Regulatory Overload

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

Analytics and research support provided by manatt

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American Hospital Association®

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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 equivilants (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 technoloty (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.

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

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. 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*.

Introduction

Every day, health systems, hospitals and post-acute care (PAC) providers confront the daunting task of complying with a mountain of federal regulations. Providers appreciate that federal regulation is intended, in large part, to ensure that health care patients receive safe, high-quality care; they prioritize regulatory review, monitoring and compliance as a critical part of their day-to-day work. But close to 24,000 pages of hospital and PAC-related federal regulations were published in 2016 alone, and staff are constantly challenged to understand and implement new or revised regulations while maintaining their core mission of providing high-quality, high-value patient care and addressing community health needs.[1] According to one report, administrative costs, including those associated with adopting and complying with health care regulations, account for 25 percent of annual hospital spending in the United States, or more than $200 billion.[2]

> "Every time something changes, there's a 'cognitive slowdown' to figure out what's being required now… It's an added salary to do this without any added clinical benefit."
>
> - Montefiore Health System

The burden is only growing. The issuance of new federal regulations has accelerated over the past decade with the enactment of major health care legislation intended to improve patient care, population health and fiscal accountability. These include the Health Information Technology for Economic and Clinical Health Act (HITECH), the Affordable Care Act (ACA), the Improving Medicare Post-Acute Care Transformation Act (IMPACT) and the Medicare Access and CHIP Reauthorization Act (MACRA). These laws and their implementing regulations require health systems, hospitals and PAC providers to report hundreds of quality, patient experience and service utilization metrics across multiple domains; implement new technologies or care management processes; and be more accountable for total cost of care. The proliferation and breadth of regulatory changes being made has begun to exceed many providers' ability to absorb them. Additionally, many of these new laws and regulations do not account for existing fraud and abuse laws and regulations, which have not evolved to reflect the movement to new care delivery models, creating barriers to innovation and making compliance with regulatory requirements challenging, inefficient and cumbersome. Perhaps most importantly, many of these regulations do not improve the quality of patient care or access to services, a point which is highlighted in this report's patient impact profiles.

The Paperwork Reduction Act (PRA)[3] of 1980 was designed to help mitigate the administrative burden generated by new regulations by providing an objective assessment of the impact a proposed or final rule has on public reporting requirements. However, the PRA looks at regulations on an individual basis. It does not take into account the additive effect of complying with multiple federal regulations issued by a variety of federal agencies, including but not limited to the Centers for Medicare & Medicaid Services (CMS), the Office of the Inspector General (OIG), the Office for Civil Rights (OCR) and the Office of the National Coordinator for Health Information Technology (ONC). Nor does the PRA consider whether federal regulations conflict with one another, or take into account state regulatory requirements or other burdens imposed by regulations governing Medicare Advantage and Medicaid managed care that are

Paperwork Reduction Act

Over time the number of federal agencies with both new authority and new reporting and record-keeping requirements has increased significantly. In turn, this growth created a substantial burden on the public to provide information. The PRA[4] was intended to diminish this growing paperwork burden related to requests for information by or for the federal government, much of which is now transmitted electronically.[5]

The PRA aimed to achieve this goal by requiring agencies to submit an Information Collection Request to the Office of Management and Budget (OMB) that describes the type of information requested, provides a reason for the request, and estimates the time and cost for the public to complete the request. The OMB must approve all federal agency requests which may impose a burden on the general public, where burden is defined as anything but "that is necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument."[6]

There is some evidence that the PRA does not seem to be working. Despite the PRA, the number of burden hours attributed to information collection, as reported in the annual Information Collection Budget, has increased steadily.[7] New requirements are passed without any efforts to streamline, combine or address the existing information collection burden.[8]

Additionally, the PRA does not account for duplicative cross-agency reporting requirements, such as from CMS, OIG, OCR and ONC, or any state regulatory reporting requirements, all of which have consistently increased over the past decade.

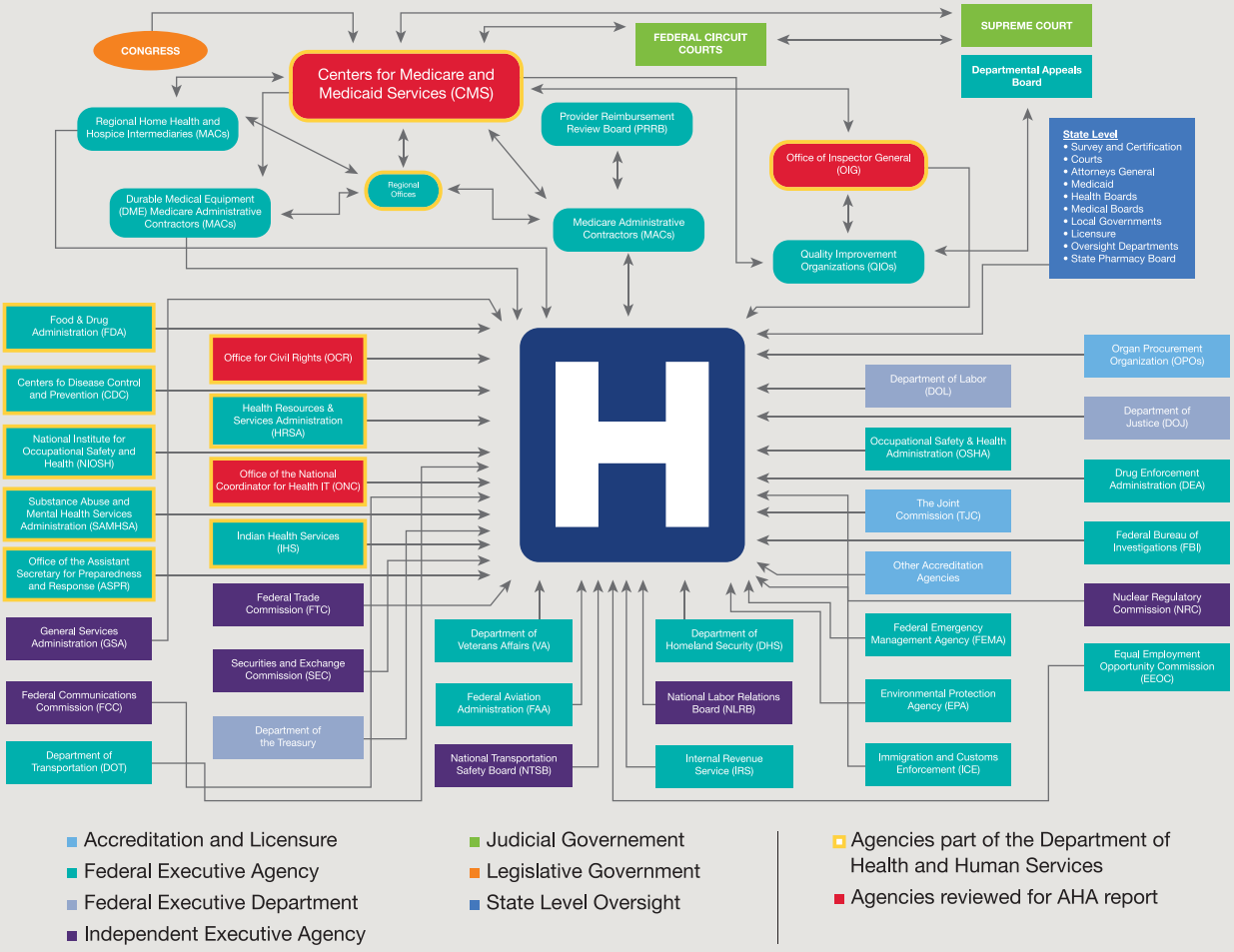
Therefore, the solution is not to analyze the reporting, or "paperwork" burden in isolation, nor, is it to focus solely on paperwork, as many of these regulations impose major administrative burden but do not require the production of additional paper or reporting. This is critical in the context of regulatory burden relief for health systems, hospitals and PAC providers, particularly during a transformative period in federal and state health care policy, when additional and revised laws and regulations are commonplace.

While the current administration has signaled its intent to provide federal regulatory relief by reviewing or delaying all pending or recently issued regulations and by requiring the repeal of two existing regulations for every newly issued rule (the "two for one" rule),[9] meaningful regulatory reform will require a focused review of hospital and PAC regulations to identify those that impose a substantial administrative burden with little or no added value to patient access, quality and safety.

imposed on providers through contracts. As a result, the PRA does not adequately measure the administrative burden that new or revised regulations impose on health systems, hospitals and PAC providers. Further, the actual impact on a particular provider will vary based on several factors, including the size, location and technical capacity of the provider; the provider's operational constraints; the number of agencies imposing regulations and the implementation time frames.

This report seeks to inform policymakers, lawmakers and the public about the administrative impact federal regulatory requirements have on the ability of health systems, hospitals and PAC providers to furnish high-quality patient care, and to offer a starting point for discussions on implementing meaningful regulatory reform. Reducing regulatory requirements that do not contribute to improved patient care will enable providers to focus on patients, not paperwork, and reinvest resources in improving care, improving health and reducing costs.

Figure A. Federal Agencies with Regulatory Authority Impacting Health Systems, Hospitals and PAC Providers



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

This report assesses the administrative impact that existing federal regulations have on health systems, hospitals and PAC providers across the following nine domains (which are further defined and described in Appendix A):

1. Quality reporting;
2. New models of care/value-based payment (VBP) models;
3. Meaningful use (MU) of electronic health records (EHRs);
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.

