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RISK MANAGEMENT JOURNAL



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Editor's Corner

AHRMNY's Risk Management Journal (RMJ) is the official journal of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) and is published several times a year.

RMJ's Mission Statement: To enhance the quality of healthcare delivery through education, research, professional practice, and analysis specific to risk management issues.

This journal contains articles on a wide variety of subjects related to risk management, patient safety, insurance, quality improvement, medicine, healthcare law, government regulation, as well as other relevant information of interest to risk managers. The articles are usually written by AHRMNY members, so the journal serves as an opportunity for members to showcase their writing talents.

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Article Requirements: Maximum article length 3,500 words. Photos should be high-resolution JPEGs (at least 300 dpi). AHRMNY will not publish articles promoting products or services.

The information presented in AHRMNY RISK MANAGEMENT JOURNAL is for educational purposes only.

Questions or comments to editors may be sent to ahrmny@gmail.com

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President's Message



Robert (Bob) Martin



Carolyn Reinach Wolf

Hello to all our wonderful fellow AHRMNY members and officers. Hard to believe we are heading down the homestretch of our Co-Presidency. It has been an honor and a privilege to serve this wonderful organization dedicated to improving health services and risk management by developing relationships between the members of the risk management stakeholders to foster an exchange of ideas and methodologies.

It's been a busy year, but a good one. Together, we have produced very successful programs, developed record membership, and fostered collaboration and coordination by our Board and Committees. The year started off with another successful ASHRM conference in San Diego with speakers from AHRMNY and capped with another fantastic reception. This was followed by a home run of a conference in Cooperstown in October continuing our expansion to include all of New York. Special thanks to the Upstate Committee for all the work to make this engagement possible. Special shout out to upstate board member Gina Kittek in that regard. We rounded out 2024 with a webinar by Dan Corcoran, HACP, President and CEO of SafeQual on December 12, 2024, addressing the new CMS Patient Structural Measure Rule. On March 13th, AHRMNY produced our annual Long Island-based half-day educational and networking program in honor of Patient Safety Week. We were pleased to have Deanna Mirro Altmann, RNC, and Mirsade Markovic, Esq., from MLMIC discussing the role of the nurse practitioner and the physician's assistant, ASHRM Journal editor and Board member Josh Hyatt discussing ethical considerations involving patients without families, and Press Ganey Director for Strategic Consulting Navy Capt. Greg Prentiss (ret.) discussing human factors. This will all lead up to the grand finale for the year: The Annual Full Day Educational Conference and Full Day Event featuring a host of break out events, a special keynote address by Justice Arthur M. Diamond (ret.) and of course networking over breakfast and lunch. Be sure to save the date: June 6, 2025, at City Winery, Chelsea Piers!

All of these events would not be possible without the tireless work of our Education Committee and Events Committee with the support of the Board. Special thanks to our President-Elect and Education Committee Chair Wilhemina Nyarko who will soon be taking the reins and putting her mark on this important organization. Special thanks to our predecessor Lori Shapiro for all her efforts to advance the organization. Additional thanks to Executive Director Kisha Wright who keeps the machine running.

Additionally, none of this would be possible without our sponsors and vendors who allow us to put on such fantastic programs at a reasonable price for members and guests. There are still sponsorship opportunities available for June 6th!

This is also a bittersweet time. Long-time Board Member and co-chair of The Risk Management Journal (RMJ) is stepping down after years of dedication that has resulted in making The RMJ the premier peer-reviewed journal for ASHRM member organizations. We thank Linda for her dedication and wish her the best in all future endeavors. We are pleased that she is continuing with AHRMNY as an active member.

We are very grateful for the dedication and assistance offered and provided by all who bring together years of experience and expertise. We are looking forward to our all-day conference on June 6, 2025 at City Winery. It will be a great opportunity to learn from our presenters, one another, and at the close of the program enjoy our always happy Happy Hour, to network, kick back, say hello to old friends and new, catch up and just relax in the beautiful setting that City Winery offers to all attendees. We wish you a wonderful end to the AHRMNY year, summer plans and whatever else is on your calendars for the coming months until we join together again come September.

With much appreciation, collegiality and friendship,

Bob Martin and Carolyn Reinach Wolf

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Diagnostic Errors: A Persistent Risk

Laura M. Cascella

The term "medical error" often conjures thoughts of wrong-site surgeries, procedures performed on the wrong patients, retained foreign objects, serious medication mistakes, and other sensational treatment mishaps. For many years, diagnostic errors largely flew under the radar and "were overlooked in the early discussions of patient safety."[1] In recent years, however, they have received more attention because of evolving care models, increased advocacy and funding, high-profile news stories, and health information technology opportunities.

Beyond patient safety, diagnostic errors also have significant implications for medical malpractice and liability risk. MedPro monitors and analyzes diagnosis-related malpractice allegations to better understand how and why diagnostic errors occur and to develop comprehensive risk education and strategies for healthcare providers. This overview article looks at the issues surrounding diagnostic errors and how they contribute to malpractice allegations and claims.

