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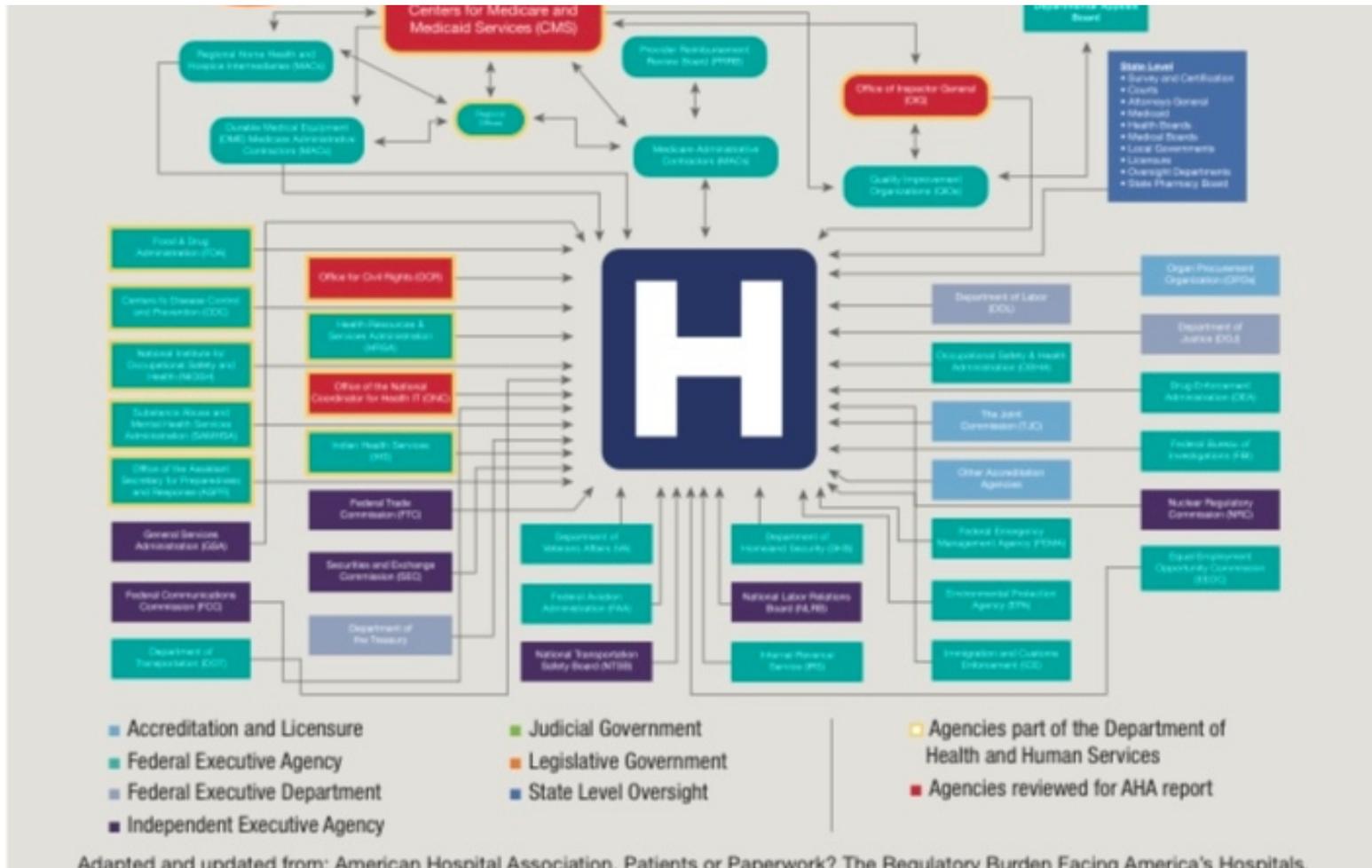
# Regulations: Both the Lifeblood and the Bane to the Existence of a Compliance Officer

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**Kathy Reep, Senior Manager**  
**Business Development and**  
**Compliance Advisory**  
**October 29, 2020**