To complete this assessment, we reviewed the Federal Register and the U.S. Code of Federal Regulations for regulations impacting hospitals and PAC providers across the nine domains. Just four agencies - CMS, OIG, OCR and ONC - are the primary drivers of federal regulation impacting these providers, though hospitals and PAC providers are subject to regulation from a range of federal and state entities (see Figure A). We then

reviewed each section of the regulations and identified discrete regulatory requirements that generate one or more administrative activities, such as:

- Creating, revising or expanding administrative policies and work flows;
- Documenting and monitoring compliance with policies and work flows;
- Hiring staff, consultants and vendors to support administrative compliance activities, such as extracting and reporting data;
- Developing and conducting trainings on administrative requirements for clinical and non-clinical staff;
- Issuing or revising and disseminating new patient notices;
- Interpreting and identifying the compliance risks associated with new regulations; and
- Purchasing or upgrading health IT.

We then catalogued 773 regulatory requirements from the four agencies that generate such administrative activities, ultimately analyzing 629 final, mandatory regulatory requirements that were in effect as of March 2017.[10,11] Figures B and C illustrate how the 629 regulatory requirements were categorized by domain. These include 341 hospital-related requirements and 288 PAC-related requirements. Hospitals that provide the full spectrum of PAC services[12] are subject to all 629 regulatory requirements.

Based on this research, we developed and issued a survey to a sub-set of American Hospital Association (AHA) members requesting information regarding the administrative burden imposed by the regulations in each of the domains. A primary goal of the survey was to quantify the full-time equivalent

Figure B. 341 Hospital-related Regulatory Requirements by Domain

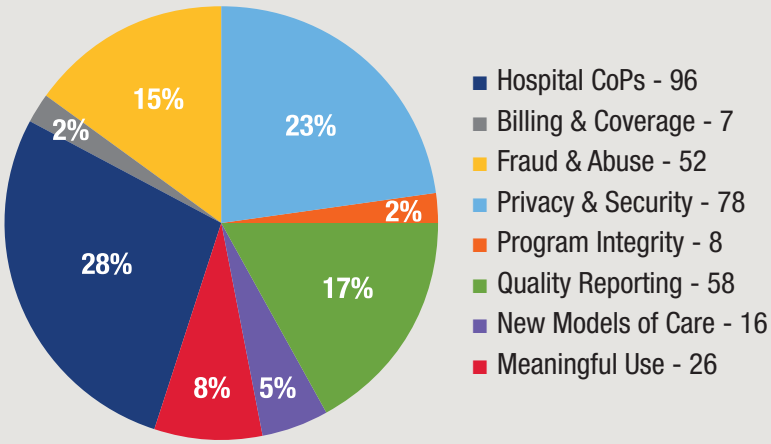


Figure C. 629 Hospital and PAC-related Regulatory Requirements by Domain

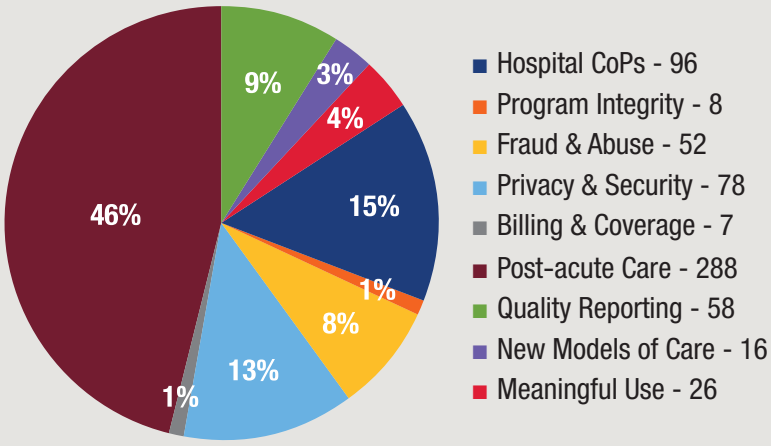


Table 1. Hospital Size Distribution, by Bed Count

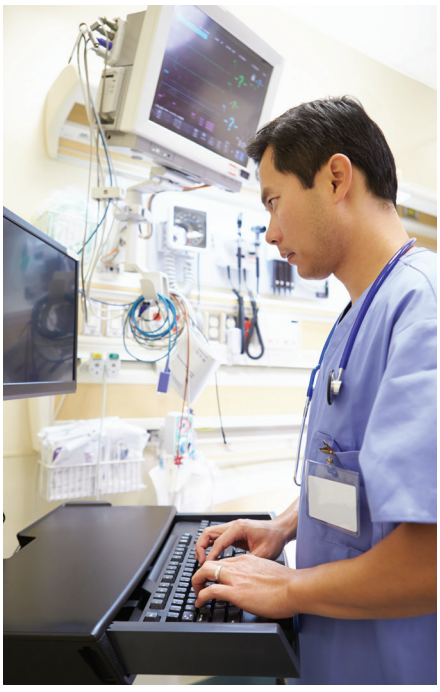
Number of hospital unit beds	Number of hospitals in each group
<50	41
50 - 99	29
100 - 199	38
200 - 299	43
300 - 399	39

(FTE) and dollar impact of the administrative responsibilities associated with compliance with federal regulations. For each regulatory requirement included in the survey, respondents were asked to estimate the number of FTEs and dollars spent on vendors/consultants, IT and other resources dedicated to ensuring administrative compliance with requirements, ***excluding*** **time and resources associated with (a) the clinical component of the regulation and (b) compliance with any similar state or accreditation requirements.**[13] Further, respondents were asked to estimate the breakdown of FTE type (clinical, executive, IT, legal and compliance, business office) across all the resources devoted to compliance. The calculations performed in this report relating to the cost of FTEs are based on statistics provided by the Bureau of Labor Statistics (BLS).[14] Therefore, a hospital's actual salary cost for a particular FTE may be different.

Survey respondents represented a total of 190 individual hospitals. Of these, 166 (87 percent) were part of a health system and 25 (13 percent) were independent acute-care hospitals. Responding hospitals were distributed across 31 states; 25 of the responding hospitals were from rural regions. The 13 health systems reported aggregate numbers that represented all of their hospitals and PAC beds, when applicable. Of the respondents, 11 health systems and 11 independent acute care hospitals had PAC beds, totaling over 1,500 PAC beds across inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs) and long-term care hospitals (LTCHs). Finally, 12 systems and 11 hospitals were affiliated with home health agencies (HHAs).

For system respondents, in order to obtain per-hospital numbers for purposes of analysis, we divided responses by their total number of hospital unit beds in the system, and then multiplied this number by the bed size for each individual hospital within the system. The same methodology was used to make geographic determinations (urban/rural), coupled with geographic data and bed counts provided from the AHA's Annual Survey. Appendix B explains the detailed survey methodology.

Individual hospitals ranged in size from 8 to 1,175 staffed beds. The distribution of hospital size by bed count is shown in Table 1.



To gather on-the-ground insights on the administrative burden experienced by health systems, hospitals and PAC providers across the nine domains, interviews were conducted with 33 senior leaders at four health systems:

- Ascension Health (St. Louis);
- CoxHealth (Springfield, Mo.);
- Kalispell Regional Medical Center (Kalispell, Mont.); and
- Montefiore Health System (Bronx, N.Y.).

The organizations were selected to represent a broad cross section of providers, including providers serving rural and urban communities; small and large health systems and hospitals; and providers with PAC facilities, both co-located with the hospital and stand-alone facilities. The interviewees were identified by the organization based on their knowledge of and experience in the nine domains.

Assessing the Impact of Regulatory Compliance on Providers and Patients

Health systems, hospitals and PAC providers spend nearly $39 billion each year on the administrative activities related to regulatory compliance. This translates into nearly $7.6 million annually for an average-sized community hospital (161 beds) and rises to $9 million for hospitals with PAC beds. As a result of this extraordinary burden, providers are struggling to balance the administrative activities necessary to comply with regulatory requirements against the clinical, operational and financial activities necessary to fulfill their clinical missions. Despite investing significant resources to comply with federal regulations, these providers feel overburdened with regulatory requirements, many of which have limited direct positive impacts on patient care. Indeed, some requirements can create unintended consequences for patients, as illustrated in the "Meet Debbie" stories.

We also found that:

- Physicians, nurses and allied health professionals are being pulled away from patient care to instead focus on regulatory compliance. Clinical staff comprise over one-quarter of the FTEs dedicated to regulatory compliance;
- CoPs and billing/coverage verification processes are the most burdensome of the nine domains analyzed;

Meet Debbie: An Introduction

Debbie is a 75-year old Medicare beneficiary. She has diabetes and high-blood pressure and takes several medications. She lives alone, and her daughter, who lives an hour away, helps to care for her. Recently, her physician told her she needs a hip replacement. Debbie wants the procedure done soon, so that she is fully recovered before her granddaughter's college graduation.

The following examples will check-in with Debbie as she undergoes her procedure and recovery to assess how regulatory burden can impact the delivery of care.