Defining Diagnostic Errors

Like the diagnostic process itself, defining diagnostic errors is not always simple or straightforward. Multiple definitions have existed in the past, and members of the healthcare community have debated the semantics of diagnostic error labeling.

1. **Delayed diagnosis:** An error that occurs when a diagnosis is not made in a timely manner. For example, a delayed diagnosis might occur if a healthcare provider fails to follow up on a critical lab result until the patient comes in for a routine appointment a year later. However, delayed diagnoses can be complex because "there are very few good guidelines on making a timely diagnosis, and many illnesses aren't suspected until symptoms persist, or worsen."[2]

2. **Wrong diagnosis:** An error that occurs if an incorrect diagnosis is made prior to the correct diagnosis. For example, a wrong diagnosis might occur if a patient is diagnosed with acid reflux when, in fact, they are having a heart attack.

3. **Missed diagnosis:** An error that occurs if no correct diagnosis is ever made. For example, following a patient's death, an autopsy reveals that the patient had undiagnosed congestive heart failure. SIDM notes that major diagnostic errors are found in 10–20 percent of autopsies.[3]

In 2015, the National Academies of Sciences, Engineering, and Medicine (NASEM) released its influential report titled *Improving Diagnosis in Health Care*. The report defined diagnostic error as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient."[4] In keeping with the modern ideal of patient-centered care, NASEM framed diagnostic errors from a patient perspective, explaining that patients ultimately bear the consequences of these errors.

The Scope of the Problem

Estimates related to the incidence of diagnostic errors tend to fluctuate and vary across specialties. Dr. Hardeep Singh, a renowned expert on diagnostic errors and a reviewer for NASEM's *Improving Diagnosis in Health Care* report, has estimated that 1 in 20 U.S. adults will experience a misdiagnosis every year.[5] SIDM notes that diagnostic errors affect an estimated 12 million Americans each year and cause more harm than all other errors combined.[6]

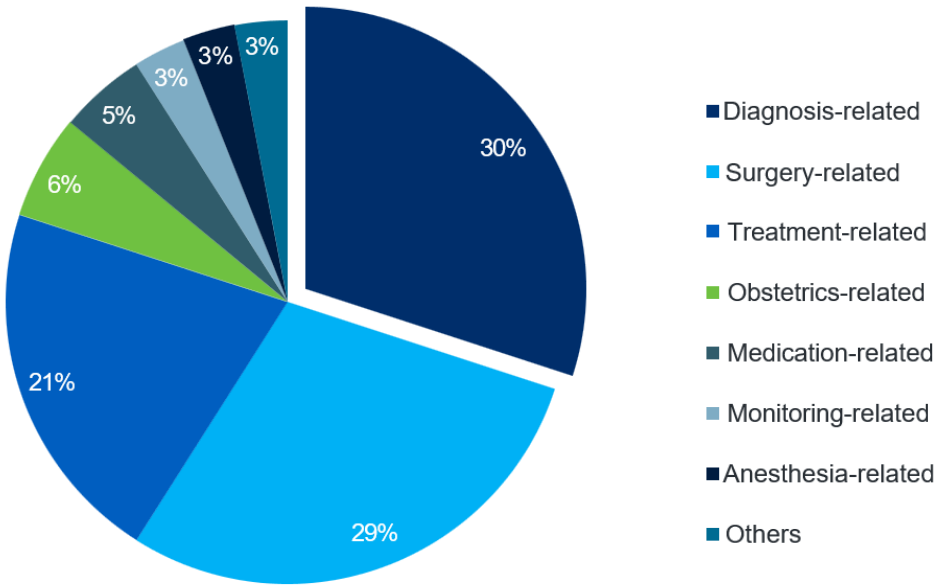
Diagnostic error statistics raise an obvious question: If these errors represent such a significant burden, why have they historically been overlooked? Finding a definitive reason is difficult, but various factors might have played a role. For example, diagnostic errors (a) often go unrecognized or unreported, (b) can be difficult to understand and measure due to the complexity of the diagnostic process and the factors that contribute to these errors, and (c) don't always have clear-cut solutions.[7] Important strides have been made in elevating awareness about diagnostic errors, but more research is needed to identify gaps in the diagnostic process and study risk-reduction techniques.

Learning from Malpractice Cases

Diagnostic errors account for a large portion of malpractice cases, severe patient harm, and costly indemnities.[8] Although diagnosis-related malpractice cases "may not be a representative measure of adverse events, they can provide insight into the types and sources of adverse events."[9]

