



Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals and Post-acute Care Providers

Executive Summary

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.

“ 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 (see box). 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. 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. Looked at in another way, regulatory burden costs \$1,200 every time a patient is admitted to a hospital.

3. **An average size hospital dedicates 59 FTEs to regulatory compliance, over one-quarter of which are doctors and nurses.**

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

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 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 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

Scope of Regulatory Burden Study

This report assesses the administrative impact that existing federal regulations from just four agencies – CMS, OIG, OCR and ONC – have on health systems, hospitals and post-acute care providers across nine domains:

1. Quality reporting;
2. New models of care/value-based payment models;
3. Meaningful use of electronic health records;
4. Hospital conditions of participation (CoPs);
5. Program integrity;
6. Fraud and abuse;
7. Privacy and security;
8. Post-acute care; and
9. Billing and coverage verification requirements.

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.

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

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. Given these findings, we have several general recommendations to reduce administrative requirements without compromising patient outcomes, both overall and within each domain.

- 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;
- Meaningful use 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, found on the next page.

AHA Recommendations for Immediate Regulatory Relief

The AHA has identified specific activities Congress and the Administration should take immediately to reduce regulatory burden and enhance care coordination, without negatively impacting patient care.

These include:

- Suspend the faulty **hospital star ratings** from the *Hospital Compare* website.
- Cancel **Stage 3 of meaningful use** of electronic medical records.
- Suspend all regulatory requirements that mandate submission of **electronic clinical quality measures**.
- Rescind the **long-term care hospital 25% rule** and instead rely on the site-neutral payment policy to bring transformative change to the field.
- Restore compliant codes that count to the **inpatient rehabilitation facility 60% rule**.
- Expand Medicare coverage of **telehealth** by removing outdated restrictions on the types of technologies covered, types of services reimbursed and locations services are provided.
- Prohibit enforcement of **direct supervision** requirements.
- Provide more regulatory flexibility in **payment reform models**, such as providing waivers for restrictive rules that stymie the redesign of episodes of care across provider settings.
- Eliminate the “**96-hour rule**” as a condition of payment for critical access hospitals.
- Modify **Medicare conditions of participation** to allow hospitals to recommend post-acute care providers.
- Create a new exception that protects any arrangement that meets the terms of an Anti-Kickback Statute safe harbor for **clinical integration** arrangements.
- Remove the mandatory free-text field from the **Medicare Outpatient Observation Notice** (MOON) and eliminate the confusing Second Important Message from Medicare.

These recommendations, and others, are more fully described in AHA letters to [President Trump](#), [CMS](#) and [Congress](#), available at www.aha.org/regrelief.