Table 2: Estimated Burden of Compliance with Regulatory Requirements for a Typical Community Hospital

Per-hospital estimate: Typical community hospital*	Staff FTEs	Up Front IT Cost	Staff Salaries	Vendors	IT-Related	Other (Training, Education)	Total Cost (By Domain)	% Of Total Cost
Hospital CoPs	23.2	$55,379	$2,600,846	$258,350	$67,605	$181,251	$3,108,052	41.0%
Billing & Coverage	17.2	$121,902	$1,229,161	$298,976	$69,382	$43,527	$1,641,046	21.6%
Meaningful Use	4.8	$410,687	$661,190	$28,353	$58,839	$11,307	$759,689	10.0%
Quality Reporting	4.6	$14,884	$605,541	$53,708	$19,197	$30,245	$708,691	9.3%
Privacy & Security	3.5	$140,553	$434,398	$35,651	$72,742	$26,680	$569,471	7.5%
Fraud & Abuse	2.3	$8,356	$277,417	$49,727	$8,800	$3,708	$339,652	4.5%
Program Integrity	2.8	$4,467	$263,533	$48,942	$12,004	$12,900	$337,379	4.5%
New Models of Care	0.6	$1,170	$82,578	$10,566	$7,117	$21,512	$121,774	1.6%
Total cost (by cost center)	59.0	$757,400	$6,154,663	$784,273	$315,687	$331,129	$7,585,752	
		% of total cost	81.1%	10.3%	4.2%	4.4%		

*Extrapolated to a typical hospital by scaling respondent responses to a per-bed figure and then multiplying by average number of beds among community hospitals (161 beds, according to 2015 AHA Annual Survey). Excludes costs related to PAC regulations.

- Quality reporting requirements are often duplicative and have inefficient reporting processes, particularly for providers participating in value-based purchasing models;
- Fraud and abuse laws are outdated and have not evolved to support new models of care, in some cases, compromising patients' access to care;
- Meaningful use has spurred provider investment in IT systems, but exorbitant costs and ongoing interoperability issues remain; and

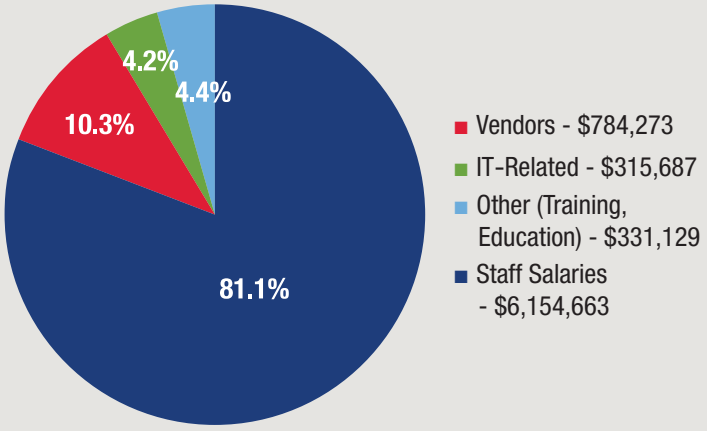
- The timing and pace with which regulations are issued creates burden in and of itself.

The quantitative research findings from the AHA member survey are shown in Table 2.

Nationally, health systems, hospitals and PAC providers spend nearly $39 billion on the administrative aspects of regulatory compliance.

Extrapolating the administrative cost estimates we obtained from our survey to all hospitals in the United States, we found that health systems, hospitals and PAC providers dedicate approximately $38.6 billion (excluding additional IT investments related to MU) each year to comply with the administrative aspects of regulatory compliance in just the nine domains we analyzed. As high as it is, this figure does not represent the full regulatory burden these providers face, as it does not take into account additional costs for activities that were outside the scope of this analysis, such as compliance with regulations that are not part of the nine domains or that were issued by other federal and state agencies (such as the Food and Drug Administration, et al.).

Figure D. Average Annual Spending by Cost Center



To set these figures in context, an average-sized community hospital (161 beds) spends nearly $7.6 million annually on administrative activities to support compliance with the reviewed federal regulations. This rises to $9 million for those hospitals with PAC beds. For the largest hospitals, those with at least 400 beds, the cost is even more astonishing – $18.8 million or more annually. In addition to these amounts, the surveyed hospitals reported making additional IT investments of almost $760,000 per hospital, or $3.7 billion nationally.

On a more granular basis, this figure translates into an annual cost of over $47,000 per hospital bed. It also means that for every time a patient is admitted to the hospital, there are almost $1,200 in regulatory costs. Staff salaries accounted for the majority of these costs – over 80 percent (see Figure D).

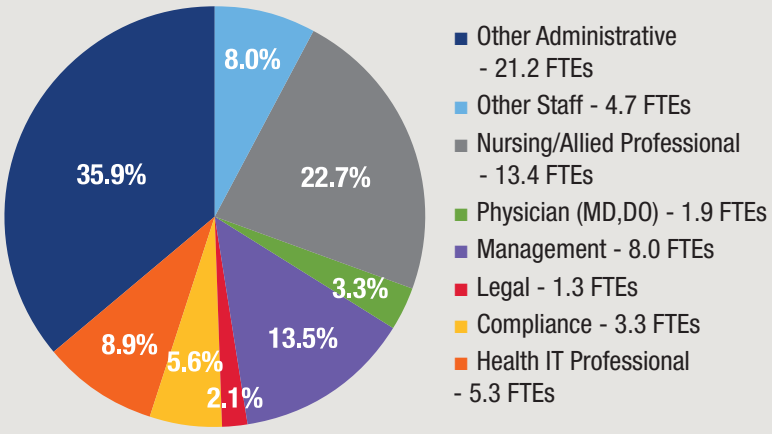
We also found that health systems benefit from economies of scale. Hospitals that are part of larger systems incurred a total of $5.1 million in costs per hospital, compared to $8 million for individual hospitals that were not part of a system.

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.

Physicians (e.g., M.D., D.O.) and nursing/allied health professionals (e.g., registered nurses, physician assistants, nurse practitioners) accounted for 26 percent of FTEs needed to comply with the federal regulations surveyed (see Figure E). Specifically, of the 59 FTEs that a typical hospital devoted to administrative activities related to regulatory compliance across the nine domains surveyed, 1.9 were physician FTEs and 13.4 were nursing/allied health professional FTEs. Health systems and hospitals with PAC beds devote an additional 8.1 FTEs to compliance with PAC regulatory requirements, of which over half were clinical staff.

Health systems and hospitals noted that this number of FTEs had grown tremendously over the past 10 years in order to keep up with understanding and complying with regulatory requirements. Interviewees expressed concern that this trend is pulling clinical staff away from patient care responsibilities and the providers' clinical missions. Specifically, hospital CoPs administrative compliance activities place significant demands on these clinical staff, with 45 percent of these administrative activities being performed by physicians, nursing and allied health professionals (see Figure F). Several hospitals reinforced this finding, stating that their clinical staff are spending increasing amounts of time on administrative activities related to regulatory compliance with the CoPs, such as designing and implementing new processes and participating in mandatory trainings. This significantly limits the time they could be spending with patients.

Figure E. Percent and Number of Average FTEs by Professional Category

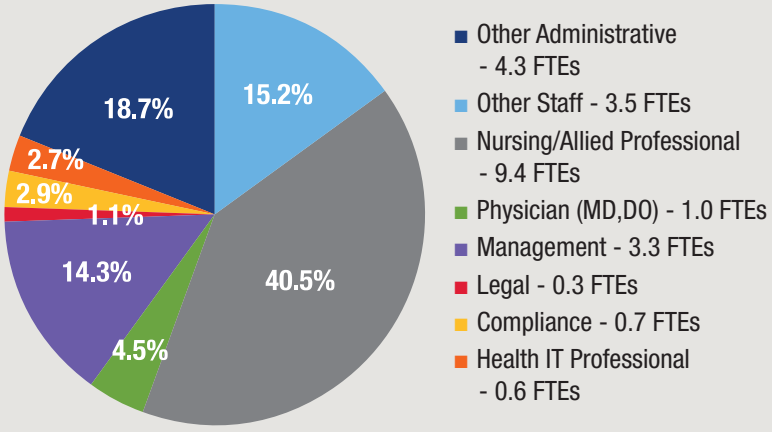


Documenting CoP adherence and billing/coverage verification processes are the most burdensome of the nine domains.

Over two-thirds of hospital regulatory compliance staff and over 63 percent of compliance costs are devoted to hospital CoP adherance and billing and coverage verification requirements, making these two domains the most burdensome of the nine we examined (see Figures G and H).

In addition, the resources dedicated to complying with the administrative aspects of the billing and coverage verification rules are disproportionate to the regulatory requirements in this area. Specifically, this domain accounts for only 2 percent of the 341 hospital-

Figure F. Division of Roles and Responsibilities for Hospital CoP Activities by Percent and Number of Average FTEs



related regulatory requirements (excluding regulations relating to PAC), but 22 percent of the total average annual cost (see Figure I).

Hospital CoPs

The Medicare CoPs require providers to adhere to established health quality, safety and operational standards in order to participate in the Medicare programs. There is tremendous value in the CoPs to ensure the safe delivery of care; however, the administrative components to certify that hospitals adhere to all standards presents a growing burden to providers. On average, hospitals spend $3.1 million for administrative compliance activities on hospital CoPs, representing the most costly of the nine domains.[15,16] Most of the $3.1 million was comprised of staff salaries ($2.6 million), but hospitals also spend, on average, $507,000 annually to support and supplement their staff in meeting hospital CoP requirements, including through engaging contractors, purchasing, maintaining and upgrading technology, and training and education.