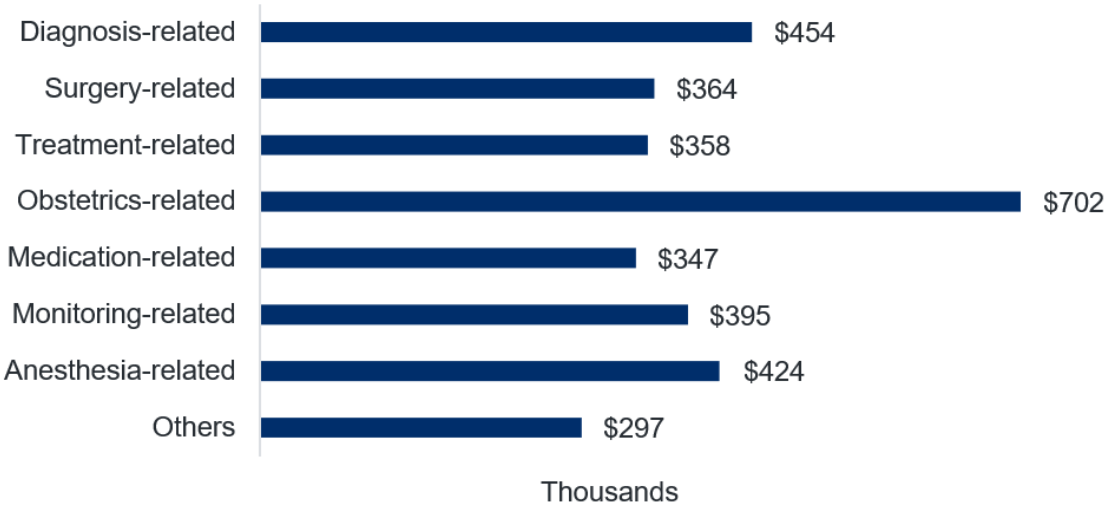
With this in mind, the following data from the National Practitioner Data Bank (NPDB) and MedPro help illustrate the impact of diagnostic errors on patient care and medical liability.

Figure 1a. Percentage of Cases by Allegation Group for Physicians, 2013 – 2022



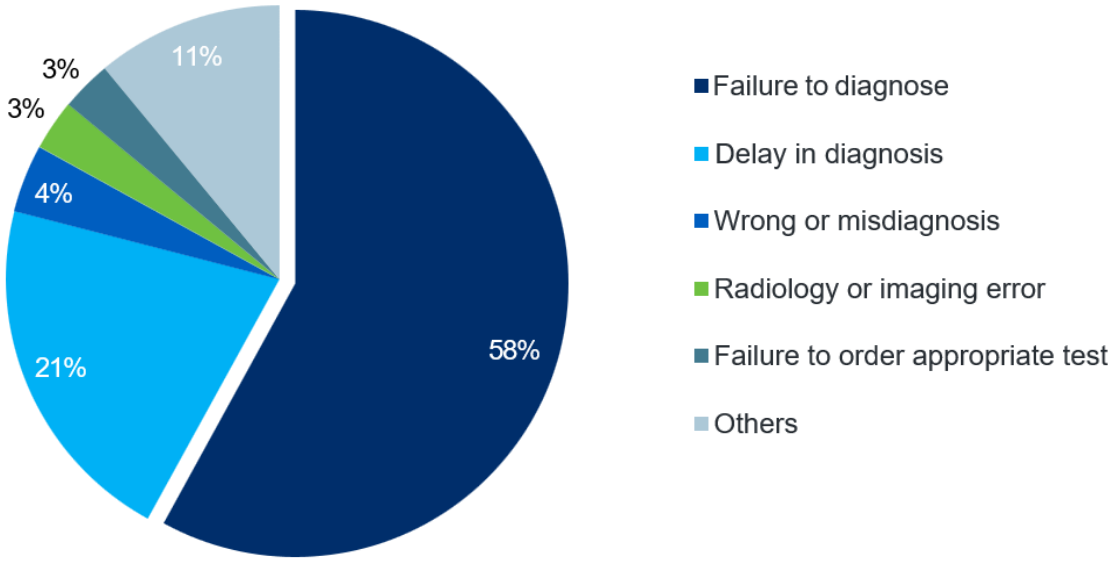
Source: National Practitioner Data Bank Public Use File, Dec. 2022. **Note:** These data do not include any payments by patient compensation funds.

Figure 1b. Average indemnity by Allegation Group for Physicians, 2013 - 2022



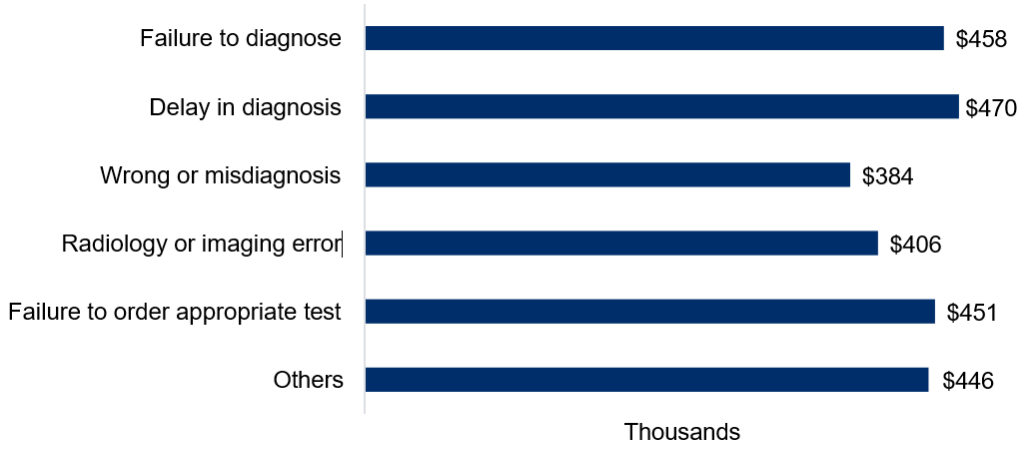
Source: National Practitioner Data Bank Public Use File, Dec. 2022. **Note:** These data do not include any payments by patient compensation funds.

