law to its original purpose, prohibiting physician ownership of businesses that benefit from their own referrals. Oversight of compensation arrangements would be under the Anti-Kickback Laws (criminal or civil), which are best suited to combat payment for referrals.

Create Anti-Kickback Safe Harbor for Patient Assistance. Hospital responsibility for patient care no longer begins and ends in the hospital setting or any other site of care provided by the hospital. Maintaining a person in the community requires more than direct patient care. It includes encouraging, supporting or helping patients access care, or making it more convenient. It would include removing barriers or hurdles for patients as well as filling gaps in needed support. However, current laws impede hospitals from providing such assistance. The general prohibition on providing anything of value to “induce” the use of services paid for by the Medicare program also applies to assistance to patients.

We urge Congress to create an Anti-Kickback safe harbor that permits hospitals to help patients achieve and maintain health. Arrangements protected under the safe harbor also would be protected from financial penalties under the Civil Monetary Penalties (CMPs) for providing an inducement to a patient.

The safe harbor should:

- *Protect encouraging, supporting or helping patients to access care or make access more convenient;*
- *Permit support that is financial (such as transportation vouchers) or in-kind (such as scales or meal preparation); and*

- ***Recognize that access to care goes beyond medical or clinical care, and include the range of support important to maintaining health such as social services, counseling or meal preparation.***

Expand Medicare Coverage of Telehealth Services. Hospitals are embracing the use of telehealth technologies because they offer benefits such as virtual consultations with distant specialists, the ability to perform high-tech monitoring without requiring patients to leave their homes, and less expensive and more convenient care options for patients. However, coverage and payment for telehealth services remain major obstacles for providers seeking to improve patient care. Medicare, in particular, lags far behind other payers due to its restrictive statutes and regulations. For example, the Centers for Medicare & Medicaid Services (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. The statute also restricts telehealth services to patients located in rural areas and in specific settings (such as a hospital or physician office) and allows only real-time, two-way video conference capabilities. Having different, more restrictive policies in Medicare creates a regulatory challenge for hospitals and health systems that want to use telehealth for the benefit of patients.

We urge the Congress to eliminate geographic and setting locations requirements so patients outside of rural areas can benefit from telehealth and expand the types of technology that can be used, including remote monitoring. We also urge Congress to work with the Administration and encourage them to expand Medicare coverage, such as by a presumption that Medicare-covered services also are covered when delivered via telehealth unless CMS determines on a case-by-case basis that such coverage is inappropriate. This change should extend to the Medicare Advantage (MA) program so that MA plans can make services delivered via telehealth available more broadly to their Medicare enrollees.

Issue a Permanent Enforcement Moratorium on the ‘96-hour’ Rule. CMS previously indicated it would begin enforcing a condition of payment for critical access hospitals (CAHs) that requires a physician to certify that a beneficiary may reasonably be expected to be discharged or transferred to another hospital within 96 hours of admission. While CAHs must maintain an annual average length of stay of 96 hours, they may offer some critical medical services that have standard lengths of stay greater than 96 hours. Enforcing the condition of payment will force CAHs to eliminate these “96-hour-plus” services. However, in the inpatient prospective payment system (PPS) final rule for fiscal year (FY) 2018, CMS indicates its contractors will make reviews of this issue a “low priority.”

The AHA appreciates CMS’s recognition that this condition of payment could stand in the way of promoting essential, and often lifesaving, health care services to rural America. However, while this moratorium offers some comfort, it does not remove the 96-hour certification requirement from the statute, and the AHA remains concerned that CAHs may still be at risk for penalties. The AHA urges Congress to permanently remove the 96-hour physician certification requirement as a condition of payment for CAHs.

Remove the Health Insurance Portability and Accountability Act's (HIPAA) Current Barriers to Sharing Patient Information for Clinically Integrated Care.

The HIPAA regulation currently restricts the sharing of a patient's medical information for "health care operations" like quality assessment and improvement activities, including outcomes evaluation, or activities that related to the evaluation of provider qualifications, competence or performance, to information about those patients for whom both the disclosing and receiving providers have – or have had – a patient relationship. The challenge that strict regulatory prohibition poses in the integrated care setting is that patients frequently do not have a relationship with all of the providers among whom information should be coordinated. A clinically integrated setting and each of its participating providers must focus on and be accountable for all patients. Moreover, achieving the meaningful quality and efficiency improvements that a clinically integrated setting promises requires that all participating providers be able to share and conduct population-based data analyses.