These costs reflect the large number of administrative activities associated with meeting the hospital CoPs, including:

- Establishing medical staff policies and procedures around hospital governance structures and responsibilities;
- Developing patient notices to inform patients of their rights and responsibilities;
- Creating and implementing staff trainings around using restraints and seclusion;
- Implementing and testing emergency preparedness programs;
- Maintaining and storing medical records; and

Figure G. Percent of Average FTEs by Regulatory Domain

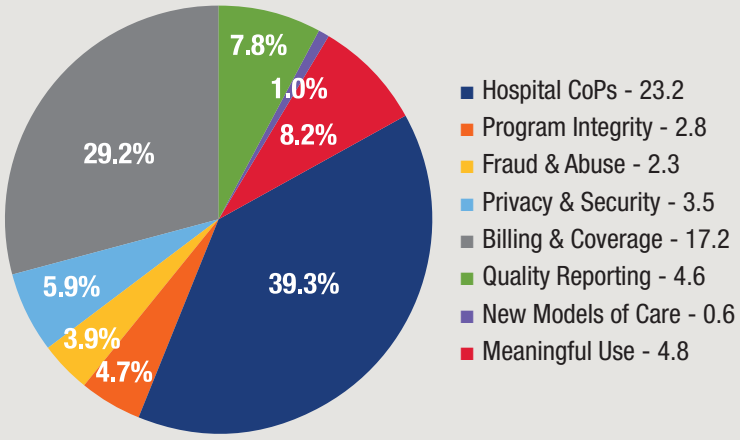


Figure H. Average Annual Costs by Regulatory Domain

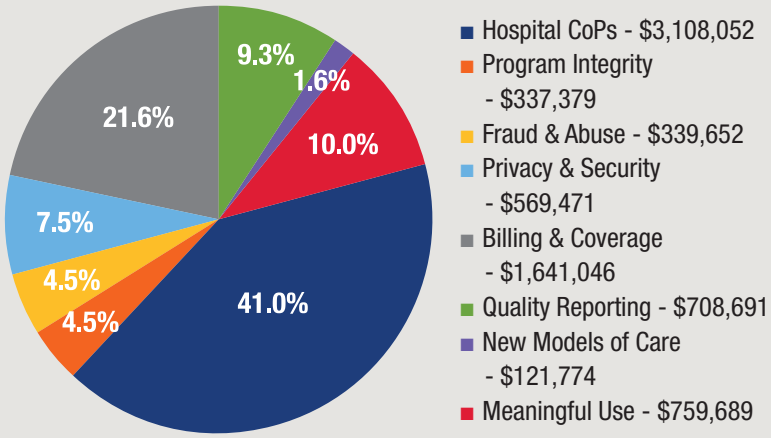
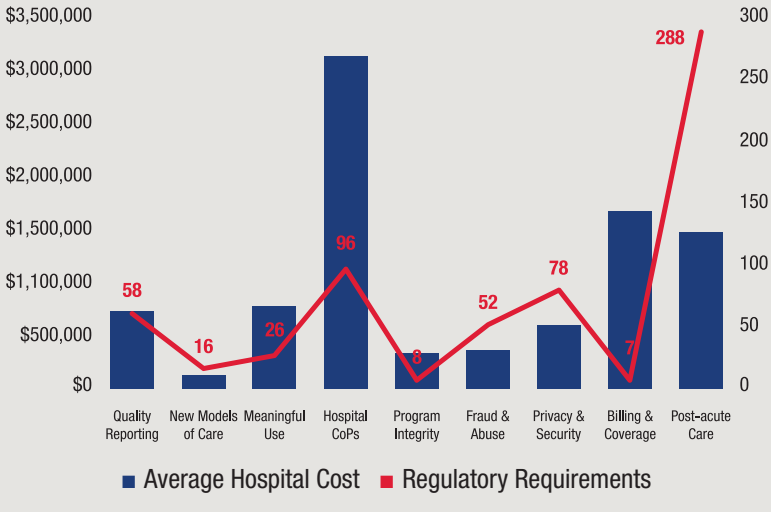


Figure I. Number of Regulatory Requirements by Domain and Annual Regulatory Burden Costs



Meet Debbie: Conditions of Participation Limit Care Coordination

After Debbie's procedure, she will look to her care team to provide direction regarding next steps in her recovery. While her doctor and nurses will share an individualized care plan with Debbie, they would like to be able to recommend a well-regarded PAC provider to assist in her recovery. However, they are unsure if they can recommend specific care providers due to language in the Medicare CoPs.

Patient impact: *While Debbie will be provided a list of providers that can provide PAC after she is discharged from the hospital, that could be stressful because she may not feel she has enough information to make an informed decision. Under some of CMS's new care models, hospitals may provide information to patients about providers with whom they actively coordinate patient care, but it is not clear whether this is permissible outside the parameters of the care model.*

- Designing, communicating and implementing quality assurance and performance improvement (QAPI) and infection control programs.

However, most hospitals also make considerable additional human and financial investments through voluntary activities associated with accrediting organizations; participation in patient safety organizations, federal government and state hospital association quality improvement projects; and hospital or system-specific initiatives. As such, even the $3.1 million represents only a portion of the resources a hospital dedicates to administrative requirements related to quality and safety.

Health systems that include PAC providers, and PAC providers themselves, must comply with even more requirements. For example, health systems that include SNFs and HHAs as part of their care continuum must comply with additional CoPs specific to those provider types; like hospital CoPs, these PAC CoPs impose administrative requirements on every aspect of their operations. Health systems and hospitals with these and other PAC settings also must comply with a myriad of conditions of payment. For example, HHAs must complete an OASIS patient assessment tool at least two to three times per patient episode. The OASIS tool contains more than 60 questions, many of which have multiple data points. These questions are only a subset of the HHA's comprehensive assessment which must be completed at the same frequency. IRFs must comply with the "60 percent" rule and the LTCHs with the "25 percent" rule, both of which necessitate FTEs and dollars dedicated to daily tracking of compliance with these requirements.[17]

While the CoPs serve an essential role, the processes for adopting, implementing, and assessing compliance with them provide numerous opportunities to minimize inefficiencies and waste:

- Variation between agencies and/or surveyors in the interpretation of how to meet specific standards consumes enormous time and effort as hospital staff seek clarity;
- New regulations that require investment in certain types of products or technologies often result in shortages; and
- Requirements that do not keep pace with the evolving health care delivery system make it challenging for hospitals to provide the best care.

Billing and coverage verification requirements

Billing and coverage verification is essential to ensuring that the care health systems, hospitals and PAC providers give patients is covered by their insurance and adequately paid; coordinating these benefits for thousands of patients through

paperwork and phone calls has long been a burdensome process. On average, hospitals spend $1.6 million annually on billing and coverage verification, representing the second most costly of the nine domains. While much of this $1.6 million is dedicated to staff salaries, 18 percent of it is being spent on outside contractors or consultants. In fact, over half (52 percent) of hospitals and health systems surveyed relied on outside contractors for eligibility verification of member enrollment and disenrollment in a health plan, and 39 percent relied on such contractors for confirming benefit coverage by a health plan.

We found that although there have been administrative simplification efforts intended to streamline the burden of manual benefits coordination, they have not gone far enough. At their core, the administrative simplification standards are intended to enable electronic communication between health plans and health systems, hospitals and PAC providers, reduce providers' paperwork burden, facilitate more timely access to care, such as through quicker prior authorization determinations, and enable providers to be paid more quickly. However, many inconsistencies remain. For example, many health plans do not use a common electronic transaction standard for prior authorization,[20] requiring providers to instead utilize web portals, fax machines, email, and spend time on the phone to submit required information. Because some payers, government agencies and others have not implemented certain billing and coverage verification activities that would create efficiencies, the providers who have invested resources in compliance — and more importantly, their patients – do not reap the full benefits of administrative simplification. One study found that, in 2016, health plans and providers could have saved an estimated $9.6 billion if the standards were universally adopted.[21]

In addition, the regulatory burden associated with billing continues even after a health system, hospital or PAC provider is paid. There are multiple – and redundant – third-party entities that contract with CMS and other payers to audit bills for compliance and medical necessity. These auditors may then take back payments from providers for services already rendered. Providers must utilize additional resources and staff time to respond to these post-payment audits that evaluate how well the health system, hospital or PAC provider met billing requirements. Responding to multiple audit programs not only imposes administrative burden, but also ties up funds in lengthy audit and appeals processes in cases when auditors make inappropriate determinations. These are additional resources not available to enhance patient care.

Meet Debbie: Delays and Compromises in Care Due to Coverage Verification

Debbie needs to schedule her upcoming hip replacement surgery. However, she cannot finalize the surgery until she knows that the hospital is an "in-network" provider for her health plan and how much will be covered by her insurance. She, like most patients, cannot afford large out-of-pocket costs associated with a surgery. The hospital admissions department expeditiously confirms Debbie's eligibility and requests prior authorization from her health plan. However, less than 1% of health plans use this transaction to respond electronically[18], and instead require manual uploads through the health plan's portal.

Patient impact: *Due to the inefficient prior authorization process, Debbie experiences physical pain by having to wait for her surgery for three weeks and anxiety about the potential costs. She worries, too, that she will not recover in time for her granddaughter's graduation. These negative experiences could have been avoided if the health plan had implemented the administrative simplification standards that enable electronic communications, reducing her wait time from several weeks to three to five days.*[19]

Meet Debbie: Quality Documentation and Reporting Burdens Limits Staff's Time to Interact with Patients

After Debbie's hip surgery, she will need physical therapy in her home. As part of the hospital's discharge plan, they will refer her to a home health agency of her choice. During Debbie's admission, her physicians, nurses and allied health professionals had to document every aspect of her care. While Debbie may not have noticed, her caregivers felt that they would have liked to spend more time with her to ensure she was fully comfortable with her individualized care plan. However, due to administrative and documentation requirements and ongoing case loads, the doctor had to move on to the next task, while assuring Debbie that she would return later to answer any questions. In addition to documenting the care provided to Debbie, the hospital had to report electronic and manually-abstracted data associated with Debbie's surgery for quality reporting programs.

