Every day, health systems, hospitals and post-acute care (PAC) providers – such as long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities and home health agencies – confront the daunting task of complying with a growing number of federal regulations. Federal regulation is largely intended to ensure that health care patients receive safe, high-quality care. In recent years, however, clinical staff — doctors, nurses and caregivers — find themselves devoting more time to regulatory compliance, taking them away from patient care. Some of these rules do not improve care, and all of them raise costs. Patients also are affected through less time with their caregivers, unnecessary hurdles to receiving care and a growing regulatory morass that fuels higher health care costs.

Trustees know how hard their hospitals and health systems are working toward achieving health care delivery transformation. It is important that trustees understand the impact of regulatory overload on health care organizations and the patients they serve.

> "Providers are dedicating approximately $39 billion per year to comply with the administrative aspects of regulatory compliance in these domains."

To quantify the level and impact of regulatory burden, the American Hospital Association (AHA) worked with Manatt Health on a comprehensive review of federal law and regulations in nine regulatory domains from four federal agencies. The study included interviews with 33 executives at four health systems, and a survey of 190 hospitals that included systems and hospitals with PAC facilities.

Major Findings

1. **Health systems, hospitals and PAC providers must comply with 629 discrete regulatory requirements across nine domains.**

   These include 341 hospital-related requirements and 288 PAC-related requirements. The four agencies that promulgated these requirements – the Centers for Medicare & Medicaid Services (CMS), the Office of Inspector General (OIG), the Office for Civil Rights (OCR) and the Office of the National Coordinator for Health Information Technology (ONC) - are the primary drivers of federal regulation impacting these providers (**see chart on Page 5**). However, providers also are subject to regulation from other federal and state entities, which are not accounted for in this report.

2. **Health systems, hospitals and PAC providers spend nearly $39 billion a year solely on the administrative activities related to regulatory compliance in these nine domains.**

   An average-sized community hospital (161 beds) spends nearly $7.6 million annually on administrative activities to support compliance with the reviewed federal regulations – that figure rises to $9 million for those hospitals with PAC beds. Nationally, this equates to $38.6 billion each year to comply with the administrative aspects of regulatory compliance in just these nine domains (**see page 6**). Looked at in another way, regulatory burden costs $1,200 every time a patient is admitted to a hospital.

3. **An average-sized hospital dedicates 59 full time equivalents (FTEs) to regulatory compliance, over one quarter of which are doctors and nurses, Page 7.**

   Physicians, nurses and allied health staff make up more than one-quarter of the FTEs dedicated to regulatory compliance, pulling clinical staff away from patient care responsibilities. While an average-sized community hospital dedicates 59 FTEs overall, PAC regulations require an additional 8.1 FTEs.

> “An average-sized community hospital spends nearly $7.6 million annually to support compliance with the reviewed federal regulations.”

4. **The timing and pace of regulatory change make compliance challenging.**

   The frequency and pace with which regulations change often results in the duplication of efforts and substantial amounts of clinician time away from patient care. As new or updated regulations are issued, a provider must quickly mobilize clinical and non-clinical resources to decipher the regulations and then redesign, test, implement and communicate new processes throughout the organization.

5. **Among the nine areas investigated, providers dedicate the largest proportion of resources to documenting Medicare Conditions of Participation (CoP) adherence and billing/coverage verification processes.**

   Over two-thirds of FTEs associated with regulatory compliance are within these two domains, which also represent 63 percent of the total average annual cost of regulatory burden.

6. **Meaningful use (MU) has spurred provider investment in IT systems, but exorbitant costs and ongoing interoperability issues remain.**

   Specifically, the average-sized hospital spent nearly $760,000 to meet MU administrative requirements annually. In addition, they invested $411,000 in related upgrades to systems during the year, over 2.9 times larger than the information technology (IT) investments made for any other domain. Regulatory compliance has required extensive investment in health IT systems and process redesign.