Figure 2a. Diagnostic-Related: Top Allegations for Physicians, 2018 – 2022



Source: National Practitioner Data Bank Public Use File, Dec. 2022. **Note:** These data do not include any payments by patient compensation funds.

Figure 2b. Diagnosis-Related: Average Indemnity for Physicians, 2018 – 2022

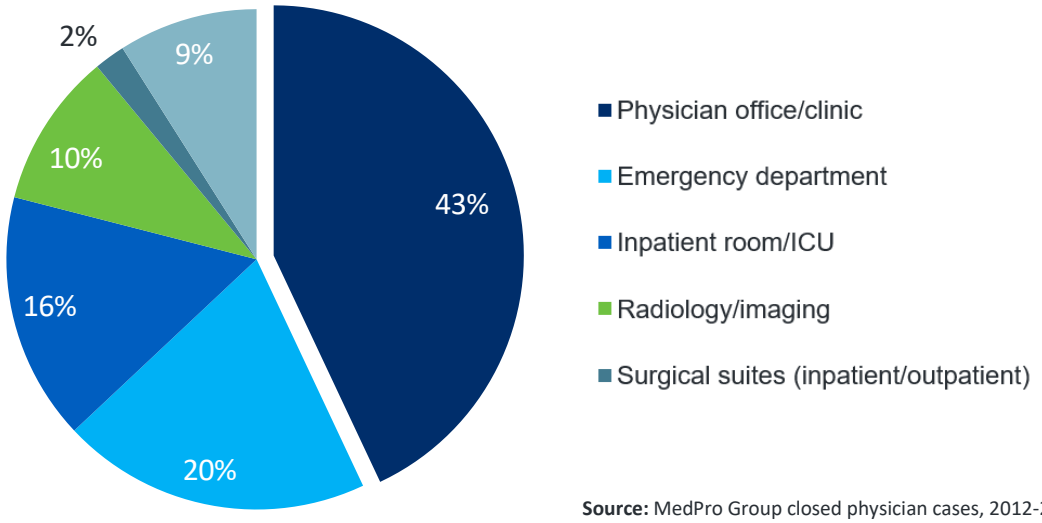


Source: National Practitioner Data Bank Public Use File, Dec. 2022. **Note:** These data do not include any payments by patient compensation funds.

The NPDB data in Figures 1a and 1b show that diagnosis-related allegations account for almost one-third of all physician cases and represent the second highest average indemnity. Figures 2a and 2b show that failure to diagnose is the top allegation category within diagnosis-related cases and accounts for the second highest average indemnity of the diagnostic categories.

MedPro closed case data from 2012 to 2023 show that diagnosis-related case volume varies based on practice setting. Across all practice settings, the majority of diagnosis-related cases are attributed to physician offices and clinics. However, when comparing cases within each location, the emergency department (ED) has the highest percentage of diagnosis-related cases. That is, while the ED only represents 20 percent of diagnosis-related cases overall, when looking at ED cases only, diagnosis-related allegations account for 64 percent of the case volume.[10]

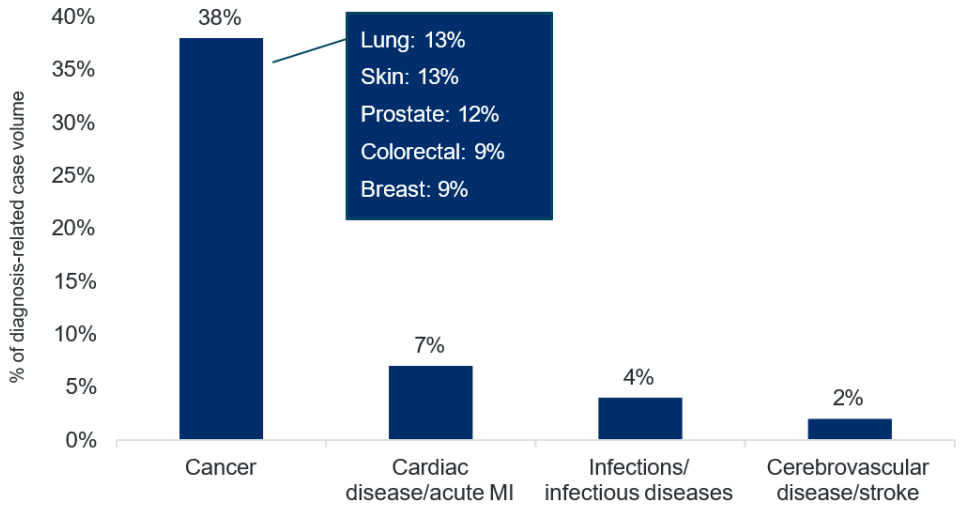
Figure 3. Diagnosis-Related Cases by Location



Source: MedPro Group closed physician cases, 2012-2023.

