American Hospital Association

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Mr. Donald Trump
President-elect of the United States
1717 Pennsylvania Avenue, N.W.
Washington, DC 20006

Dear President-elect Trump:

On behalf of the American Hospital Association's (AHA) nearly 5,000 member hospitals, health systems and other health organizations, and our 43,000 individual members, I am writing to thank you for your interest and commitment to addressing regulatory reform. As noted in our letter dated November 30, the regulatory burden faced by hospitals is substantial and unsustainable.

We appreciate your Administration's willingness to modify or eliminate duplicative, excessive, antiquated and contradictory provider regulations. Reducing administrative complexity in health care would save billions of dollars annually and allow providers to spend more time on patients, not paperwork. The Centers for Medicare & Medicaid Services (CMS) and other agencies of the Department of Health and Human Services (HHS) released 43 proposed and final rules affecting hospitals and health systems in the first 10 months of this year alone, comprising almost 21,000 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.

Please find attached a document that lays out actions your Administration could take immediately to reduce the burden on hospitals, health systems and the patients we serve. It includes actions that could be taken by CMS, other agencies within HHS and other departments of the federal government.

Again, we thank you for your focus on this critical issue. We look forward to working with you and your Administration.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer

American Hospital Association®

Regulatory Relief Actions

The balance between flexibility in patient care and regulatory burden seems to have reached a tipping point. The Centers for Medicare & Medicaid Services (CMS) and other agencies of the Department of Health and Human Services (HHS) released 43 hospital-related proposed and final rules in the first 10 months of the year alone, comprising almost 21,000 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.

There are numerous duplicative and excessive rules and regulations. The AHA suggests the following actions to immediately reduce burdens on hospitals and patients. These regulations are promulgated by CMS (Table 1), other agencies within HHS (Table 2) and other departments of the federal government (Table 3).

TABLE 1. ACTIONS TO BE TAKEN BY CMS

Action	Description
Suspend hospital star ratings	Despite objections from a majority of the Congress, CMS published a set of deeply flawed hospital star ratings on its website this fall. 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. ***The AHA calls on the Administration to suspend the faulty star ratings from the Hospital Compare website.***
Cancel Stage 3 of "meaningful use" program	Hospitals face extensive, burdensome and unnecessary "meaningful use" regulations from CMS that require significant reporting on the 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 in 2018. 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 urges the Administration 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, 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 reporting requirements	Hospitals have spent significant time and resources to revise certified EHRs to meet CMS electronic clinical quality measure requirements for 2016, with no benefit for patient care. Moreover, CMS acknowledges that the electronic test submissions by hospitals and physicians do not accurately measure the quality of care provided. Despite these facts, CMS regulations double the electronic clinical quality measure reporting requirements for hospitals for 2017, creating additional burden without an expectation that the data generated by EHRs will be accurate. ***The AHA urges the new Administration to suspend all regulatory requirements that mandate submission of electronic clinical quality measures.***

Action	Description
Remove faulty hospital quality measures	Improvements in quality and patient safety are accelerating, but the ever increasing number of conflicting, overlapping measures in CMS programs take time and resources away from what matters the most – improving care. Most recent measure additions to the inpatient quality reporting (IQR) and outpatient quality reporting (OQR) programs provide inaccurate data, and do not focus on the most important opportunities to improve care. ***We urge the Administration to remove all IQR and OQR measures added to the programs on or after Aug. 1, 2014. These measures also should be removed from CMS pay-for-performance programs, such as readmissions and hospital value-based purchasing.***
Eliminate unfair Long-term Care Hospital (LTCH) regulation	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% reduction, on average, to one out of two current cases – **CMS should rescind the 25% Rule and instead rely on the site-neutral payment policy to bring transformative change to the LTCH field.**
End onerous home health agency pre-claim review	CMS's mandatory Medicare demonstration to test pre-claim review is causing patient care and payment delays in the first of five states under the program. Launched in Illinois in August 2016, the demonstration added unnecessary processes and paperwork, which, when fully implemented, will impact an estimated 1 million home health claims per year. ***The AHA urges the Administration to end this onerous demonstration program.***
Restore compliant codes for inpatient rehabilitation facility (IRF) 60% Rule	During the transition to ICD-10-CM, CMS reduced the number conditions that qualify toward compliance under the IRF "60% Rule," which is a criterion that must be met for a hospital or unit to maintain its payment classification as an IRF. Yet certain codes that qualified under ICD-9-CM were inadvertently omitted as a result of the conversion to ICD-10-CM. ***We urge the Administration to restore those codes that counted toward the 60% Rule presumptive compliance test, but lost their eligibility as of June 1, 2016, during the transition to the new coding system.***
Postpone and reevaluate 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. ***We urge the Administration 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.***
Withdraw proposed mandatory Part B drug demonstration	CMS has proposed a mandatory Medicare demonstration program that would unfairly hold hospitals financially accountable for the high prices charged by drug manufacturers. ***The AHA urges the Administration to withdraw this proposed rule.***

