The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

Statement of

The Hospital and Healthsystem Association of Pennsylvania

for the

Republican Policy Committee

Pennsylvanian House of Representatives

presented by

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Health care is among the most regulated industries in the nation. While government oversight is appropriate to ensure that patients receive safe, high-quality care, the reality is that layers of regulatory requirements and processes too often take providers away from the bedside, stifle innovation, add unnecessary administrative burdens, and strain facilities' finances.

Hospitals and health systems are diagnosing and treating Pennsylvanians in an extremely dynamic environment. Patients are choosing to seek care at different times and in different ways; workforce shortages are at crisis levels; clinical breakthroughs happen every day; technology is evolving at ever-faster rates; health information and data is transforming how we deliver care; and health care business models are constantly shifting in an effort ensure facility viability and access to care.

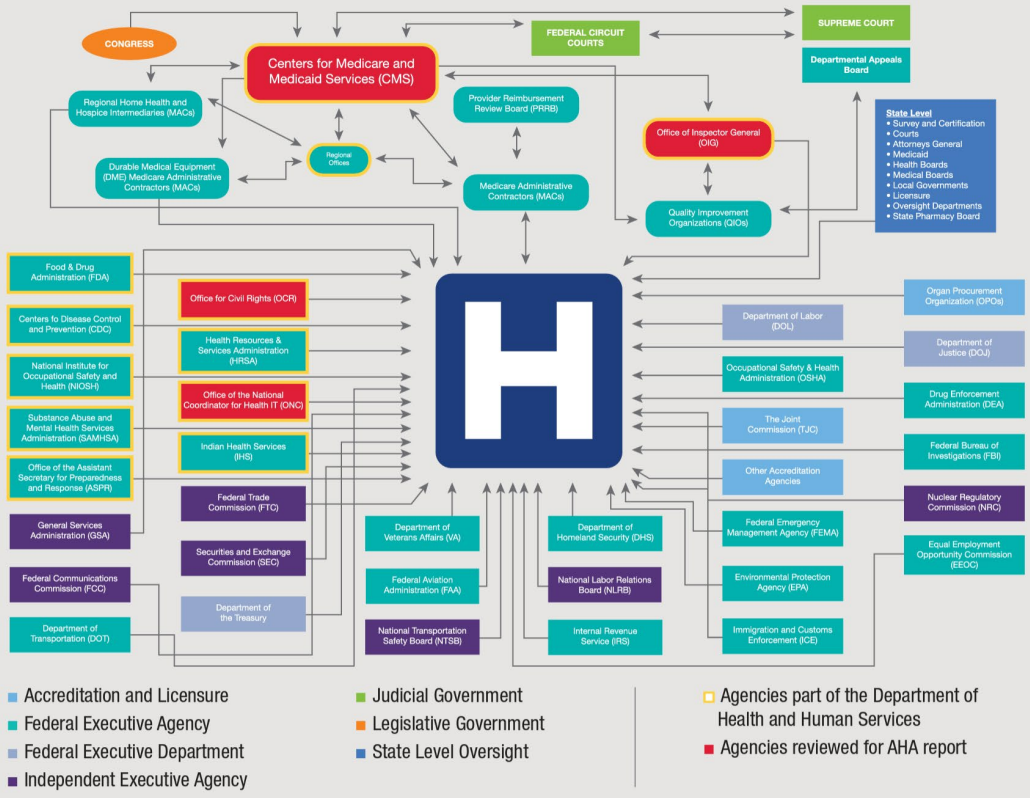
Regulations should absolutely work to ensure patient and provider safety, but they should not deny the reasonable flexibility that health care providers need to be able to meet the real-time needs of the communities they serve.

Federal Regulatory Landscape

While this hearing is rightfully focused on Pennsylvania, it is impossible to consider our state regularity landscape without first understanding the extremely complex federal requirements with which it intersects.

The true scope and impact of federal regulatory requirements on hospitals is difficult to quantify due to the sheer number of federal agencies with regulatory authority and the increasingly complex nature of health systems. Five years ago, the American Hospital Association (AHA) partnered with Manatt Health to examine the federal regulatory landscape for health systems, hospitals, and post-acute care providers. According to their report—at the federal level alone—there are more than 43 agencies, offices, and departments to which hospitals are accountable, not including Congress, the Supreme Court, and federal district courts.

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.

The analysis focused on federal law and regulations across nine domains from just four federal agencies: the Centers for Medicare & Medicaid Services (CMS), the Office of Civil Rights, the Office of the Inspector General, and the Office of the National Coordinator for Health IT. The report attempted to quantify the impact and cost of a portion of these agencies and the regulations under their purview.

As of March 2017, the four agencies highlighted in the report accounted for more than 600 discrete regulatory requirements on health systems, hospitals, and post-acute care providers. While that is a startling number from just four oversight entities, the estimate only included requirements that generated one or more administrating activities, i.e., creating or revising policies and workflows or documenting and monitoring compliance. The report further indicates that many of these regulatory requirements do not lead to improvements in patient care.