Congress should require that the HIPAA medical privacy regulation enforced by the Office for Civil Rights permit a patient's medical information to be used by and disclosed to all participant providers in an integrated care setting without requiring that individual patients have a direct relationship with all of the organizations and providers that technically "use" and have access to the data.

Allow Treating Providers to Access Patients' Substance Use Disorder Treatment

Records. Requiring individual patients' consent for access to records from federally funded substance use treatment programs, as current requirements do, is an obstacle to integrated patient care and, in some cases, may endanger patients' health.

Congress should enact the reforms included in the Overdose Prevention and Patient Safety Act (H.R. 3545) to fully align requirements for sharing patients' substance use disorder treatment records with HIPAA regulations that allow the use and disclosure of patient information for treatment, payment and healthcare operations. Doing so would improve patient care by ensuring that providers and organizations who have a direct treatment relationship with a patient have access to his or her complete medical record.

Prohibit Enforcement of Federal Contractor Requirements Against Hospitals

Receiving TRICARE and Other Federal Health Care Reimbursement Programs.

For several years, the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) has attempted to extend its oversight and enforcement of federal contractor status to hospitals solely because they receive reimbursement under TRICARE, the Federal Employee Health Benefits Program (FEHBP), and even federal health care reimbursement programs like Medicare Parts C and D. Federal contractor status imposes enormous recordkeeping and reporting burdens on hospitals that already are subject to other federal, state and local nondiscrimination laws. OFCCP offered some limited relief in 2014 by agreeing to a five-year moratorium on enforcement for TRICARE providers, including those receiving reimbursement from FEHBP and other health care programs. Hospitals that

otherwise are holders of separate, independent non-health care related federal contracts or subcontracts appropriately are excluded from the enforcement moratorium.

We urge Congress to reintroduce and pass the Protecting Health Care Providers from Increased Administrative Burdens Act, which would help ensure the continuing availability of a robust network of hospital care for TRICARE and FEHBP participants by clarifying that OFCCP's oversight and enforcement activities do not extend to hospitals that provide services to military families, federal employees and other recipients of care under federal health reimbursement programs.

Suspend Hospital Star Ratings. Despite objections from a majority of Congress, CMS published a set of deeply flawed hospital star ratings on its website in July 2016. 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. We continue to be concerned that CMS's chosen methodology is the wrong approach and that arbitrary decisions made to assign star ratings have far too much impact on how a hospital is rated. Our concern is amplified by the fact that further analysis performed since the star ratings were first released show that substantive errors were made in executing CMS's chosen methodology. As a result, far too many hospitals have been classified into the wrong star rating categories.

We urge Congress to require CMS to suspend the faulty star ratings from the Hospital Compare website immediately.

Cancel Stage 3 of the "Meaningful Use" Program. Hospitals face extensive, burdensome and unnecessary "meaningful use" regulations from CMS that require significant reporting on use of electronic health records (EHRs) with no clear benefit to patient care. These excessive requirements are set to become even more onerous when Stage 3 begins. They also will raise costs by forcing hospitals to spend large sums upgrading their EHRs solely for the purpose of meeting regulatory requirements. The AHA appreciates that CMS recently made Stage 3 optional in 2018; however, further changes are needed.

We urge Congress to direct CMS to cancel Stage 3 of meaningful use by removing the 2018 start date from the regulation. The Administration also should institute a 90-day reporting period in every future year of the program, eliminate the all-or-nothing approach, and gather input from stakeholders on ways to further reduce the burden of the meaningful use program from current requirements.

Suspend Electronic Clinical Quality Measure (eCQM) Reporting Requirements. Hospitals are required to report eCQMs in the Hospital Inpatient Quality Reporting Program and the EHR Incentive Program, but report several challenges to successful submission of eCQM data. It is difficult and costly to bring information from other systems into the certified EHR for electronic quality reporting, the same information must be entered in several places in the EHR to support electronic measure reporting and the clinical processes need to be revised to support data capture for eCQM data reporting.