# Overwhelmed with Regulations?



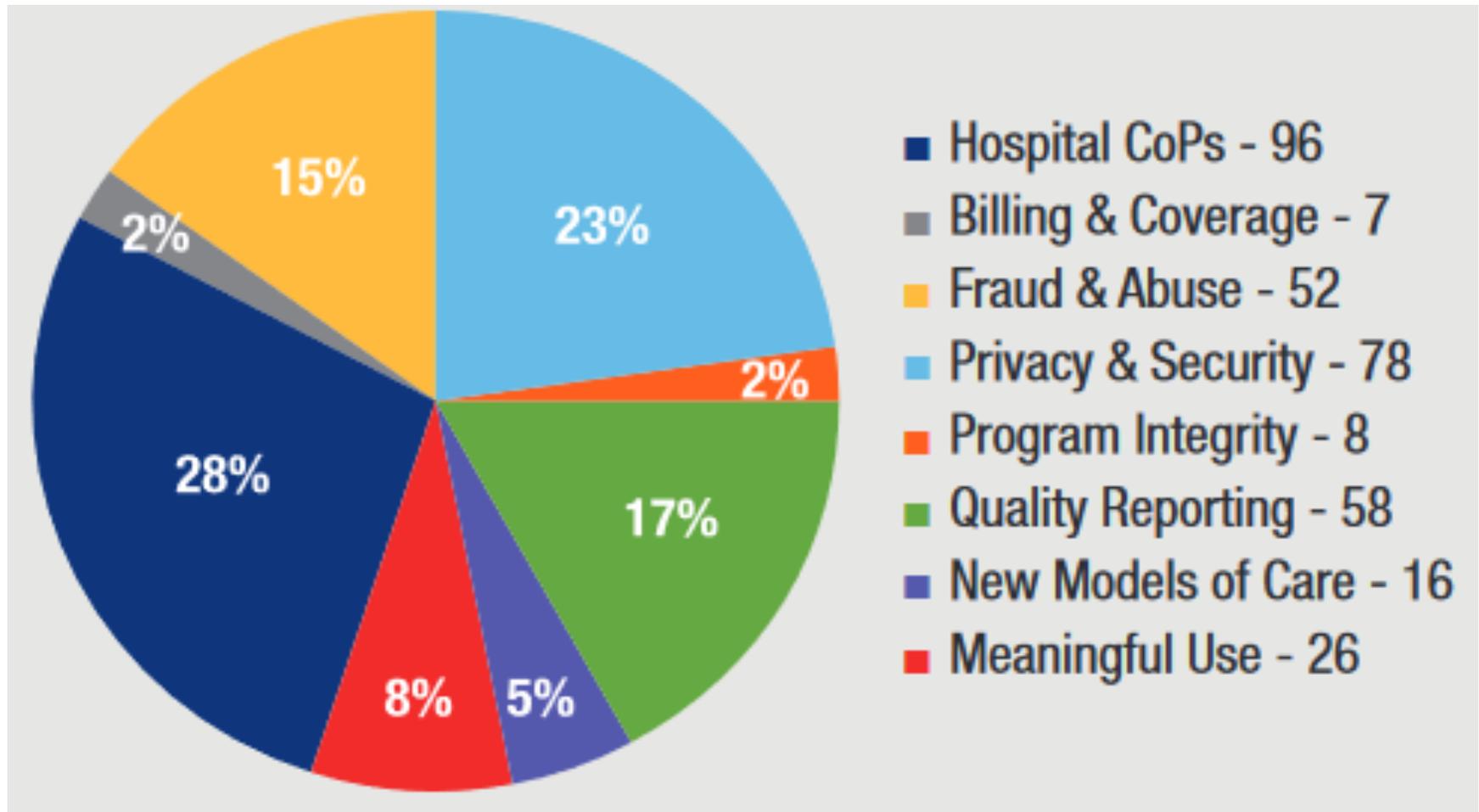
# The Need for Regulatory Reform

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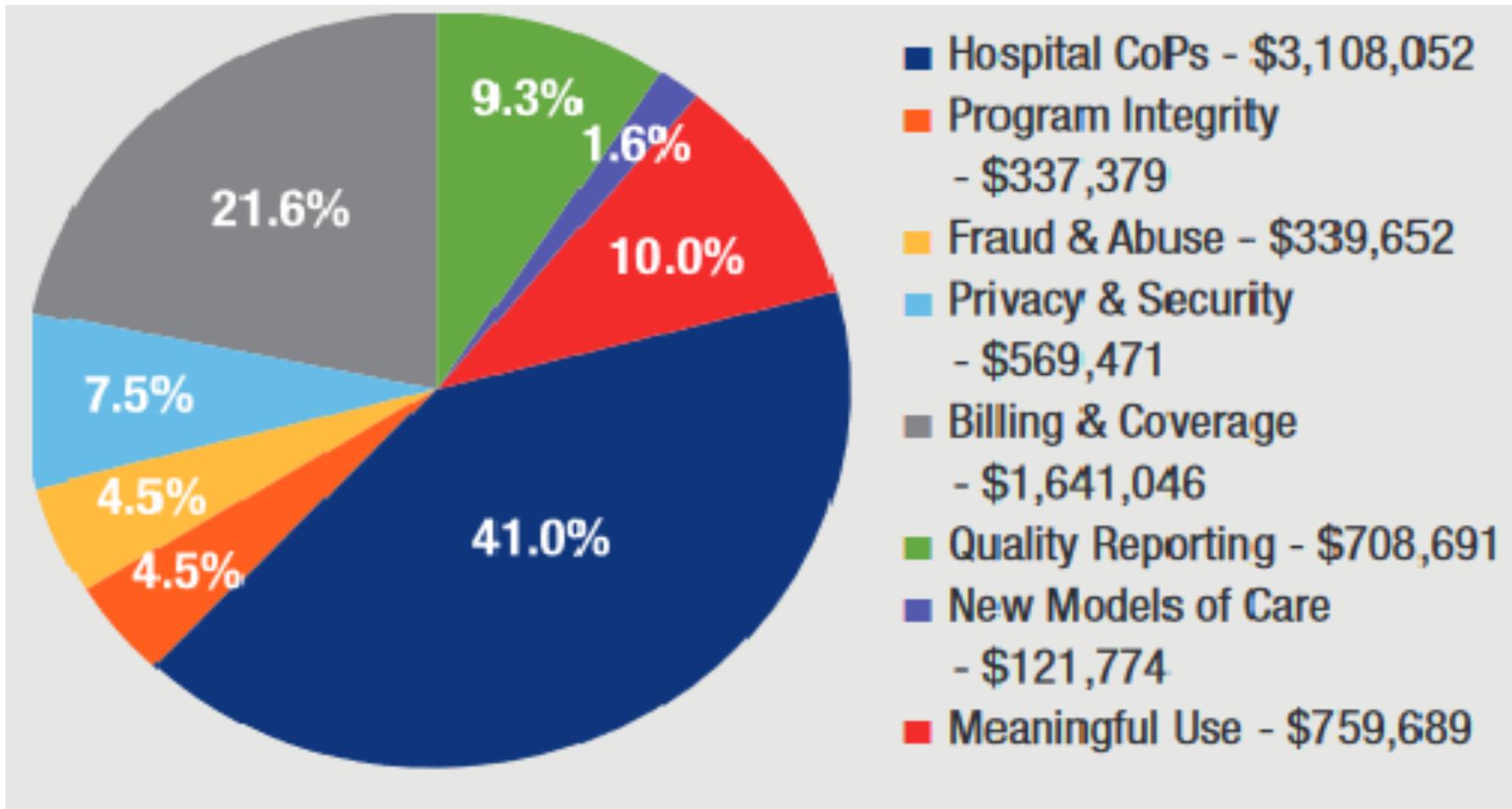