Patient impact: *Debbie spends less time with her physicians, nurses and allied health professionals because an increasing amount of their time is spent documenting and entering data for quality and other reporting programs. In fact, almost 50% of a physician's workday is spent on data entry and other administrative desk work, while only 27% is spent on direct clinical face time with patients.*[30] *In addition, substantial investments in health IT and staff to pull, report and validate the data are large investments that cannot be used to improve care delivery through increasing staff, providing clinical training, modernizing the facility and upgrading hospital equipment. Furthermore, questions remain regarding whether the reported quality metrics are actually ones that enable the evaluation of quality.*

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

Quality reporting requirements create duplication of effort and inefficiency, with unknown patient benefit.

CMS has required hospitals to report quality metrics for many years. Health systems, hospitals and PAC providers encourage this drive toward improving quality of care, but duplicative and misaligned reporting requirements, many of which require manual data extraction, create inefficiency and consume significant financial resources and clinical staff time. For example, in the past decade,[22] CMS has greatly expanded hospital[23] and PAC quality reporting requirements: in 2019, hospitals will have more than 80 measures to report for CMS hospital quality measurement, a number that does not include measures related to PAC or for physician performance.[24] In addition, inpatient psychiatric facilities, end-stage renal disease centers, ambulatory surgical centers and each PAC setting have their own quality reporting programs. Not surprisingly, significant financial resources are being consumed by these activities. On average, hospitals spend approximately $709,000 annually and devote 4.6 FTEs – over half of whom are clinical staff – on administrative aspects of quality reporting.

Unfortunately, these quality reporting metrics do not always provide new data to CMS; instead, they require health systems, hospitals and PAC providers to report the same data or subsets of data several different ways and times. In a 2013 study, the AHA examined the challenges of quality reporting and the burden imposed on hospitals; the concerns identified then continue today.[25] For example, hospitals participating in both the Hospital Inpatient Quality Reporting Program (HIQRP) and the MU program described how the two programs defined the same measure differently and required reporting using two different submission methods to two different CMS divisions. CMS recently relaxed the amount of quality reporting required for MU; however, health systems and hospitals must continue to invest the time to collect and report the quality measures electronically, and question whether these measures improve patient care.[26]

Hospitals submitting electronic clinical quality measures (eCQMs) in the HIQRP and the EHR Incentive Programs report several concerns, including the inability of EHRs to

capture and reuse information gathered during the course of care for eCQM reporting, difficulty with bringing information from other departments' information systems into the EHR, and the need to modify clinical workflows to support data capture for eCQM reporting.[27] eCQM measure specifications also can change in substantive ways from year to year, causing health systems and hospitals to use significant resources to make annual changes to their eCQM data collection and reporting processes.[28] All these efforts do not necessarily produce valid data, as there are concerns about the current accuracy of eCQMs.[29]

> "We report on over 200 different quality metrics across all payers, including Medicare fee-for-service and the various VBP programs in which we participate [e.g., the Medicare Shared Savings Program, Comprehensive Primary Care Program Plus, et al].
>
> - Ascension Health

Many of the measures that health systems and hospitals must report may not lead to better identification of opportunities to improve care. The purpose of quality measurements is twofold: 1) to provide patients and community members with information enabling them to make informed choices when selecting a provider, and 2) to highlight areas where a hospital or health system can focus energy and resources to support better patient outcomes. Both purposes are well-served if measures are well-constructed, based on the best available science, and focused on issues of critical importance to patient outcomes and patient safety. The current number of reported measures is not only large, but also may not be the right ones to drive change that will make meaningful differences in patient outcomes. A smaller number of "measures that matter" would decrease burden and increase the value of reporting.

The quality reporting burden is magnified by participation in new models of care/value-based purchasing models.

The transition from fee-for-service to value-based payments has increased the quality reporting burden, as new models of care have their own reporting requirements to evaluate the programs' effectiveness. While many models are voluntary,[31] some are mandatory. For example, participation in the Comprehensive Care for Joint Replacement (CJR) model is currently required for hospitals within 67 selected Metropolitan Statistical Areas (MSAs), though CMS has proposed to reduce the number of mandatory MSAs. Under CJR, hospitals work with physicians and PAC providers to improve quality and coordination from the initial hospitalization related for a hip or knee replacement through the recovery process. In this and other value-based payment programs, CMS holds participating hospitals financially accountable for the quality and cost of an episode of care and incentivizes increased coordination of care across hospitals, physicians and PAC providers. In order to avoid a financial penalty under these programs, in addition to collecting, validating and submitting relevant data, hospitals must create and distribute new patient notices and document every aspect of their relationship with certain providers to avoid fraud and abuse scrutiny. In many instances, hospitals must adopt, implement, or update technology and software in order to be compliant.

Fraud and abuse requirements are outdated and have not evolved to support new models of care, in some cases compromising access to care.

The Stark Law and the Anti-Kickback Statute (AKS) are intended to prevent financial arrangements that steer referrals. However, these laws present significant barriers to the implementation of new models of care that seek to reward value and care coordination. Both laws were envisioned as ways to curb potential abuse of fee-for-service payment, whereas care coordination incentivizes quality, value-driven care. As such, the Stark Law and AKS were not designed to facilitate the types of collaboration and financial alignment of health systems, hospitals, PAC providers and their referral sources that is necessary to be successful under new models of care. Recognizing that these laws may impede care transformation, the federal government authorized CMS to waive certain fraud and abuse laws for providers participating in certain demonstration projects.[32] While providers welcome the waivers, many (most significantly, rural providers) find the disparate and complex processes for each program to be unnecessarily burdensome. Indeed, providers participating in some of the mandatory and voluntary models have incurred significant administrative costs when submitting Stark Law and AKS waiver requests for these programs.

Furthermore, even when a provider does receive a waiver, the exception does not apply beyond the specific demonstration or model.[33] The lack of protections extending care innovations to other Medicare patients or individuals enrolled in Medicaid or commercially-insured

> "The fact that the waivers are essential to successfully participate in these models reflects how antiquated these laws are."
> - Montefiore Health System

plans minimizes the efficiencies and cost savings realized through these types of models and demonstration projects. For example, interviewees cited a desire to build high-performing, narrow provider networks that rely on shared risks and incentives; however, outside of VBP

Primer on the Stark Law and Anti-Kickback Statute (AKS)

The Stark Law prohibits a physician from referring a patient for inpatient, outpatient or other "designated health services" covered by Medicare if the provider to whom the referral is made has a financial relationship with the physician, unless the relationship satisfies a Stark Law exception. Financial relationships may be direct or indirect, and consist of ownership interests or compensation arrangements such as salaried employment, independent contractor compensation or in-kind payments. The Stark Law is a strict liability statute, and any violation requires refunding payments to the government for the services provided pursuant to that self referral and may include harsher penalties.

The AKS is a criminal statute that makes it illegal for any person to knowingly and willfully exchange anything of value in return for or to influence the referral of individuals for items or services covered by a federal health care program, including Medicare and Medicaid. While compliance with a safe harbor is not mandatory to avoid criminal liability, if all the elements of a safe harbor are satisfied, an arrangement is insulated from prosecution. Arrangements falling outside a safe harbor are evaluated on a case-by-case basis to determine whether any remuneration was intended to induce referrals.

The Stark Law and the AKS have specific exceptions and safe harbors, respectively, related to physicians' employment and contractor relationships, and to a hospital's ability to cover physician recruitment and relocation expenses or to provide physicians with incidental benefits, health IT subsidies and other nonmonetary compensation. Meeting these requirements entails extensive documentation, careful contract drafting, and often an external and expensive fair market value assessment to show that compensation to a physician is within a range acceptable to regulators.

Meet Debbie: Fraud and Abuse Regulations Prevent Incentivizing High-value Care Delivery

Debbie's surgery requires a hip implant. These implants vary widely in cost, though there are many lower cost models that have similar efficacy as the more expensive models. While the hospital encourages physicians to utilize models from a pre-approved list, clinicians may use the implant with which they feel most comfortable.

Patient impact: *If Debbie's physician selects a more expensive model, she could potentially face additional out-of-pocket costs, depending on her insurance coverage. While the hospital would like to encourage physicians to select from the pre-approved list of implants, they have been unable to move forward on a program that would share cost-savings derived from selecting high-value implants with doctors due to concerns about whether the program could create a violation of the AKS.*

models, these relationships could be viewed as inducements and are prohibited in the existing regulatory environment.

Complying with the Stark Law and the AKS poses a challenge and requires attorneys, compliance specialists, and market compensation analysts to evaluate each relationship that has the potential to implicate these laws. This evaluation may be required for something as routine as employing or contracting with a physician or making arrangements with specialty practices. The key to compliance with many of the exceptions and safe harbors is ensuring that any payments under the arrangement are consistent with staying within prescribed salary standards for a given position in a given geographical market, which may make it more difficult to recruit providers in certain markets.