Hospitals are able to compare the chart-abstracted measure reported and the eCQM reported for the same quality measure and see the eCQM does not yield the same result. Every year, CMS updates requirements for eCQM data reporting. As a result, hospitals invest resources to annually update their technology and train their staff to collect and report eCQM data that does not accurately measure the quality of care for the measure topic.

The AHA urges Congress to require the Administration to suspend all regulatory requirements that mandate submission of eCQMs.

Use Only Measures that Truly Matter. Public transparency regarding hospital and other provider quality would be supported by thinking strategically about the information most useful to the public. CMS currently publishes data on nearly 90 measures of hospital quality. In addition, it publishes star ratings and data on what Medicare pays for services at each hospital. All of this provides a complex, confusing and sometimes conflicting set of signals to the public about a hospital's quality. Continued expansion of this haphazard set of information is less useful to the public than a strategically chosen, consistently collected set of information on each hospital.

The AHA urges Congress to require CMS to work with a variety of stakeholders, including the AHA, to identify what the critical indicators of quality and safety are that would be useful to patients and communities, and that would foster meaningful improvements in the quality of care. These discussions should guide CMS's thinking as it considers what measures need to be built, which existing measures would provide meaningful additions to its programs, and which measures currently used in programs should be removed.

Eliminate Regulatory Barriers that Prevent Exploration of Innovative Strategies and Alternative Payment Models (APMs). As providers work to implement new, innovative payment and delivery models that seek to ensure access, increase quality and reduce unnecessary costs, they frequently encounter regulatory barriers to care coordination.

Many of these barriers are addressed specifically in this letter, but we also urge Congress on an overarching basis to urge CMS to eliminate them so that hospitals and their communities may successfully coordinate care and ensure that it is provided in the right place at the right time. ***For example, hospitals participating in APMs should have maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals.*** This includes providing waivers of, for example, the inpatient rehabilitation facility (IRF) "60% rule," the IRF "three-hour rule," and the home health homebound rule.

In addition, in 2015, the AHA Board of Trustees created a task force to examine ways in which hospitals and health systems can help ensure access to primary care, emergency departments, psychiatric and substance use treatment services, prenatal care and more essential services in vulnerable communities. The task force considered a number of

integrated, comprehensive strategies to reform health care delivery and payment. Their report presents nine options communities may select based on their unique needs, support structures and preferences. In addition to these options, the task force also identified federal policies, such as aspects of the fraud and abuse laws, that serve as barriers to successful implementation of these strategies.

Permanently Eliminate Unfair the Long-term Care Hospital (LTCH) ‘25% Rule’.

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% Rule” has become outdated, excessive and unnecessary. The purpose of the 25% 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 – we have called for the 25% Rule to be withdrawn by CMS under its own authority.

We appreciate that the agency placed a moratorium on enforcement of the 25% Rule for FY 2018 in order to evaluate the long-term need to retain the policy in light of the impact of LTCH site-neutral payment. However, we urge Congress to prohibit CMS from implementing the 25% Rule.

Examine IRF ‘60% Rule’. The 60% Rule is designed to focus IRF services on particular types of patients, requiring 60 percent of cases for a prior 12-month period to have one of 13 qualifying conditions (“CMS 13”) or a qualifying comorbidity. However, the CMS 13 were implemented in 2004 and may no longer align with current medical practice or the current patient mix that reflects substantial regulatory intervention by CMS, including new admissions criteria in 2010, and more recently, marketplace changes related to APMs. Some of our members believe that the 60% Rule is out of date and no longer warranted. As stated in our June 2017 comment letter to CMS, we urge the agency to implement a transparent process to re-evaluate the 60% Rule in recognition of the policy's limitations, most notably its arbitrary access restrictions for patients with diagnoses outside of the CMS 13 qualifying conditions.

The AHA urges Congress to require a study of the 60% Rule to determine how the field has evolved since the CMS 13 were created in 2004.

Improve Consistency and Accuracy of IRF ‘Three-hour Rule’ Enforcement. Medicare has a long-standing requirement that IRF patients require and receive at least three hours of therapy a day, the “preponderance” of which must be one-on-one. However, our members report that some of CMS’s contractors are interpreting this requirement in an extremely inconsistent, and often, inaccurate manner. This has led to some instances in which payment was denied even though the vast majority of the therapy provided was one-on-one.