Health care regulations change at an incredible pace and require a team of highly trained staff to monitor and operationalize new and modified requirements. There is a constant need to re-write or revise policies, develop programs, and train staff to respond to evolving regulatory requirements and sub-regulatory guidance. Data suggests that an average-size hospital dedicates 59 employees to regulatory compliance and that more than a quarter of these are doctors and nurses. It is unacceptable that administrative activities to support compliance pull providers away from the bedside at a time when health care workforce shortages are at critical levels. And, it is worth noting that this estimate reflects only time spent on compliance-related administrative activities and does not include clinical components of state regulations or accreditation requirements.

The cost of administrative activities related to regulatory compliance for health systems is exorbitant. The AHA report estimates that hospitals and post-acute providers collectively spend nearly $39 billion a year on the administrative activities related to regulatory compliance, which translates to $7.6 million annually for average-sized community hospitals (roughly 150 beds); $9 million for average-sized hospitals with post-acute care beds; and almost $19 million for hospitals with more than 400 beds. Based on these estimates, the federal regulatory burden equates to an average cost of $1,200 per patient admitted, or $47,000 per hospital bed, per year.

This regulatory burden is not exclusive to hospitals. The Medical Group Management Association conducts an annual survey assessing the impact of the regulatory landscape on medical practices. In 2022, almost 90 percent of respondents said that the overall regulatory burden over the last 12 months had increased. As part of the same survey, 97 percent of providers indicated that a reduction in regulatory burden would allow them to reallocate resources toward patient care.

State Regulatory Landscape

The state regulatory landscape is only slightly less complicated than the national landscape and adds several layers of complexity to hospital compliance efforts. Some of the entities to which

hospitals and health systems are accountable in Pennsylvania include the departments of Health, Human Services, State, Drug and Alcohol Programs, Aging, Education, Insurance, and Environmental Protection, as well as PEMA, the Patient Safety Authority and Pennsylvania Health Care Cost Containment Council, for example. Hospitals also meet requirements of or may be scrutinized by state-contracted managed care organizations, county authorities, the Attorney General, the General Assembly, and the courts.

It is important to note that a number of these entities struggle with their own workforce, business process modernization, information technology, funding, and oversight challenges, even as they are consistently asked to 'do more with less' and keep pace with rapidly evolving industries. It would be beneficial to streamline their efforts to focus on tasks that are truly meaningful to increase access to and assure the quality of care in Pennsylvania.

From professional licensing to construction permitting, the scope of regulation that touches Pennsylvania's hospitals is immense. For the purposes of today's hearing, we will narrow our observations to select regulations that are implemented by the Department of Health.

Research from the Mercatus Center at George Mason University estimated that, in 2017, "Ambulatory Health Care Services" were the fourth-most regulated industry in Pennsylvania, with more than 5,500 "industry-relevant restrictions" in place at the time. They note that Title 28 of PA Code (health and safety), which includes hospital licensure regulations, contains more than 7,900 requirements.

In addition to the sheer volume of requirements, Pennsylvania's hospitals and health systems face unique challenges because the commonwealth's hospital licensure regulations are so old. Much of our current regulatory structure remains in place from the 1980's—so, for example, our regulations do not even contemplate the internet, much less telehealth, electronic health records, or modern employee operations and care team structures.

In addition to being out-of-touch, outdated regulations require the state to issue a high volume of sub-regulatory guidance and result in a number of ways that the interpretation for what is considered acceptable compliance can vary across the state, from region to region or audit to audit, for example.

The Department of Health currently provides such sub-regulatory guidance to hospitals via electronic message board posts that are removed within six months and are not archived on the department's website. Once guidance is removed, the state typically does not provide other ways to access it so that hospital regulatory and compliance teams can refer back during internal policy reviews.

Beyond the antiquated regulatory language and transitory message board posts, there are few resources available to assist hospitals with assuring that they are developing and implementing policies and procedures that the department will deem compliant. At the federal level, CMS has alleviated similar issues by sharing the interpretive guidance used by its surveyors. Such a measure should be encouraged at the state level as well.

State Regulations Not in Sync with Federal Requirements

Again, the hospital community affirms its belief that government oversight is appropriate to assure our shared commitment to providing patients with safe, high-quality care. Many regulations, however, impose administrative burden with little or no positive effect on patient safety. Both the regulated organization and the government entities charged with inspecting, validating, and assuring compliance incur burdens.

In Pennsylvania, health systems must create, maintain, and assure compliance of separate governing documents and bylaws for each individual hospital. Likewise, health systems must appoint medical staff, seek credentials, and grant privileges, for example, on a task-by-task and facility-by-facility basis. (28 PA Code Chapter 103 and 107).

In some cases, each provider must complete the entire onboarding process—two written references, verification of orientation and competencies, etc.—for each facility in which they may eventually practice. This makes it difficult, for example, to allow nurses to move easily between facilities and affects some specific clinical areas more than others, i.e., imaging, radiology, cardiology, sleep labs, etc. Federal requirements permit a unified and integrated approach across all facilities in a health system, which cuts red tape to allow well-qualified practitioners to treat patients when and where they are needed most.