Further analysis of diagnosis-related cases in physician offices and clinics reveals cancer as the leading condition cited in these cases. The top five types of cancer cited are lung, skin, prostate, colorectal, and breast.

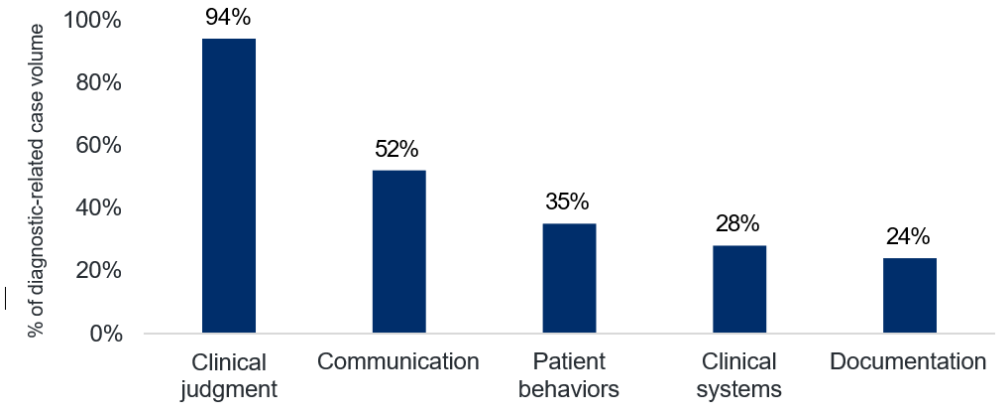
Figure 4: Top Conditions in Diagnosis-Related Cases in Physician Offices/Clinics



Source: MedPro closed physician cases, 2012–2023.

MedPro data also give insight into the factors that contribute to diagnostic errors. Contributing factors are multi-layered issues or failures in the process of care that appear to have contributed to the patient outcome and/or to the initiation of the case, or they had a significant impact on case resolution. Clinical judgment is the most prevalent contributing factor; it is noted in almost every diagnosis-related allegation for physicians — a rate slightly less than double that of the next most common risk factor (communication).

Figure 5: Top Risk Factors in Diagnosis-Related Allegations



Source: MedPro closed physician cases, 2012–2023. **Note:** Totals exceed 100 percent because generally more than one factor is associated with each case.

Within the broad areas of risk noted in Figure 5 are more specific issues that lead to diagnostic failures or mishaps. Examples of such issues include:

- Cognitive and affective biases
- Breakdowns in communication between systems and providers and between providers and patients
- Vulnerabilities in clinical workflow processes and organizational policies
- Issues with information synthesis

Further, cases may involve multiple contributing factors and more than one provider. For this reason, strategies to address these errors should target their common contributing factors, rather than "just attempt to augment knowledge or clinical skills related to specific diseases because such interventions may not generalize across diseases or care settings."[11]

From a risk management perspective, identifying and understanding the factors that contribute to diagnostic errors is an important first step in devising feasible risk-reduction strategies for various practice settings.

Take-Away Message

Diagnostic errors represent a common, serious, and costly risk. Although not all diagnostic errors result in adverse events, many do — creating legitimate patient safety and liability concerns. By identifying and better understanding the factors that contribute to diagnosis-related malpractice cases, healthcare organizations and providers can implement corrective actions to improve quality of care and reduce liability exposure.

References on page 34

About the Author



Laura M. Cascella, MA, CPHRM, is the medical writing and publication management lead at MedPro Group. She has more than 20 years of experience in health communications and content development and has authored and contributed to numerous print and digital publications and health education programs.

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CMS PSSM: Team Planning to Succeed with a Heavy Lift

Dan Corcoran

CMS is taking additional action to combat preventable patient harm by publishing its vision of excellence in patient safety, and compelling healthcare systems to understand it. This vision is outlined and backed by 27 "measures" (standards and practices) across five domains, accompanied by a score that will be published after healthcare systems complete attestations, one per measure, on how their healthcare system measures up to CMS's vision. The attestation for the calendar year 2025 will be made public on CMS Care Compare in October 2026.

Healthcare systems are financially compelled to understand the CMS vision, complete the gap analysis, and submit an electronic attestation of the results on time. Through a harsh scoring system, hospitals are also somewhat compelled to follow through on CMS's desire for healthcare systems to follow their vision.

Most healthcare systems will score zero on a five-point scale if they do not make at least some investment to align with CMS's vision.

About the Article

This article's content comes from SafeQual, performing an analysis on the CMS PSSM and enhanced by conversations with many industry professionals, including the volunteers from ASHRM's Education Committee, SafeQual' advisory board, and industry peers.

How CMS Compels You

First, hospitals are compelled to learn about CMS's vision for patient safety excellence by performing a gap analysis between their healthcare systems' current patient safety practices and CMS's vision, which is described in 27 measures (formerly 25).