7. **Quality reporting requirements are often duplicative and have inefficient reporting processes, particularly for providers participating in value-based purchasing models.**

   An average-sized community hospital devotes 4.6 FTEs – over half of whom are clinical staff – and spends approximately $709,000 annually on the administrative aspects of quality reporting. Duplicative and misaligned reporting requirements, many of which require manual data extraction, create inefficiencies and consume significant financial resources and clinical staff time.

8. **Fraud and abuse laws are outdated and have not evolved to support new models of care.**

   The Stark Law and the Anti-Kickback Statute (AKS) can be impediments to transforming care delivery. While CMS has waived certain fraud and abuse laws for providers participating in various demonstration projects, those who receive a waiver generally cannot apply it beyond the specific demonstration or model. The lack of protections extending care innovations to other Medicare patients or Medicaid and commercially-insured beneficiaries minimizes efficiencies and cost savings realized through these types of models and demonstration projects.

General Opportunities to Reduce Burden

A reduction in administrative burden will enable providers to focus on patients, not paperwork, and reinvest resources in improving care, improving health and reducing costs. The study report provides several general recommendations to reduce administrative requirements without compromising patient outcomes.

- Regulatory requirements should be better aligned and consistently applied within and across federal agencies and programs, and subject to routine review for effectiveness to ensure the benefits for the public good outweigh additional compliance burden;
- Regulators should provide clear, concise guidance and reasonable timelines for the implementation of new rules;
- CoPs should be evidence-based, aligned with other laws and industry standards, and flexible in order to support different patient populations and communities;
- Federal agencies should accelerate the transition to automation of administrative transactions, such as prior authorization;
- MU requirements should be streamlined and should increasingly focus on interoperability, without holding providers responsible for the actions of others;
- Quality reporting requirements should be thoroughly evaluated across all programs to better determine what measures provide meaningful and actionable information for patients, providers and regulators;

- PAC rules should be reviewed and simplified to remove or update antiquated, redundant and unnecessary rules; and
- With new delivery system and payment reforms emerging, Congress, CMS and the OIG should revisit the Stark Law and AKS and their respective regulations, as well as other requirements aimed at combating fraud, and make meaningful changes to ensure that statutes provide the flexibility necessary to support the provision of quality, high-value care.

Separately, the AHA also offers recommendations for immediate regulatory relief. These recommendations, and others, are more fully described in AHA letters to President Trump, CMS and Congress, available at http://www.aha.org/regrelief.

Federal regulation is largely intended to ensure that health care patients receive safe, high-quality care. However, clinical staff – doctors, nurses and caregivers – are increasingly devoting more time to regulatory compliance and spending less time delivering patient care. The daunting task of complying with the growing number of federal regulations leads to clinician/ administrative burden, financial burden and obstruction of care delivery transformation.

Questions for Boards

Trustees are in a unique position to examine these burdens and review potential solutions for their health care organizations to ensure an environment that supports the safe delivery of care.