- Regulatory burden overwhelming providers
  - Diverting clinicians from patient care
  - \$39 B spent by health systems, hospitals, and post-acute care providers annually on non-clinical regulatory requirements
    - 629 mandatory regulatory requirements (341 for hospitals, 288 for post-acute)
  - \$7.6 million per community hospital annually to comply
    - Regulatory burden costs \$1,200 every time a patient is admitted to a hospital

# Hospital Requirements by Domain



# Average Annual Compliance Costs



# Estimated Burden of Compliance



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%
<b>Total cost (by cost center)</b>	<b>59.0</b>	<b>\$757,400</b>	<b>\$6,154,663</b>	<b>\$784,273</b>	<b>\$315,687</b>	<b>\$331,129</b>	<b>\$7,585,752</b>	
		% 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.

# Needed Regulatory Relief

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- How do you spell R-E-L-I-E-F?
  - Reasonable timeframes for the implementation of new rules
  - Disaster waivers automatically issued
  - Modify CoPs to allow hospitals to recommend post-acute providers
  - Accelerate transition of electronic transactions such as prior authorizations
  - Physician certification of outlier claims (really, do you do this?)
  - Exclude hospitals from reporting appropriate use criteria

- Brand memo: use of guidance documents for false claims actions
  - Justice Department “may not use noncompliance with **guidance documents** as a basis for proving violations of applicable law”
  - **Guidance documents** do not create substantive legal requirements, only a statute or regulation does
  - **Guidance documents:** Medicare billing manuals, special fraud alerts, coverage determinations, preambles to rules, frequently asked questions

- *Federal Register* NPRM issued August 20
  - HHS Good Guidance Practices
  - Applies to all divisions of HHS other than FDA
- Purpose of the proposed rule
  - Increase accountability
  - Improve fairness of guidance issued by HHS
  - Guard against unlawful regulations through guidance
  - Safeguard the principles of the US administrative law system
- Guidance defined
  - *Includes statements of general applicability intended to govern the future behavior of regulated parties*

- Guidance includes, but not limited to –
  - Letters
  - FAQs
  - Bulletins
  - Advisories
  - Preambles
  - Compliance guides
  - Video, audio, and web-based formats
- *Documents designed to shape the behavior of regulated parties would be considered guidance if they ... set forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation*

- What does the proposed rule say?
  - *No guidance document issued by HHS would be able to direct parties outside the Federal government to take or refrain from taking action, except when restating – with citations to statutes, regulations, or binding judicial precedent – mandates contained in a statute or regulation*
  - All guidance documents must reference – in Code of Federal Regulations format – the provision that being referenced
- RFI issued for feedback on which current guidance documents should be required to go through formal notice and comment rulemaking
- If finalized, rule requires all enforceable guidance to move to [www.hhs.gov/guidance](http://www.hhs.gov/guidance) by 11/16/20

Could it be that we will move from shades of gray to pure black and white when it comes to compliance guidance?

Questions:  
Kathy Reep  
[kreep@pyapc.com](mailto:kreep@pyapc.com)



800.270.9629 | [www.pyapc.com](http://www.pyapc.com)