The AHA urges Congress to direct CMS to further educate its contractors on interpretation and enforcement of the three-hour rule in an effort to improve accuracy and consistency.

End Onerous Home Health Agency Pre-claim Review. Under CMS's home health pre-claim review demonstration, home health agencies in five states were unfairly subjected to a mandatory Medicare demonstration launched in August 2016 that is testing a requirement for pre-claim review. Launched in Illinois in August 2016, but currently under a national pause, the demonstration added unnecessary and complex time and paperwork requirements, which, if fully implemented, would impact an estimated 1 million home health claims per year.

The AHA supports the Administration's current pause on this onerous demonstration. We urge Congress to require CMS to instead consider more targeted policies, such as education and other interventions that focus only on agencies and/or claims with high payment error rates. Home health agencies with no payment or fraud issues should face no additional compliance interventions.

Postpone and Re-evaluate Post-acute care Quality Measure Requirements. Recent laws and regulations are rapidly expanding the quality and patient assessment data reporting requirements for post-acute care providers. The requirements have been implemented aggressively, and without adequate time for stakeholder input. The result is duplicative reporting requirements – such as two different mandated ways of collecting patient functional status data for IRFs – and enormous confusion in the field.

Congress should direct CMS to suspend any post-acute care quality reporting requirements finalized on or after Aug. 1, 2015, and to work with the post-acute care community to develop requirements that strike a more appropriate balance between value and burden.

Protect Medicaid Disproportionate Share Hospital (DSH) Payments. CMS's final rule that addresses how third-party payments are treated for purposes of calculating the hospital-specific limitation on Medicaid DSH payments could deny hospitals access to needed Medicaid DSH funds. The Medicaid DSH program provides essential financial assistance to hospitals that care for our nation's most vulnerable populations. CMS has characterized this rule as interpretive and a clarification of existing policy. But, in reality, the rule is substantive and establishes new policy that could significantly limit or eliminate some hospitals' access to Medicaid DSH funds.

Congress should require CMS to withdraw its final rule on Medicaid DSH third-party payments. If the agency does move forward, however, any change in policy with regard to the calculation of the hospital-specific DSH limitation should only apply prospectively, which will give states and hospitals sufficient time to make needed adjustments to ensure compliance. Given the current litigation pending in federal court

regarding CMS's policy in this area, to do otherwise would be to create unnecessary confusion for state Medicaid programs and DSH hospitals.

Preserve Medicaid Supplemental Payments in Managed Care. CMS's final rule on Medicaid supplemental payments in managed care would limit states' ability to increase or create new pass-through payments for hospitals, physicians or nursing homes under Medicaid managed care contracts. CMS previously provided for a 10-year phase-out of these pass-through payments, from 2017 to 2027, because of the size, number and complexity of hospital pass-through payments programs. However, in the rule, CMS requires that, for state pass-through payment programs to qualify for the 10-year transition period, they had to be in place as of July 5, 2016. This effectively moves up the start of the phase-out period from 2017 to July 5, 2016.

The AHA urges Congress to direct CMS to withdraw the final rule on Medicaid provider pass-through payments in Medicaid managed care. We are concerned that this further limitation on pass-through payment programs could adversely affect hospitals dependent on these supplemental payments.

Stop Federal Agency Intrusion in Private Sector Accreditation Standards. HHS has the authority to determine whether private-sector accrediting bodies' standards and survey processes meet or exceed the Conditions of Participation (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 health care 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 since the Department says it has no other way to determine if the standards and processes are "at least as good" as its own standards. This limits innovation in the private sector that encourages greater attention to safety and quality.

The AHA asks the Committee to direct the Administration to limit its oversight of private sector standards to those for which there are compatible requirements in the CoPs. Further, Congress should direct CMS to be flexible in allowing alternative articulations of standards and should monitor relevant data to ensure the alternative language provides similar or better protection from harm. This will ensure CMS's oversight does not limit the ability of private-sector entities to innovate and to differentiate themselves in the marketplace.