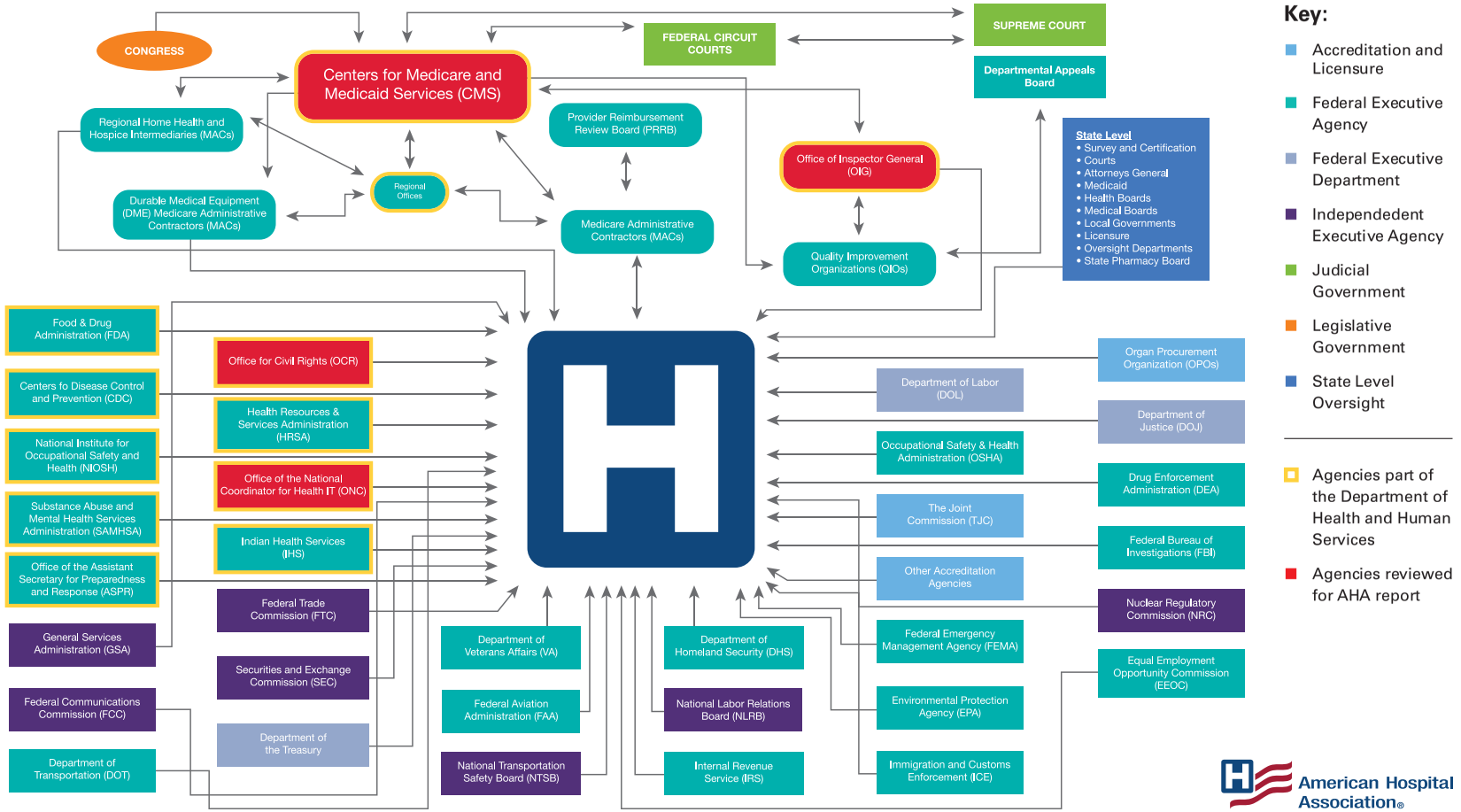
- How has compliance with current regulatory requirements affected our health care organization (e.g., ability to advance care delivery transformation, taking time away from patient care, creating significant administrative/clinical burden, etc.)?
- What steps can our organization take to reduce the burden of regulatory compliance?

Additional Resources

Selected AHA resources on regulatory burden are available at www.aha.org/regrelief.

Federal Agencies with Regulatory or Oversight Authority Impacting Hospitals

Four federal agencies account for 629 regulatory requirements that health systems, hospitals and post-acute care providers must comply with, yet providers are subject to regulation and oversight from many other sources.



Adapted and updated from: American Hospital Association. Patients or Paperwork? The Regulatory Burden Facing America's Hospitals. May 2001.

American Hospital Association®

Regulatory Burden Overwhelming Providers, Diverting Clinicians from Patient Care

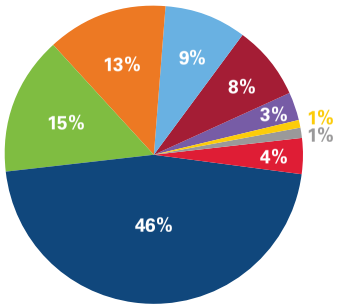
Regulations are essential to ensure safety and accountability. However, the rapid increase in the scope and volume of mandatory requirements diverts resources from the patient-centered mission of health systems, hospitals and post-acute care providers.