Online tools, such as the one offered by IHI.org in the reference section below, are available to do a lightweight gap analysis. Serious gap analysis in pursuit of scoring above zero is a fool's errand unless you first attain leadership's commitment to invest serious resources to build a verifiable process that is repeatable across a team of people. Some measures require verification down to the unit level of your healthcare system, as the scoring system offers no partial credit for missed or incomplete measures in any of the five domains.

Hospitals will report their gap to the PSSM through the National Healthcare Safety Network (NHSN) platform in the form of attestations. Detailed guidelines and additional resources are being developed to assist hospitals in evaluating their safety activities across the five domains.

Failure to comply with the reporting requirement will result in a penalty calculated as a percent of revenue.

Hospitals may feel compelled to do far more than just report, for example, they may desire to change their processes to mirror CMS's vision. That requires even more resources.

Hospitals Impacted by the Rule

Temporarily, CMS is not compelling this gap analysis for certain types of hospitals, such as psychiatric, rehabilitation, children's, and critical access hospitals, that are exempt from the requirements.

The rule applies to all other acute care hospitals participating in the Hospital Inpatient Quality Reporting (IQR) and PPS Exempt Cancer Hospital Quality Reporting (PCHQR) programs.

How the PSSM Scoring System is Harsh

For each domain where every measure receives a yes, the hospital scores one point—not one point per measure, just one point for the domain in total.

The reverse is true: If any one unit in a hospital does not comply with every measure, all the hospitals sharing the same CMS Compliance Number (CCN) score zero for that domain.

Hospitals can earn up to five points – one point in each domain in which they provide affirmative attestations for every measure. **No partial credit**.

The many ways for a hospital to score a zero out of five include:

1. The hospital performs at 80% in each domain; the score is zero.
2. The hospital performs about 100% yet is missing one element of a measure in every domain; the score is zero.
3. The hospital performs 100% of all measures in every domain, except one unit, that is missing an element from every domain, the score is zero.
4. The hospital is performing to a full 100% of all measures, while another hospital within the CMS Certification Number (CCN) scores zero; all hospitals score zero.

Is this unreasonable? Is this any different than the conditions of participation (CoP) that require 100% compliance with a standard, as opposed to 80%?

Unwanted Intrusion or Desired Incentive

If you are proud of how your healthcare system has integrated patient safety best practices into all its processes, and this does not match CMS's vision, you may find the new rule intrusive.

If you want change in your healthcare system, if you want vacant positions filled or new technology added, you may instead look at this as a tool to advocate for funding.

There's nothing like, "Hey boss, under the new rule, on a scale of 0 to 5, we score a zero today." I don't know how much effort is required, but for starters, we need more people and better data.

The Five Domains of PSSM

1. **Leadership Commitment**: Hospital leadership must demonstrate a firm commitment to eliminating preventable harm.

   In domain 1, attestation C is "Our hospital governing board, in collaboration with leadership, ensures adequate resources to support patient safety (such as equipment, training, systems, personnel, and technology).". Can you answer Yes?

   Also in domain 1, attestation E is "C-suite executives and individuals on the governing board are notified within 3 business days of any confirmed serious safety events resulting in significant morbidity, mortality, or other harm. Do you have the technology to do this securely with processes to protect PHI and document compliance?

2. **Strategic Planning and Organizational Policy**: Hospitals must establish clear strategies and policies that prioritize patient safety.

   In domain 2, attestation C "Our hospital has implemented written policies and protocols to cultivate a just culture that balances no-blame and appropriate accountability and reflects the distinction between human error, at risk behavior, and reckless behavior.".

   Being able to say mostly yes to this, not entirely yes, perhaps your burn unit fails in this regard,

scores a zero for the whole domain, and every hospital sharing the CMS Certification Number (CNN). Yes or No.

3. **Culture of Safety and Learning**: This domain focuses on fostering a culture where safety is integrated into the hospital's daily operations, emphasizing learning and continuous improvement.

   It gets more challenging in domain 3. In attestation D, there are 7 high reliability practices listed, your hospital needs to have fully and completely implemented a minimum of 4 practices in every unit of your hospital. Answering yes requires every unit of the hospital.

4. **Accountability and Transparency**: Hospitals must maintain transparency and accountability, ensuring that safety issues are addressed openly and promptly.

   In domain 4, accountability and transparency, attestation C "Patient Safety metrics are tracked and reported to all clinical and non-clinical staff and made public in hospital units, displayed on units so patients, families, and visitors can see".

   Are you ready to have a sub-set of your patient safety dashboards displayed publicly, in every unit? Are you going to use computer monitors or paper to do that? Are you going to document for five years what was shown?

   Is your staff ready to handle questions on your KPI's? More on this later.

5. **Patient and Family Engagement**: Active involvement of patients and families in safety initiatives is essential to prevent harm and improve outcomes.

   In domain 5, patient and family engagement, attestation D "Patients have comprehensive access to and are encouraged to view their own medical records and clinician notes via patient portals and other options, and the hospital provides support to help patients interpret information that is culturally- and linguistically-appropriate as well as submit comments for potential correction to their record."