While these requirements are burdensome for providers, more importantly, in some cases they negatively impact patients' access to care. For example, patients are negatively impacted by certain AKS requirements. Even some that were recently eased, such as the Local Transportation Safe Harbor, do not go far enough to assist patients and provide them with access to care. Under the Local Transportation Safe Harbor, health systems, hospitals and PAC providers now may provide free or discounted transportation to their patients without the transportation being considered remuneration (or an inducement). But, they can only do so if they do not market or publicly advertise the availability of transportation assistance; as a result, many vulnerable

Disproportionate Impact of Fraud and Abuse Laws on Rural Providers

The Stark Law and AKS burdens are magnified among rural providers, stymying their ability to recruit and retain providers. CoxHealth and Kalispell Regional Health – two rural health systems that have hospitals that serve wide geographic regions – highlighted their challenges in this regard.

The Stark Law and AKS require physician arrangements to be memorialized in a writing signed by the parties to support exceptions to the laws. In addition, for any potentially suspect relationship, the provider must demonstrate the compensation is consistent with fair market value, evaluating all non-monetary compensation, regardless of how small, and ensure that all agreements with a physician made over time cross reference one another.

Rural settings offer a limited number of employers and it is therefore more common that a physician or his or her family member has a financial relationship with a referral or referring entity that triggers Stark implications. For example, a family member has a higher probability of being employed by an entity to which the physician or hospital refers. Physicians also may provide services to a number of a provider entities. These relationships require rural providers to analyze and document compliance with the Stark Law and AKS frequently, but rural providers do not have the scale to employ dedicated legal and compliance support to manage exceptions.

patients may not even know the service is available. In addition, the transportation must be local, and the AKS has defined "local" transportation distance to be 25 miles in an urban area and 50 miles in a rural area. However, for many rural providers, 50 miles is not nearly a large enough distance to provide transportation to many of the patients they serve, which inhibits physical access to care for patients.

The Stark Law and AKS are not the only fraud and abuse laws increasing administrative costs. Due to the concerns regarding fraud and abuse within the Medicare home health program, CMS developed additional requirements to validate that beneficiaries require home health, including a mandate that a physician certify home health eligibility in-person. This requirement has created a redundancy in documentation for patients that move to home health from a hospital. Specifically, HHAs were already required to obtain physician orders and a plan of care signed by a physician who certified that the patient met the home care requirements. For patients coming from the hospital directly into a HHA, requiring additional documentation of a face-to-face encounter between the referring physician and patient, when such an encounter clearly occurred during the preceding hospital stay, is unnecessary and unlikely to prevent HHAs from fraudulently documenting a patient's eligibility for care.

For more information on legal barriers to care coordination, please visit *www.aha.org/regrelief*.

Meaningful use has spurred provider investment in IT systems, but exorbitant costs and ongoing interoperability issues increase provider burden.

The MU program was established in 2009 as part of the HITECH Act. MU requires eligible hospitals and professionals[35,36] to meet certain measures in order to demonstrate meaningful use of certified EHR technology to avoid Medicare payment penalties. For example, if a hospital fails to meet a MU objective, such as use of computerized provider order entry, by a single percentage point the hospital will fail to meet MU and will be exposed to significant payment penalties.[37] That said, there was broad consensus among interviewees that the MU program was effective in moving providers to EHR and to more secure, electronic exchange of patient information.

However, compliance with Stages 1 and 2 of MU has been a heavy lift for health systems and hospitals, due in part to the

Meet Debbie: Meaningful Use Requirements Can Detract from Patient Care

During her stay in the hospital, Debbie noticed that the nurses and doctors spent a lot of time looking at the computer rather than talking to her. Sometimes, it seemed like they were having trouble locating the information they needed quickly, and would be frustrated with the number of screens and clicks they needed to go through. In addition, although her hospital has met the MU requirements and would like to share her records with her PAC provider, the home health agency (HHA) where Debbie receives services cannot receive the electronic files as it does not have the financial resources to invest in this activity and was not a part of the MU program. The hospital defaults to faxing the information. Finally, the hospital shows Debbie how to access her portal before she leaves the hospital. However, Debbie is not tech-savvy and worries about whether she will remember how to access the portal when she is home and not feeling well. She prefers to communicate with her health care providers in person or by phone. Her daughter would like to be able to access Debbie's records online, but finds it frustrating to access a separate portal for each doctor Debbie sees, as well as the hospital portal. Also, she cannot access information from the HHA, as it does not have a portal.

Patient impact: *Debbie feels like the computer is getting between her and her caregivers, as her physicians and nurses are required to spend more and more time performing electronic tasks.[34] Then, when she is discharged, the hospital is unable to share its information electronically with the HHA, resulting in a delay in the HHA receiving the information. Separately, Debbie prefers not to use the patient portal, while her daughter is frustrated that she must visit separate portals for each care provider in order to have complete information about her mother's care.*

short implementation timeframe and the need for dedicated staff, extensive investment in health IT systems and process redesign. On average, surveyed hospitals spend $760,000 annually meeting these requirements, most of which is being used to hire and maintain additional staff. Hospitals made additional IT investments averaging $411,000 during the year for MU, an investment more than 2.9 times larger than that made in any other area.[38] These costs do not include the time clinicians now spend entering patient data into EHRs – a significant task that contributes to clinician burn-out and takes time away from patient interactions. In addition, they do not include the time of IT professionals needed to implement and run core systems.

> "It is not add a piece and take a piece away, it is always add 2 or 4 new pieces."
> - Kalispell Regional Medical Center

Finally, the timelines for providers to achieve MU varied widely. Specifically, the timeline for hospitals was aggressive, while the timeline for physicians was more relaxed, and other providers, such as PAC providers and the Indian Health Service, were exempt from MU entirely. Therefore, many health systems and hospitals had the capability to transmit electronic information as required under MU, but could not transmit the information to their referral partners. As a consequence of this inefficiency, as well as others, interviewees felt that administrative challenges associated with MU compliance far exceeded any improvement to a

Challenges of Meaningful Use Across the Care Continuum

Implementing an EHR is one step toward achieving MU standards for a hospital, but achieving electronic data exchange goals is contingent on changes also being adopted by continuum-of-care partners that do not have the same requirements. A lack of care partners with compatible IT systems has magnified the challenges facing hospitals as they strive to meet MU requirements, as evidenced by the experience of Montefiore Health System in Bronx, N.Y. It has 11 hospitals and 180-plus locations across three counties. Montefiore has an established EHR system and successfully met all its MU requirements. The health system has a wide range of partners along the continuum of care and, despite having robust EHR capabilities in place, highlighted the challenges of transmitting electronic data as a significant administrative burden.

For example, hospitals are required to transmit transition of care (TOC) summaries to the next provider of care for more than 10 percent of the patients they discharge. However, many partner providers, such as PAC providers and community physicians, do not have the capabilities to electronically receive these TOC summaries. To meet MU requirements, many health systems reported having to subsidize PAC providers' and community physicians' capabilities to avoid the health system receiving penalties. When subsidy was not possible, hospitals and health systems had to design and implement manual workarounds (e.g., printing and faxing a TOC document on the day of discharge) to meet the regulatory requirement. These workarounds pose an increased administrative and/or financial burden on hospitals and health systems, and hold them accountable for other providers' lack of capability.

Hospitals also are required to successfully acquire and maintain Direct email addresses of providers for secure electronic transmissions (the Direct email standard is required by ONC and CMS). Access to the Direct address information is complicated, as community and PAC providers often do not know their addresses and there is no central directory to consult. Although providers can sometimes get an address from health information exchanges, they are often charged for it. Consequently, the hospital or health system must devote time and resources to chase down addressees in order to avoid penalties. In some cases, community physicians would share the address to meet their own reporting requirements but would not send or accept information through direct messaging, necessitating a manual workaround despite the existence of the proper functionality.

patient's quality of care as a result of these activities. As the example illustrates, CMS should better align requirements and scale back requirements that hold hospitals accountable for the technology capability and actions of others.

> "60 days is not enough time to get ready and to implement changes [after a regulation is finalized]."
> - CoxHealth

The timing and pace with which regulations are released make regulatory compliance challenging and generates additional burden.

The frequency and pace with which regulations change also creates administrative burden. Regardless of the type of regulation or domain, a significant investment of staff time and resources is required in order to make the necessary changes to comply. Adding to this, health systems, hospitals and PAC providers are often required to comply with regulations promulgated from multiple federal agencies in very short timeframes. One example highlighted by the interviewees was the 2017 Medicare physician fee schedule final rule. It was released by CMS in November 2016 and required hospitals to be compliant by Jan. 1, 2017. Doing so required changes to payment policies and quality provisions; the implementation of these changes had a significant administrative impact on IT systems, training for personnel and operational modifications.

Staff resources are key to the compliance process. As new or updated regulations are issued, a provider must quickly mobilize staff — not only those who are already dedicated to quality reporting, legal and compliance functions, who may be committed to maintaining compliance or other important functions, but also care delivery staff, who are shifted away from their patient care responsibilities. This team must meet to decipher the regulations; sometimes clarify the requirements with regulators and trade associations; and redesign, test, implement and communicate new processes throughout the organization. This necessity results in less time for hospital care delivery and diversion of resources. Providers' privacy and security staff must be particularly nimble at staying abreast of regulatory and sub-regulatory changes that can impact their accountability for compliance. For example, OCR recently released guidance that warned providers that the agency considers any ransomware attack to be a data breach and a Health Insurance Portability and Accountability Act (HIPAA) violation.[39]

Coming into compliance with new or updated regulations also generally involves changing the provider's EHR to modify how information is documented, collected and reported. These IT changes are costly and their design, testing and implementation requires lead time, particularly when they involve a vendor. The required implementation timelines do not account for all the process work required; providers must develop manual workarounds to comply with the regulation, while simultaneously working to implement a permanent solution.