Once in practice, the federal and state timelines for verifying and updating a provider's training and qualifications are also misaligned. Federal review is required at three-year intervals, while the state mandates a two-year timeframe. Aligning the state with the federal requirements in this instance would immediately reduce the administrative burden of this activity by almost 30 percent.

State regulatory requirements around physical space and procedure rooms do not align with federal requirements. 'Class three' rooms, for example, are used for procedures like breast biopsies. Pennsylvania's requirement is that these rooms be 600 square feet, while CMS sets a threshold of 400 square feet. The result is that existing spaces between 400 and 600 square

feet, which could otherwise be used for these procedures under federal regulations, cannot be used to care for patients in Pennsylvania.

Another vivid illustration is that Pennsylvania's hospital regulations actually still require that "Library services shall be made available in the hospital to the medical and hospital staff. There shall be books, periodicals, and other materials appropriate to meet their needs." (28 PA Code Chapter 145) In the age of the internet, this is an absurd requirement and, thankfully, the Department of Health recognizes it as such and waives it. It nonetheless requires hospitals to waste time and energy to ensure proper documentation so as to not run afoul of state requirements and the state must grant an exception. There is no similar requirement from CMS or The Joint Commission, the most widely recognized private accrediting organization in the nation.

These are just a few examples, there are several more regulations that could be modified to better align with federal and accrediting organization requirements.

Processes for Adding Equipment or Services

The Health Care Facilities Act, 35 P.S. § 448.808(a)(1)-(4), authorizes the Pennsylvania Department of Health to license health care facilities, provided that all safety requirements are met and the facility is in substantial compliance with all rules and regulations.

Under 28 PA Code 51.3 (a)(h)(1), hospitals are required to provide at least a 60-day notice before the state will process requests to use new equipment or to offer new services. The regulation can be applied so broadly that the process may be required for what could be perceived as procedural changes rather for meaningful changes with implications for patient safety. For example, if a hospital is deploying new equipment but the only change from existing equipment is a model number, should this process apply—particularly if there is no change to the way the equipment is operated or the training for staff prior to using the equipment remains the same? Should non-care-related physical modifications—such as moving televisions in patient rooms—require on-site state inspections before patients can be cared for in those spaces?

Prior to 2020, such a notice would typically trigger an on-site occupancy survey by the Department of Health to confirm that the details of the notification were factual. As hospitals and health systems grew, their requests far outpaced the department's resources available for on-site approvals. In many cases—i.e., installation of a new model of equipment already used by staff in the facility—an on-site survey was not immediately necessary to assure patient safety.

In June 2020, the department created a process to streamline such approvals. Sixty days prior to using new equipment or offering a new service, hospitals can now submit an attestation that they are in compliance with the state's regulations. In itself, the submission does necessarily negate the necessity of on-site activity; however, if a facility does not hear back from the department within 60 days, it can assume that the service or equipment has been approved.

The Department of Health monitors these changes by evaluating 20 percent of the attestations submitted by each facility the next time a regulator is on site. If a certain number of the attestations are out of compliance, the surveyor will review 100 percent of submissions from the previous 12 months.

The hospital community greatly appreciates the creative thinking and flexibility demonstrated by the department when it introduced the attestation process. The regulated community, however, would appreciate additional, predictable, structured opportunities to work with state regulators to help craft and improve real-world solutions—such as this—to comply with state requirements.

Exceptions

Another current mechanism to try to allow for regulatory flexibility in Pennsylvania is an exceptions process managed by the Pennsylvania Department of Health (defined by 28 PA Code §51.31–51.34) through which hospitals can apply to be exempt from specific regulations under certain conditions. The policy authorizes the department to grant exceptions when hospitals and ambulatory surgical facilities face unreasonable hardship in attempting to come into compliance. Such exceptions can also be granted if a regulation impedes a facility's ability to provide higher quality care, to operate more efficiently, or to develop an innovative program.

In the same spirit and with some acknowledgement of the outdated nature of Pennsylvania's regulations, the department offers a structured—formally referred to as 'expedited'—exceptions process for a select set of regulations. If hospitals comply with minimum requirements, expedited exceptions are granted with the expectation that the health, safety, or welfare of patients will not be compromised.

Again, the hospital community appreciates the state's willingness to consider extenuating circumstances for barriers to full compliance by granting exceptions that do not compromise patient safety. However, the sheer fact of and volume at which these processes are used underscores the need for Pennsylvania's regulations to be revised at the most fundamental level.

We look forward to working with you, your colleagues in the Senate, the governor, state regulators, and other stakeholders to streamline Pennsylvania's health care regulatory structure to align more closely with patient-care goals and allow for our sector to more fully realize its potential as leading national innovators in the health care field.

AHA Report https://www.aha.org/sites/default/files/regulatory-overload-report.pdf

Medical Group Management Association Annual Regulatory Burden Report, October 2022: https://www.mgma.com/getmedia/4bfd2489-6099-49e5-837f-f787d6d0a30f/2022-MGMA-Regulatory-Burden-Report-FINAL.pdf.aspx?ext=.pdf

A snapshot of Pennsylvania Regulation in 2017 https://www.quantgov.org/pa-snapshot