Reduce Burden Associated with Validation Surveys. To help assess an accreditation organization's processes and performance, CMS conducts follow-on "validation" surveys of some hospitals that have recently undergone an accreditation organization review. Compliance surveys are necessary; they also are very time consuming and labor intensive. Requiring a hospital to undergo two surveys in a relatively short time period can be

extremely burdensome and can consume resources that are better directed to patient care and quality improvement.

We suggest that the Committee urge the Administration to identify ways to make this validation process more effective and efficient. For example, the agency, accreditation organizations and hospitals could consider whether CMS auditors could join an accreditation survey instead of conducting separate surveys altogether.

Promote Transparency and Timeliness in the Development and Release of Interpretive Guidance. Newly finalized rules, such as changes to the CoPs, can become effective before interpretive guidance is released. Thus, hospitals may invest time and resources to implement a new regulation without the benefit of clear expectations about how to meet the standards.

We urge Congress to encourage CMS to continue the trend of prioritizing the development of guidance after a rule is finalized, which can help avoid the possibility that hospitals will need to modify or revamp their implementation efforts once the guidance is released. In addition, when guidance is updated due to internal CMS policy changes (rather than being issued subsequent to a final rule), or when policies are articulated in the State Operations Manual for the first time, CMS should provide stakeholders a reasonable timeframe for implementation. While this timeframe may be relatively short for many changes, it may need to be longer when structural changes, new equipment, or substantial staff training is required. Further, CMS should publicly post draft guidance for a limited period of time on its website, so that providers may ask questions and identify potential unintended consequences of new policies.

Undo Agency Over-reach on So-called ‘Information Blocking’. Hospitals want to share health information to support care and do so when they can. But technology companies and the federal government have so far failed to create the infrastructure to make sharing information electronically easy and efficient. CMS is asking hospitals to attest to three separate statements indicating:

- that they did not “knowingly and willfully take action to limit or restrict the compatibility or interoperability” of their certified EHR;
- that they have implemented the technology to support “secure and trusted bi-directional exchange” of health information; and
- have “responded in good faith and in a timely manner” to requests for exchange information from others.

The last two of the three attestations go beyond both statutory intent and the current capability of the technology hospitals have available to them. That unfairly places hospitals at risk of payment penalties for technical issues outside of their control.

The AHA urges Congress to direct the Administration to remove the second two attestations, keeping only the statutory requirement that hospitals did not knowingly or

willfully take action to limit or restrict the compatibility or interoperability of their EHRs.

Hold Medicare Recovery Audit Contractors (RACs) Accountable. Medicare RACs are paid a contingency fee that financially rewards them for denying payments to hospitals, even when their denials are found to be in error.

The AHA urges Congress to require the Administration to revise the RAC contracts to incorporate a financial penalty for poor performance by RACs, as measured by Administrative Law Judge appeal overturn rates.

Adjust Readmission Measures to Reflect Differences in Social Risk Factors. A body of research demonstrates that readmissions are higher in communities that are economically disadvantaged. This is because patients' likelihood of being readmitted is affected by access to resources that help them continue to heal post-discharge from the hospital, such as affordable medicines, primary care physicians, exercise and appropriate foods. For this reason, the 21st Century Cures Act requires CMS to implement sociodemographic adjustment in the hospital readmissions penalty program starting in FY 2019. At the same time, a recent series of reports from the National Academy of Medicine show that other outcome measures, such as 30-day mortality rates and measures of efficiency and patient experience, are similarly impacted by sociodemographic factors. Moreover, a report from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) shows that providers caring for large numbers of poorer patients are more likely to perform worse on a wide range of hospital, physician and post-acute care pay-for-performance programs.

The AHA urges Congress to direct CMS to ensure its implementation of the social risk factor adjustments in the hospital readmissions penalty program is done in a transparent and fair manner. It also should use the evolving science around the best ways to adjust for social risk factors to update its approach as needed. Finally, Congress should require CMS to incorporate social risk factor adjustment into its other quality measurement and pay-for-performance programs where necessary and appropriate.