A Starting Place for Solutions

This report identifies several opportunities for federal regulators to reduce regulatory burden for providers when it does not contribute to better patient outcomes, including ensuring that regulations are aligned with one another and reevaluating laws and regulations that impede care redesign. For examples, the hospital CoPs, quality reporting requirements, and the fraud and abuse laws readily present opportunities for reform.

Health systems, hospitals and PAC providers recognize that regulatory requirements and standards frequently provide value, and certain requirements are critical to ensuring the provision of safe, high-quality care. However, many requirements are redundant, contradictory and provide little or no value. We have identified several opportunities to reduce administrative requirements without compromising patient outcomes, both at a global level and within each domain.

At a global level, regulatory requirements should be better aligned and consistently applied within and across federal agencies and regulatory domains to help meet program objectives and reduce redundancy. For example, fraud and abuse rules should be modernized across the board and not just in certain demonstration programs. Quality reporting should be aligned across all programs so that, for example, eCQMs do not duplicate existing inpatient reporting requirements. Furthermore, regulatory requirements should be routinely reviewed for their effectiveness. This regulatory review should be done across all requirements, evaluating whether the benefits for the public good outweigh the burden on those that must comply. When creating new regulatory requirements, federal departments should provide clear guidance and interpretation and allow sufficient time for implementation. Regulators should consult with providers and comprehensively analyze the impact on operations. If compliance will require significant effort to understand and implement changes, sufficient time to implement modifications should be provided.

This report also identifies the following areas for improvement:

- 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;

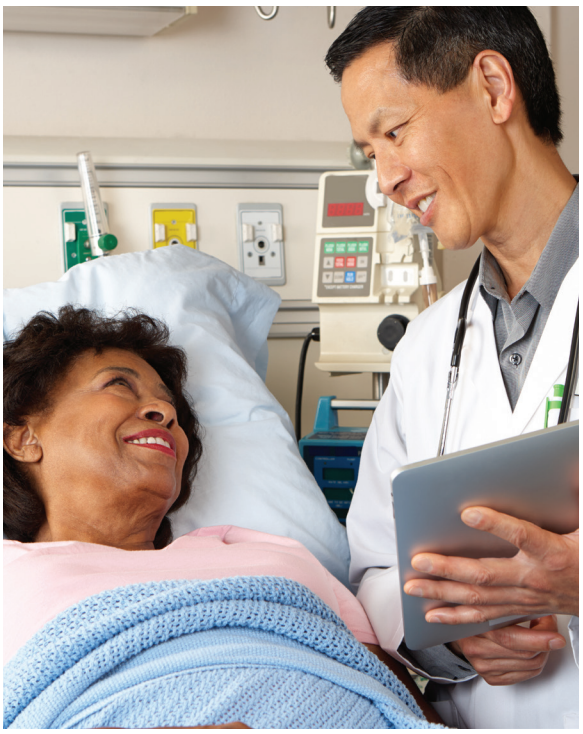
- Quality reporting requirements should be thoroughly evaluated across all programs to determine what measures provide meaningful and actionable information for patients, providers and regulators. As part of this evaluation, CMS should consider if "topped out" measures should be retired. CMS also should review program measures for consistency in definition and reporting methodology while streamlining reporting requirements that do not materially impact a measure's validity. Before increasing the number of quality metrics, which increases administrative burden and costs, there must be a thoughtful assessment of what metrics actually measure quality and positively impact patient care both in the short and long term;

- PAC rules should be reviewed and simplified to remove or update any antiquated, redundant or unnecessary rules; and

- With new delivery system and payment reforms emerging, a one-by-one review of fraud and abuse laws and regulations in the context of disparate programs will soon, if it has not already, become unwieldy. This is an opportune time for Congress, CMS and the OIG to revisit the Stark Law and AKS and their respective regulations, as well as other requirements aimed at combating fraud, to make meaningful changes to these rules, as the *AHA has recommended*. At a minimum, CMS and the OIG should make the waiver program available outside of the demonstration projects and models, and should allow existing waivers to apply to similar arrangements for Medicaid or commercial payers.

Conclusion

Health systems, hospitals and PAC providers are besieged by federal regulatory requirements promulgated by CMS, OIG, OCR and ONC, many of which are duplicative and cumbersome and do not improve patient care. In addition to the regulatory burden put forth by those agencies, health systems, hospitals and PAC providers are subject to regulation by additional federal agencies, such as the Department of Labor, the Drug Enforcement Administration, the Food and Drug Administration and by state licensing and regulatory agencies. They also operate under stringent contract requirements imposed by payers, such as Medicare Advantage, Medicaid Managed Care plans and commercial payers, which also require reporting data in different ways through different systems. States and payers contribute to burden through, for example, documentation, quality reporting and billing procedures layered on top of the federal requirements.



Regulatory reform aimed at reducing administrative burden must not approach the regulatory environment in a vacuum — evaluating the impact of a single regulation or requirements of a single program — but instead must look at the larger picture of the regulatory framework and identify where requirements can be streamlined or eliminated to release resources to be allocated to patient care. Additionally, a one-size-fits-all approach may not be possible; the review must consider the unique burdens faced by rural providers, health systems with PAC providers, health systems participating in new models of care, and small hospitals.

Regulations are important and essential to ensure that health systems, hospitals and PAC providers are environments that support the safe delivery of care. However, the outsized growth of staff and resources devoted to regulatory and compliance-related functions illustrates that a step back is needed; federal agencies should review and streamline requirements to reduce the overhead cost of health care and allow providers to focus on their mission of caring for patients.

Selected AHA resources on regulatory burden (available at www.aha.org/regrelief):

- Billing and coverage: *AHA TrendWatch: Administrative Simplification Strategies Offer Opportunities to Improve Patient Experience and Reduce Costs*
- Fraud and abuse: *Legal (Fraud and Abuse) Barriers To Care Transformation and How to Address Them*
- Meaningful use and health IT: *Hospitals Advance Information Sharing but External Barriers to Increased Data Exchange Remain*
- Quality reporting: *Hospitals Face Challenging Using Electronic Health Records to Generate Clinical Quality Measures*
- Program integrity: *The Real Cost of the Inefficient Medicare RAC Program*

Appendix A – Regulatory Program Descriptions

Quality Reporting – Federal quality reporting requirements that obligate health systems, hospitals and PAC providers to furnish data related to certain quality measures to CMS. Each quality reporting program has its own set of requirements regarding the data that must be reported; how it must be reported; the impact of the quality metrics on reimbursement, if any; and how the results of reported quality measures are made available to the public. The quality reporting programs discussed in this paper include the Hospital Inpatient Quality Reporting Programs (HIQRP) and the Hospital Outpatient Quality Reporting Program (HOQRP), as well as programs that pull data from those two programs, such as Hospital Readmission Reduction Program (HRRP), the Hospital Value-Based Purchasing Program (HVBPP), the Hospital-Acquired Condition (HAC) Reduction Program, and the Physician Quality Reporting System (PQRS). PAC providers' also have reporting programs: the SNF Value-Based Program, the SNF Quality Reporting Program, the HHA Quality Reporting Program and the LTCH Quality Reporting Program.

New Models of Care/VBP Models – Federal requirements that health systems, hospitals and PAC providers must meet in order to participate in certain innovative new models of providing and paying for services. Participation in some of these models is voluntary, and others are mandated for providers in certain geographic regions. Compliance with each of the different program requirements includes submitting data, auditing, creating patient notices and conducting complex analytics. The programs also provide health systems, hospitals and PAC providers the opportunity to apply for waivers of CoPs and certain fraud and abuse laws. The new payment models discussed in this paper include the Cardiac Care Bundled Payment model (CCBP), the Comprehensive Care for Joint Replacement model (CJR) and the Cardiac Rehabilitation (CR) incentive payment model.[i]

MU of Electronic Health Records – Federal health information technology (health IT) programs with which certain health care providers must comply — specifically, the Medicare and Medicaid EHR Incentive Programs, which require eligible hospitals and professionals to demonstrate meaningful use of certified EHR technology in order to avoid payment penalties. Among other things, the EHR incentive programs require eligible hospitals to implement and use clinical decision support tools to improve performance on high-priority health conditions; use computer-provider order entry for a defined percentage of medication, laboratory and radiology orders; and transmit a certain percentage of prescriptions electronically. Other federal health IT programs include the health IT standards and requirements of the Quality Payment Program established under MACRA, which supersedes the EHR Incentive Payment program for eligible professionals effective as of 2017, as well as the electronic clinical quality measures that health systems and providers are required to use for reporting under various programs, including the HIQRP.

Conditions of Participation (CoPs) – Federal requirements with which hospitals, critical access hospitals, inpatient rehabilation facilities (IRFs) and long-term care hospitals (LTCHs) must comply in order to participate in the Medicare program. These CoPs require hospitals to establish, review and revise policies and procedures; collect and report data; develop and issue patient notices; comply with specific building codes; establish committees to address quality, credentialing and other activities; document specific elements of patient care and services in specific ways; and make medical records available to patients. This report addresses compliance generally with all of the CoPs.