$39 BILLION

Spent by health systems, hospitals, and post-acute care providers each year on non-clinical regulatory requirements

629 mandatory regulatory requirements

- Hospitals have to comply with 341 mandatory regulatory requirements.
- Post-acute care providers have an additional 288 requirements.



Percent & Number of Regulations, by Domain

- **7** - Billing & Coverage
- **8** - Program Integrity
- **26** - Health IT/ Meaningful Use
- **288** - Post-acute Care
- **96** - Hospital Conditions of Participation CoP
- **78** - Privacy & Security
- **58** - Quality Reporting
- **52** - Fraud & Abuse
- **16** - New Models of Care

$7.6 MILLION

per community hospital spent annually to comply

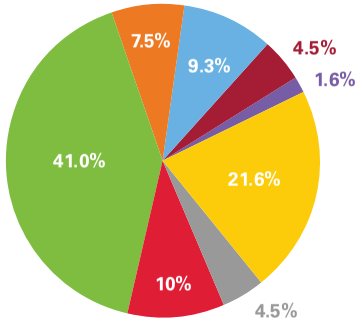
- This figure rises to $9 million for those hospitals with post-acute care.
- For the largest hospitals, costs can exceed $19 million annually.
- The average hospital also spends almost $760,000 annually on the information technology investments needed for compliance.

Patients are affected by excessive regulatory burden through:

- Less time with their caregivers
- Unnecessary hurdles to receiving care
- Higher health care costs.

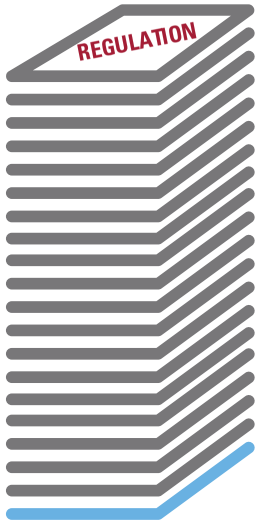
Medicare conditions of participation (CoP), billing and coverage determinations are the most costly areas:

- The Medicare COPs are important to ensure that care is provided safely and meets standards.
- However, these requirements need to be evaluated carefully to ensure they actually improve safety.
- Existing guidance to simplify billing and coverage determinations should be adopted universally by payers and others to achieve savings.



Percent of $7.6 Million per Hospital Spent on Regulatory Burden

- $1.6M - Billing & Coverage
- $570K - Privacy & Security
- $340K - Program Integrity
- $710K - Quality Reporting
- $760K - Health IT/ Meaningful Use
- $340K - Fraud & Abuse
- $120K - New Models of Care
- $3.1M - Hospital COPs



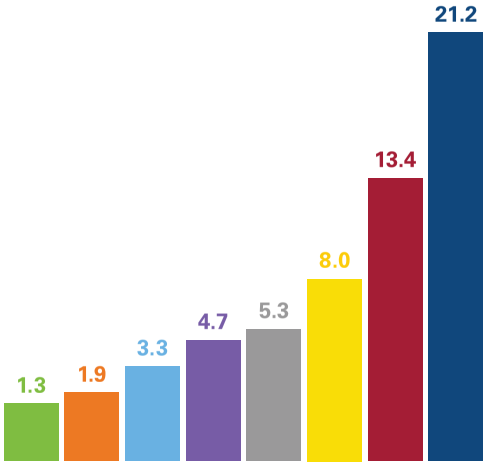
Regulatory burden costs

$1,200

every time a patient is admitted to a hospital

15 doctors & nurses per hospital for compliance

- 59 full-time equivalent staff are required in each hospital to meet the demands of regulations.
- Over one-quarter of these FTEs are doctors and nurses, who could otherwise be caring for patients.



FTEs Dedicated to Regulatory Burden per Hospital

- Legal
- Health IT Professional
- Physician (MD, DO)
- Management
- Compliance
- Nursing Allied Health
- Other Staff
- Other Administrative

Source: Data from the American Hospital Association Report: Regulatory Overload - Accessing Regulatory Burden on Health Systems, Hospitals and Post-acute Care Providers.

Reducing regulatory requirements will allow providers to focus on patients, not paperwork.

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