Make Future Bundled Payment Programs Voluntary. Through the Center for Medicare and Medicaid Innovation (CMMI), CMS has established a new mandatory bundled payment model for cardiac care and also expanded a mandatory bundled payment model for comprehensive joint replacements. Recently, CMS proposed to cancel implementation of these two mandatory models. While we support offering providers opportunities to explore new payment models, CMMI has engaged in regulatory overreach by making them mandatory.

The AHA urges Congress to ensure that any new bundled payment programs are voluntary. Hospitals should not be forced to bear the expense of participation in these complicated programs if they do not believe they will benefit patients.

Delay Payment Impact and Reduce Burden of Program that Encourages Appropriate Use Criteria (AUC). The Protecting Access to Medicare Act (PAMA) requires CMS to establish a program that promotes AUC for advanced diagnostic imaging. The statute requires that payment be made to the furnishing professional for an applicable advanced diagnostic imaging service only if they indicated on the claim that the ordering professional consulted with a qualified clinical decision support mechanism as to whether the ordered service adheres to applicable AUC. Although this is a very burdensome requirement for hospitals to implement, we appreciate that CMS has taken a thoughtful and deliberate approach to this program, most recently by proposing in the 2018 Physician Fee Schedule (PFS) rulemaking to delay until Jan. 1, 2019, the requirement that professionals furnishing advanced diagnostic imaging report on the ordering professional's consultation of appropriate use criteria. Further, CMS has proposed that 2019 would be an "educational and operations testing year," where the agency will pay claims regardless of whether AUC consultation is reported.

We urge Congress to delay these AUC policies until 2020. We also urge Congress to require CMS to explore alternative methods of implementing the policies that do not require the furnishing professional to report information on the claim.

Rescind 'JW Modifier' Requirement for Certain Drug Claims. Currently, providers are required to report the "JW modifier" on certain Part B drug claims for discarded drugs/biologicals in single-dose or single-use packaging, as well as document the amount of discarded drugs/biologicals. Compliance with this requirement requires complex coordination and specialized information technology (IT) solutions. In addition, it poses a patient safety concern because it requires both the amount of medication administered and the amount of medication discarded to be recorded on the patient's bill, as well as in the patient's chart. Including two amounts for a single administration of medication increases the possibility of human error in entering and reviewing the record during the course of treatment.

The AHA urges Congress to direct CMS to withdraw this requirement.

Issue a Permanent Enforcement Moratorium on Direct Supervision Requirements. In the 2009 outpatient PPS final rule, CMS mandated a new policy for "direct supervision" of outpatient therapeutic services that hospitals and physicians recognized as a burdensome and unnecessary policy change that could harm access to care in rural and underserved communities. Because CMS characterized the change as a "restatement and clarification" of existing policy in place since 2001, hospitals, particularly small and rural hospitals and CAHs, found themselves at increased risk of unwarranted enforcement actions. For calendar years (CYs) 2010-2013, in response to hospital concerns, the agency prohibited its contractors from enforcing the direct supervision policy. While Congress has since extended this enforcement moratorium through 2016, this annual reconsideration of the misguided direct supervision policy places these hospitals in an uncertain and untenable position. CMS recently proposed to reinstate the enforcement moratorium. However, it did so only for 2018 and 2019 in order to give these hospitals more time to comply with the

supervision requirements and providers time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a recommended change in supervision level. While we appreciate CMS's proposal, allowing more time to comply will not help these vulnerable hospitals due to ongoing physician shortages in these communities and the advisory panel process does not provide enough relief to address the larger issues of personnel shortages and costs.

We continue to recommend that the Congress permanently prohibit CMS from enforcing the direct supervision regulations in CAHs and small and rural hospitals.

Remove the Mandatory Free-text Field from the Medicare Outpatient Observation

Notice (MOON). The MOON's mandatory free-text field requires that hospital staff describe the patient-specific clinical considerations made by their physician when ordering outpatient observation services rather than inpatient admission. This requirement is burdensome to hospitals and of no benefit to patients. For example, it negatively impacts the hospital's workflow by precluding hospital registration or access staff from preparing the MOON. This is because the medical record does not contain information about why a patient is not an inpatient; rather, it contains information about the patient's evolving clinical situation during his or her outpatient observation encounter. In addition, these clinical specifics would be difficult and confusing for most beneficiaries to understand. In contrast, beneficiaries who do wish to understand such clinical specifics would have ample opportunity to ask questions during the required oral explanation of the MOON.