Protect Medicaid DSH hospital payments	CMS's proposed rule that addresses how third-party payments are treated for purposes of calculating the hospital-specific limitation on Medicaid disproportionate share hospital (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 that this rule is 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. ***The AHA urges the new Administration not to finalize CMS's proposed rule on Medicaid DSH and the treatment of third-party payments.***
Preserve Medicaid supplemental payments in managed care	CMS published a proposed rule that 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. According to the proposed rule, 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. CMS has effectively moved up the start of the phase-out period from 2017 to July 5, 2016. The AHA is concerned that this further limitation on pass-through payment programs could adversely affect hospitals dependent on these supplemental payments. ***The AHA urges the new Administration not to finalize CMS's proposed rule on Medicaid provider pass-through payments in Medicaid managed care.***
Stop federal agency intrusion in private sector accreditation standards	HHS has the authority to determine that private sector accrediting bodies standards and survey processes are equivalent to or better than the 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 sectors' 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 urges the Administration to find better ways to judge the equivalency of private sector standards and survey methods that do not limit the ability of private sector entities to innovate and to differentiate themselves in the marketplace.***
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 went beyond statutory intent in 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 the Administration to remove the second two attestations, keeping only the statutory requirement that they 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 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 socio-demographic factors	Hospital readmission measures and other outcome measures have been publicly reported and used to penalize poor performance. But because they lack appropriate adjustment for the impact of the community and other factors, those hospitals serving certain communities sustain larger penalties. ***The AHA calls upon the Administration to immediately adjust the readmission measures to account for sociodemographic factors beyond hospitals' control.***
Provide more regulatory flexibility in payment reform models	CMS's continued application of fee-for-service (FFS) regulatory barriers within payment reform models often hinders providers' ability to identify and place beneficiaries in the most clinically appropriate setting. It also inhibits their ability to test new, more patient-centered and streamlined clinical pathways. Testing new approaches in an environment free from artificial barriers to care coordination, such as the IRF 60% Rule and the home health homebound rule, will more effectively advance solutions that improve clinical outcomes and reduce overall costs and variation. ***As such, the AHA encourages the Administration, to the greatest extent of its authority, to waive the regulations that CMS or Congress established for use in a FFS reimbursement, but that stymy the redesign of episodes of care across provider settings.***
Make future bundled payment programs voluntary	Through the Center for Medicare and Medicaid Innovation (CMMI), CMS has established or proposed to establish mandatory bundled payment models. While it is important to offer opportunities to explore new payment models, CMMI has engaged in regulatory overreach by making them mandatory. Hospitals should not be forced to bear the expense of participation in complicated new programs if they do not believe they will benefit patients. ***AHA urges the Administration to make any new bundled payment programs voluntary.***
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, 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 AHA urges the Administration 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.***
Prohibit enforcement of direct supervision requirements	In the 2009 OPPS 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 critical access hospitals (CAHs), found themselves at increased risk of unwarranted enforcement actions. For CYs 2010-2013, in response to hospital concerns, the agency prohibited its contractors from