Program Integrity – Federal requirements and programs were established to ensure that Medicare payments are proper and to promote compliance with Medicare coverage and coding rules. Hospitals and PAC providers are required to establish compliance programs that, among other things, have a dedicated compliance officer and perform internal auditing and monitoring to self-detect and report on noncompliance and receipt of improper payments. Coding must be in compliance with the National Correct Coding Initiative.

The federal programs established to monitor and audit Medicare payments and provider compliance with coverage and billing requirements are abundant, and each requests medical records and other documentation as part of its review and issues findings requiring a response in order to avoid denials, recoupment or other penalties. The programs discussed in this report include Medicare Administrative Contractors, Recovery Audit Contractors, Zone Program Integrity Contractors, Supplemental Medical Review Contractor and the Comprehensive Error Rate Testing Program.

Fraud and Abuse – Federal laws and regulations that aim to limit fraud and abuse in the federal health care system by governing financial relationships between entities that refer patients for whom payment is made under Medicare and Medicaid. Failure to comply with these requirements can result in a hospital, health system, or PAC provider incurring criminal, civil and administrative penalties. These laws and regulations have certain exceptions or safe harbors that, in order to be met, require careful contract drafting, documentation and fair market value assessments. The fraud and abuse laws discussed in this report include the Physician Self-Referral Law (Stark Law), the Anti-Kickback Statute, and law and protocols requiring returning overpayments.

Privacy and Security – Federal regulations established under the Health Insurance Portability and Accountability Act (HIPAA) that apply to health systems, hospitals and PAC providers and are designed to ensure the security and privacy of patient health information. The elements of HIPAA's privacy and security regulations that are discussed in this paper include requirements regarding data privacy and data security; patient rights with respect to data maintained by health systems, hospitals and PAC providers; breach notification requirements; and privacy and security audits.

Post-acute Care (PAC) – Federal programs and regulations with which PAC providers must comply in order to either participate in or receive reimbursement under Medicare. These requirements include the respective CoPs applicable to skilled nursing facilities (SNFs) and home health agencies (HHAs) that require these entities to establish, review and revise policies and procedures; collect and report data; develop and issue patient notices; establish committees to address quality, credentialing and other activities; document specific elements of patient care and services in specific ways; and make medical records available to patients. Other requirements applicable to IRFs and LTCHs require these entities to carefully track data to avoid technical violations of regulations that would affect reimbursement. This report focuses on PAC provider data collection requirements, SNF and HHA CoPs, IRFs' compliance with the 60% rule, and LTCH compliance with requirements related to co-location and the site-neutral payment and 25% rule exemptions.

Billing and Coverage Verification/Administrative Simplification – Federal regulations that establish standards and security protocols for handling electronic health care billing and claims transactions among providers and payers (e.g., eligibility, enrollment, billing, payment, remittance) designed to increase efficiency in claims processing and protect the confidentiality of health information. Certain related activities, such as coding the claims to meet these requirements and appealing denials, remain manual. The administrative simplification requirements discussed in the report include electronic transmissions for health care claims, encounter information, claim status, payment and remittance advice, coordination of benefits, health plan eligibility, enrollment status, premium payments, and referral certification and authorization.

i. At the time of this report's publication, CMS has proposed cancelling the Cardiac Rehabilitation incentive payment model and the three inventive models collectively referred to as the Episode Payment Models. In addition, CMS has reduced the number of geographical areas that would be mandated to participate in Comprehensive Care for Joint Replacement model. See 82 Fed. Reg. 39310.

Appendix B – Survey Methodology

Manatt surveyed the American Hospital Association's membership to quantify the cost of compliance with different regulatory programs. Respondents were representatives for individual hospitals and hospital systems, with total responses representing 190 hospitals. Of these 190 hospitals, 166 came from one of 13 health systems and 25 were standalone acute care hospitals. Survey questions focused on whether the hospital or health system had to hire any full-time equivalent (FTE) employees, contract with a third-party vendor, and/or implement any new technology of software to manage compliance with each regulatory program.

Hospital systems in the survey reported aggregate numbers representing all of their hospitals. To extrapolate hospital-level costs among system respondents, we divided their response by their total system beds, and then multiplied this number by the bed size for each individual hospital within the system. This enabled segmentation of the analysis based on individual hospital characteristics, such as the presence of PAC beds.

For each of the nine domains, we identified all hospitals that reported a cost for at least one of the regulatory programs within that domain, such as hiring additional employees, contracting with a third-party vendor, implementing new technology systems, or costs associated with other resources. The responses were totaled, and then divided by the total number of beds represented by the reporting hospitals in that domain to derive a per-bed statistic. This per-bed statistic was then multiplied by the average number of beds in a community hospital (161) and the total number of beds nationally in community hospitals (782,772) to estimate average per-hospital burden and a total national burden, respectively. For the post-acute care regulatory requirements, PAC beds were used rather than total hospital beds to better estimate costs in this domain. Hospital bed counts and other attributes were taken from the 2015 AHA Annual Member Survey.

Sources

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3. 44 U.S.C. §§ 3501-3520.

4. Codified in its current form in 1995.

5. Congressional Research Service. (2007, Jan. 4). Paperwork Reduction Act Reauthorization and Government Information Management Issues: CSR Report RL30590. A paperwork reduction goal of 10 percent was set for the first two authorization years, and 5 percent annually for each year thereafter. Accessed July 31, 2017 *https://fas.org/sgp/crs/secrecy/RL30590.pdf*.

6. 5 C.F.R. 1320.3(h)(1).

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8. Ibid.

9. Exec. Order No. 13771, 82 FR 9339 (2017), *https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling*; Exec. Order No. 13777, 82 FR 12285 (2017), *https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda*.

10. The research scope also included MACRA/MIPS, proposed hospital discharge planning CoPs, final home health CoPs that were not yet in effect, and some "voluntary" quality reporting programs that have a financial penalty associated with not participating. However, the focus of this paper is primarily on the regulations in effect as of March 2017.

11. We researched 749 federal regulatory requirements in the nine domain areas, but excluded from the survey those requirements that were voluntary, proposed and not yet final, or final but not yet in effect as of March 2017.

12. For the purpose of this report, PAC services include Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs).

13. One survey question asks respondents to assess the administrative burden of The Joint Commission accreditation.

14. Survey categories (e.g., nursing, physician, management) were linked to broad groups based on the Bureau of Labor Statistics (BLS) 2010 Standard Occupational Classification (SOCs). SOCs were then linked to their corresponding category in the 2016 BLS National Occupational Employment and Wage Estimates. The SOC lists are updated approximately every 10 years, with 2010 being the most recent. Wage estimates are calculated annually. Estimates represent national averages, and do not account for geographic differences. While HHAs were included in the PAC survey, we do not know how many respondents had HHAs because respondents were not required to provide this information.

15. Some costs represented may overlap with costs associated with meeting voluntary accrediting standards.

16. These costs do not include CoPs that are more directly associated with clinical care, such as the requirements to provide a 24-hour nursing service, managing and operating a pharmacy, or providing radiology, laboratory, and dietetic services.

17. To be paid by Medicare at the IRF reimbursement rate, at least 60 percent of the facility's admissions must have one of 13 qualifying medical conditions. Under the 25 percent threshold rule, a LTCH's payments are reduced if a LTCH admits more than 25 percent of its patients from a single hospital, unless limited exceptions apply.

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19. Ibid., footnote 9.

20. Ibid., p. 7.

21. Council for Affordable Quality Healthcare. CAQH Index 2016. *https://www.caqh.org/sites/default/files/explorations/index/report/2016-caqh-index-report.pdf*

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23. Some of the quality and pay for performance programs that require reporting include: HRRP, the HIQRP, the Hospital Outpatient Quality Reporting Program, the HVBPP, the HAC Reduction Program, and certain MIPs and the PQRS/VBP.

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26. Ibid.

27. Ibid.

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29. Ibid.

30. Sinsky, Christine, et al. (2016, Dec. 6). Allocation of physician time in ambulatory practice: A time and motion study in 4 specialties. Annals of Internal Medicine.

31. At the time of this paper's publication, CMS has proposed cancelling the Cardiac Rehabilitation incentive payment model and the three inventive models collectively referred to as the Episode Payment Models. In addition, CMS has reduced the number of geographical areas that would be mandated to participate in Comprehensive Care for Joint Replacement model. See 82 Fed. Reg. 39310.

32. Soc. Sec. Act. § 1115A(d)(1).

33. See CMS.gov, "Fraud and Abuse Waivers," accessed July 14, 2017, *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html*.

34. Sinsky, Christine, et al.

35. The following hospitals are eligible to participate in the Medicare EHR incentive program: subsection (d) hospitals (essentially, acute care hospitals), critical access hospitals and Medicare Advantage-affiliated hospitals. The following professionals are eligible to participate in the Medicare EHR incentive program: doctors of medicine, osteopathy, dental surgery, dental medicine, podiatry and optometry, as well as chiropractors.

36. As of 2017, physicians and professionals no longer participate in the Medicare EHR incentive program; instead they participate in the Quality Payment Program established under MACRA, and are subject to the health IT standards and requirements established under that program.

37. American Hospital Association (2017), "Getting Meaningful Use Right," p. 2, accessed July 31, 2017, *http://www.aha.org/advocacy-issues/factsheets/fs-meaningfuluse.pdf*.

38. Billing and coverage transaction activities averaged an upfront IT investment of $702,000.

39. U.S. Department of Health and Human Services. Fact sheet: Ransomware and HIPAA. Accessed August 20, 2017. *https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf*

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