The AHA recommends Congress direct CMS to remove this field from the MOON. It should be replaced with CMS-prepared standard language that describes the established reason that physicians order observation services for patients. Indeed, CMS itself acknowledged the standard explanation for why a patient is placed in outpatient observation status and included it in the preamble to the FY 2017 inpatient PPS final rule.

Eliminate the Observation Hours Carve-out Policy. Currently, CMS requires that hospitals "carve out" from their count of observation hours the time involved in furnishing other diagnostic or therapeutic services that also require active monitoring. Doing so is burdensome for hospitals, as it requires manual estimation and recording of the time required to complete each separate service. It also is unnecessary given that payment for all observation services is now packaged and, in most cases, diagnostic or therapeutic services furnished in conjunction with observation no longer separately paid. Further, CMS itself has decided to disregard this "carving out" of time from observation services in its final policy for implementing the Notice of Observation Treatment and Implication for Care Eligibility Act. That is, in determining whether a hospital has furnished more than 24 hours of observation services to a Medicare beneficiary (thus, triggering the MOON notification), CMS instructed hospitals to disregard this notion of "billable hours" and instead directed hospitals to count the time directly as clock hours from the initiation of observation services.

The AHA recommends that Congress direct CMS to eliminate the current requirement that hospitals “carve out” from its count of observation hours the time involved in furnishing other diagnostic or therapeutic services that also require active monitoring.

Eliminate Second Important Message from Medicare. Currently hospitals are required to provide a written explanation of a beneficiary’s appeal rights and obtain a signature at the time of admission (known as the “Important Message”). In addition, the hospital must provide this message a second time (known as the “Second Important Message”) to the beneficiary if the initial message was provided more than 2 days prior to discharge. Presenting the beneficiary with the same information twice in one stay leads to confusion and feelings of being overwhelmed with paperwork. It also is burdensome and redundant for the hospital and staff.

We urge Congress to direct CMS to eliminate the requirement for a second notice in these circumstances. Any benefit to presenting a second message is outweighed by the added confusion to the patient and burden borne by the hospital.

Allow Flexibility for Providers Who Want to Share Treatment Space to Address Gaps in Patient Access to Care. 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 undermine broader goals to provide more coordinated and patient-centered care at lower cost.

The Committee should urge CMS to allow shared space arrangements that are established for the purposes of ensuring easy patient access to necessary care and/or care coordination. Such arrangements should be allowed regardless of whether they do not have separate spaces, entrances and/or waiting areas. Congress should require CMS to release co-location guidance that allows for this appropriate flexibility by the end of this fiscal year.

Clarify Medicaid Payment Policies Regarding Justice-involved Individuals Receiving Inpatient Care. For patients in the custody of law enforcement, some hospitals provide general acute care beds in special units that are guarded and have appropriate security features, such as metal detectors and controlled entrances. Secure units enable hospitals to maintain a safe environment for patients, visitors and staff while providing prisoners and jail inmates access to needed care. Last year, the CMS Survey and Certification Group confirmed that these units are allowed in Medicare-certified hospitals. However, page 13 of an April 28, 2016 [memo](#) from the Center for Medicaid and CHIP Services contains language that appears to prohibit federal financial participation for care provided in secure units.

We ask the Committee to consider legislation directing CMS to allow hospitals to continue to have secure units and to ensure that if patients treated in these units are otherwise eligible for Medicaid, their costs may continue to be billed to Medicaid.

Modify CoPs to Allow Hospitals to Recommend Post-acute Care Providers. CMS's discharge planning regulations have been interpreted to prevent a hospital from offering advice to a patient on the selection of a provider for post-hospital care. However, efforts to prevent unnecessary readmissions and improve the health of individuals with chronic medical conditions have shown that coordination of care makes a difference in patient outcomes. This kind of coordinated care is essential to meeting the goals of the new payment models and would benefit all patients.

The AHA urges Congress to require that the CoPs be modified to establish that, while the choice must always be up to the patient, a hospital may make recommendations about post-acute care providers.