   Another example of a best practice being elevated to a standard. Are all your hospitals in your CMS Certification Number (CCN) staffed to handle this consistently, or only when a key employee is not on paid time off? Will patient expectations grow to have this available more often?

Does This Fall Under Risk Management?

During a recent ASHRM education content committee call I chair, one member remarked that CMS might be "going too far and too fast" with PSSM. Another member asked whether the PSSM falls under their purview.

While many aspects of PSSM intersect with other areas of responsibility, risk management in the ERM Clinical/Patient Safety, Operational, and Strategic domains is clearly impacted.

ASHRM is also providing content on this subject matter. As of this writing, ASHRM has one recorded webinar introducing PSSM (see references at the end of this article), which is available as a resource to help you understand the early barriers you will encounter in your organization and your potential role in this new framework.

Next Steps for you as a Risk Manager

Assuming the talk of PSSM does not have you heading for the door to retirement or a career switch, here are some next steps for you to personally contemplate.

First, consider whether you, as a leader, are ready to take on this challenge as a leader. Do you have a strong second in command, someone who can manage details and delegation, so you can succeed at continuously evaluating progress and making adjustments to stay on track with an end-of-2025 deadline? Does it make sense to polish your primary skills through professional organizations?

Could it also make sense to advocate for a dedicated project manager to work on the details of the gap analysis, advocate for funding, and organize change management across all the units in your hospital rather than rely on you and the core leaders in safety, quality, and compliance?

Become familiar with the 27 measures to determine what conversations you need to have with your CMO and CNO, as well as your safety, quality, and risk management peers. Increase your professional skills in using technology like ChatGPT, dashboards, and project management. Sometimes, basic familiarity with each can enhance the value of your primary skills.

Delegate or become the expert on how your healthcare system operates with its PSO.

Look to budget money and have multiple staff members become familiar with relevant ASHRM playbooks. Patient Safety, Root Cause Analysis, and Human Capital.

For yourself, consider the Leadership Playbook for Healthcare Risk Professionals and Enterprise Risk Management Playbooks.

Every measure in PSSM has been implemented by somebody. As your peers look to gain insight from others who have implemented it, help them choose processes that also mitigate litigation risks to the healthcare system and/or look to gain insight from your professional organization on mitigating those risks as well.

Some litigation risks that come to mind include:

- Displaying patient safety KPI's in every unit, requirements for harm disclosure to families being made within one hour of discovery. How will that one hour be documented? Will nurses place that in the electronic health record?
- Be aware of a much greater amount of information being exposed to board members. One of the requirements is to notify board members within 3 days of a serious event, will information leave your protected patient safety system and now be discoverable? Is PHI being deidentified?

Next Steps for your Healthcare System

Starting early on the 27 measures can offer substantial advantages to achieving the score your healthcare system should earn. Consider the following steps:

- **Leadership Engagement**: Ensure leadership knows extensive resources are needed, including potential staffing, technology, and operational shifts. Build a commitment to allocating resources for a qualitative, quantitative, actionable, and repeatable gap analysis at annual intervals, or the time put into the first gap analysis may just be you spinning your wheels.
- **Eliminate EGO in GAP Analysis:** Ensure any initial GAP analysis does not overstate your healthcare system's readiness to score high on PSSM. The scoring system's designers are well aware of the pitfalls of past attestation methods, making this version much harder to pass. Manage ego by communicating that a score of 1 or less is not unexpected, as CMS is forcefully compelling change.
- **Staffing Needs**: Assess whether there are urgent staffing vacancies that must be filled before proceeding. Is funding available to hire additional staff in patient safety, quality, risk, and compliance areas?
- **Consulting Resources**: If your budget allows, consider engaging consulting organizations, but be aware that their top resources may be booked quickly.
- **Technology Assessment**: Evaluate existing technology infrastructure. Are you facing technological debt that might hinder success? Will necessary technology decisions need to be made soon to ensure you have the data required before the end of 2025?
- **Data & KPI's:** When conducting a gap analysis between the 27 PSSM measures and current practices in your healthcare system, emphasize the data and KPIs related to patient harm early on. Are incidents being reported at a convincing rate, such as 15 events per bed? Is apparent cause analysis (mini root cause) being conducted on 70% or more of events within 14 days? If not, prioritize the necessary efforts and resources to enhance safety culture and data collection. This foundational data is crucial.

Final Thoughts

When I think of all of you, I can't help but reflect on the groundbreaking innovations that have originated within our New York healthcare systems. The volume of talent and expertise among the leaders here at AHRMNY and across our state's healthcare community is unparalleled. So many of our local healthcare organizations have received leadership awards as recently as December, and I wonder why New York isn't the center of excellence in patient safety or the top leader in ASHRM.

That landscape could shift. CMS has boldly pulled the leadership crown away from Chicago and temporarily claimed it for its Maryland-based organization with its required gap analysis and 5-point scale. They've thrown down the gauntlet, challenging healthcare systems nationwide to reach higher standards. Intentionally lacking in specifics like KPIs, this isn't just a contest of compliance—it's an opportunity to innovate, lead, and define the future of patient safety.