	enforcing the direct supervision policy. While Congress has extended this enforcement moratorium annually since 2014, this annual reconsideration of the misguided direct supervision policy places these hospitals in an uncertain and untenable position. ***The AHA urges the Administration to permanently prohibit its contractors from enforcing the direct supervision regulations in CAHs and small and rural hospitals.***
96-Hour Rule	CMS has indicated it would begin enforcing a condition of payment for 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. ***CMS should not enforce this provision.***
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 subvert broader goals to provide more coordinated and patient-centered care at lower cost. ***CMS should stop categorically disallowing visiting specialist leased space arrangements simply because they do not have separate spaces, entrances and/or waiting areas.***
Rescind CMS guidance prohibiting the use of secure units in hospitals treating patients who are prison or jail inmates	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 provide a safe environment for patients, visitors and staff while providing prisoners and jail inmates access to needed care. However, CMS recently issued a memorandum to state survey agency directors disallowing secure units. ***We urge the Administration to rescind the guidance pertaining to secure units immediately and clarify that hospitals may have designated inpatient secure units, as well as specific outpatient spaces, as long as these dedicated spaces improve safety and do not interfere with access to quality care.***
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 to 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 the Administration to amend the CoPs to establish that, while the choice must always be up to the patient, a hospital may make recommendations about post-acute care providers.***
Create Stark regulatory exception for clinical integration arrangements	Hospitals cannot succeed in their efforts to coordinate care and participate in new payment models because of outdated regulations, such as the Anti-Kickback Statute and the "Stark" law. ***A new exception should be created that protects any arrangement that meets the terms of the newly created Anti-Kickback safe harbor for clinical integration arrangements.***

TABLE 2. ACTIONS TO BE TAKEN BY OTHER AGENCIES IN HHS

Action	Description
Create Anti-Kickback regulatory safe harbor for clinical integration arrangements	***The Office of the Inspector General should 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:*** • A program must be documented. • Performance practices must use an objective methodology, be verifiable and be supported by credible medical evidence. They must be individually tracked, in the aggregate be reasonable for patient care purposes, and be monitored throughout the term of the arrangement to protect against reductions or limitations in medically necessary patient care services. • Payments must reflect the achievements of a physician, a physician practice or the program and be auditable through documentation retained to support the program as established and implemented. ***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. The Medicare Quality Improvement Organizations (QIOs) 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 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.***
Create Anti-Kickback regulatory safe harbor for assistance to patients	***This type of safe harbor is necessary so that hospitals can help patients realize the benefits of their discharge plan and maintain themselves in the community. 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);

	• 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; and • Remove the regulatory prohibition on a hospital offering advice to a patient on the selection of a provider for post-hospital care or suggesting a specific facility (or through other legislation).
Maintain timely patient access to laboratory developed tests	In October 2013, the Food and Drug Administration (FDA) issued a draft Framework for Regulatory Oversight of laboratory-developed tests (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 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. ***The AHA urges the new Administration not to finalize the flawed framework and, instead, to work 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.***
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 the Administration to eliminate the "one-mile" limitation and replace it with an alternative approach.***
Re-focus ONC on certification of EHRs	As the regulatory agency overseeing health information technology, the Office of the National Coordinator (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 in HITECH but not created**. *The AHA urges the Administration to focus the work of ONC narrowly on standards and certification, including development of robust testing of products to show they are interoperable*.**
Remove the Health Insurance Portability and Accountability Act (HIPAA) regulation's 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 relate 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 frequently patients 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. ***The HIPAA medical privacy regulation enforced by the Office for Civil Rights should permit a patient's medical information to be used by and***

	disclosed to all participating 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 their patients' substance use disorder records	Requiring individual patient's consent for access to addiction records from federally funded substance use treatment programs, as current requirements do, is an obstacle to an integrated approach to patient care. It also may unknowingly endanger a person's recovery and his or her life. ***The Administration should fully align requirements for sharing patients' substance use records with the requirements in the HIPAA regulation 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.

TABLE 3. ACTIONS TO BE TAKEN BY OTHER DEPARTMENTS

Action	Description
Protect hospital-based accountable care from restrictive 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, hospitals need to integrate with physicians and other providers in their community to reward coordinated patient care. A restrictive Internal Revenue Service (IRS) ruling is standing in the way of hospitals meeting those demands. ***It is imperative that IRS publish guidance affirming that tax-exempt hospitals may participate in a private sector accountable care organization without generating adverse tax consequences.***
Extend the moratorium on 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, FEHPB and even federal health care reimbursement programs like Medicare Part C and D. Federal contractor status imposes enormous affirmative action 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 program. Hospitals that otherwise are holders of separate, independent non-healthcare-related federal contacts or subcontracts appropriately are excluded from the enforcement moratorium. ***OFCCP should continue the moratorium on enforcement of federal contractor status for hospitals.***