Maintain Timely Patient Access to Laboratory Developed Tests (LDTs). In October 2013, the Food and Drug Administration (FDA) issued a draft Framework for Regulatory Oversight of LDTs. Many hospitals and health care systems develop and use LDTs, which provide timely patient access to accurate and high-quality testing for many conditions for which no commercial test exists or where an existing test does not meet current clinical needs.

The AHA urges Congress to ensure that FDA does not finalize the flawed framework and, instead works with stakeholders to develop a solution that will ensure that the technological and clinical innovation that is essential to the development of LDTs remains unrestricted; that the quality and reliability of LDTs are maintained at the highest levels possible; and that LDTs continue to be widely accessible to patients. The AHA is concerned that the FDA's framework, while well-intentioned, is inappropriate and will lead to a loss of patient access to many critical tests.

Maintain Timely Patient Access to Compounded Drugs. In April 2016, the FDA issued a draft guidance for hospital and health system compounding of drugs that included an exception to its "prescription requirements." This provision was intended to allow hospital pharmacies to compound and distribute a limited amount of drug products prior to the receipt of a patient-specific prescription as long as the compounded products were used only within the hospital's facilities for its own patients. Yet, this exception included an arbitrary and unworkable provision that will limit the distribution of these compounded products only to those hospital facilities located within a one-mile radius of the hospital's compounding pharmacy.

The AHA urges Congress to ensure that FDA removes the "one-mile radius" limitation and replace it with an alternative approach that would support the existing hospital and health system care delivery model and also put into place widely vetted, evidence-based

limits on anticipatory compounding in hospitals and health systems to ensure safe, high-quality patient care. Specifically, the FDA should: (1) use the beyond-use date (BUD) timeframes contained in USP Chapters 797 and 800 to limit distribution; and (2) retain the FDA's proposed requirements that non-patient-specific compounded drugs are distributed only to health care facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that these drug products are only administered to patients within the health care facilities, pursuant to a patient-specific prescription or order.

Halt Use of Encounter Data to Formulate MA Risk Scores. CMS uses a blended risk score to calculate MA payments. Specifically, the agency uses both Risk Adjustment Processing System data and encounter data. Collection of encounter data is significantly burdensome for both providers and plans. Provider data collection systems and processes were not designed for such a task, and collecting the necessary information often requires significant back-and-forth between both parties. Despite these efforts, the accuracy of such data has been challenged by the Government Accountability Office (GAO). In updating an earlier report on the use of encounter data, GAO found that “CMS has yet to undertake activities that fully address encounter data accuracy... Given the agency’s limited progress, GAO continues to believe that CMS should implement GAO’s July 2014 recommendation that CMS fully assess data quality before use.”

We appreciate that the agency reduced the percentage of the risk score that will be based on encounter data earlier this year. However, we encourage Congress to direct CMS to halt use of encounter data entirely until the issues related to data quality and provider and plan burden are addressed.

Re-focus the Office of the National Coordinator for Health IT (ONC) on Certification of EHRs. As the regulatory agency overseeing health IT, ONC should be focused on work to advance health information standards, certification criteria and the information exchange infrastructure. ONC should prioritize work to confirm that certified EHRs perform as described and are fit for their intended purpose. The use of certified EHRs by hospitals and clinicians also would be enhanced by the availability of the conformance testing infrastructure required by law but not created. The 21st Century Cures law directed CMS to create a hardship exception from negative payment adjustments for eligible hospitals, critical access hospitals and eligible clinicians in the event their EHR becomes decertified during or in the year prior to a performance period. However, more assurance that the certified EHRs conform to the certification criteria is needed.

The AHA urges Congress to require that the work of ONC focus narrowly on standards and certification, including development of robust testing of products to show they are interoperable.

Protect Hospital-based Accountable Care from Restrictive Internal Revenue Service (IRS) Ruling. Public policy makers are calling for hospitals to coordinate care for their communities and make other improvements in delivering population health. To do that,

The Honorable Pat Tiberi
August 25, 2017
Page 19 of 19

hospitals need to integrate with physicians and other providers in their community to reward coordinated patient care. A restrictive IRS ruling is standing in the way of hospitals meeting those demands.

We urge Congress to ensure that the IRS publishes guidance affirming that tax-exempt hospitals may participate in a private-sector accountable care organization without generating adverse tax consequences.