The question remains: Can New York rise to this challenge? Can our healthcare systems, consultants, and technology companies work together to claim that crown for serving our communities the best?

The path ahead is not without challenges. Implementing CMS's vision requires investments in staffing, technology, and leadership, but there's also an opportunity here. Each healthcare system has the flexibility to adapt the CMS framework to meet the unique needs of its community. By leveraging the CMS Patient Safety Structural Measure as a tool for advocacy, we can secure the resources necessary to build a foundation for excellence.

I urge you to guide the leaders in your organizations to prioritize these investments. Collaborate across institutions, share best practices, and tailor solutions to our diverse demographics. Together, we can not only meet CMS's standards but exceed them, demonstrating that New York is the true leader in patient safety innovation.

The crown is within reach. Let's take it—together.

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About the Author



Dan's industry leadership includes contributions to AHRMNY as board member and education committee volunteer, PFPS US advocacy committee volunteer, ASHRM past EDC Education Committee Chair, HFMA Metro NY Chapter past Board Member and Technology-Education Committee Chair. Dan speaks and writes on PSSM, HRO, QAPI, and AI-related issues in healthcare.

Dan Corcoran is the founder and CEO of SafeQual, providing cloud-based enterprise software that reduces the effort of health care teams who ensure safety, quality, compliance, and risk management, aiming for zero harm and integrating CMS patient safety structural measure across their organizations.



MEMBER SPOTLIGHT

Join us in congratulating the following AHRMNY members for volunteering to share their achievements featured in this edition's MEMBER Spotlight

Tiffany Wickes-DeMillio, RN, FASHRM - Catholic Health



Tiffany was promoted to Assistant Vice President for Safety and High Reliability at Catholic Health. In this new role, she will have the opportunity to utilize her Risk/Safety experience to ensure the highest standards of safety and reliability across all entities within Catholic Health. Tiffany looks back on her 14 years of service at St. Francis Hospital fondly and brings to Catholic Health all she has learned. Tiffany hopes that her expertise and vision will be invaluable as the organization continues to enhance safety protocols and reliability measures.

Additionally, at the last ASHRM Conference in San Diego, Tiffany was presented with the distinction of Fellow of the American Society for Healthcare Risk Management (FASHRM). This distinction recognizes outstanding achievements and contributions to the healthcare risk profession.

Tiffany is a current member of AHRMNY and also serves as a Board Member.

Mary Steffany, RN, DFASHRM



In January of 2025, Mary was awarded the designation of Distinguished Fellow of the American Society for Health Care Risk Management (DFASHRM). This designation recognizes Mary for outstanding individual achievement of professional excellence in the health care risk management profession.

Mary is a current member and past-president of AHRMNY.

Dawn Pignatelli, Esq. - Bartlett LLP



In June of 2024, Dawn was promoted to partner at Bartlett LLP.

Dawn is a current member of AHRMNY and serves as a Board Member. Dawn also Chairs AHRMNY's Bylaws Committee.

Fixed Staffing Rations: A Band Aid or a Cure?

Summary of the Minimum Staffing Standards for Long-Term Care (LTC) Facilities and Medicaid Institutional Payment Transparency Report Rule

Michelle Frankel, Sharon Scheuermann, and Mario Giannettino

The Centers for Medicare and Medicaid Services (CMS) issued the Minimum Staffing Standards for Long-Term Care (LTC) Facilities and Medicaid Institutional Payment Transparency Reporting proposed rule in early September 2023.[1] The main goal is to promote and improve patient safety and quality of care by establishing minimum staffing requirements. Such requirements are intended to address understaffing concerns, which have long been a hurdle in the industry but were worsened by the COVID-19 pandemic. CMS received over 46,000 public comments about the proposed rule and affirmed the Final Rule on April 22, 2024 with some changes compared to the proposal including an increase in hours per resident day from 3 to 3.48 hours.[2]

The main requirements of the Final Rule include "…a total nurse staffing standard of 3.48 hours per resident day (HPRD), which must include at least 0.55 HPRD of direct registered nurse (RN) care and 2.45 HPRD of direct nurse aide care. Facilities may use any combination of nurse staff (RN, licensed practical nurse [LPN] and licensed vocational nurse [LVN], or nurse aide) to account for the additional 0.48 HPRD needed to comply with the total nurse staffing standard."[3] The Final rule also requires facilities to have an RN on-site 24 hours, 7 days per week and enhanced facility assessment requirements.

The Final Rule is being implemented over time with three phases over a three-year period in non-rural areas. The three phases are as follows: "Phase 1- Within 90 days of the Final Rule publication, facilities must meet the facility assessment requirements. Phase 2 — Within two years of the Final Rule publication, facilities must meet the 3.48 HPRD total nurse staffing requirement and the 24/7 RN requirement. Phase 3 — Within three years of the Final Rule publication, facilities must meet the 0.55 RN and 2.45 NA HPRD requirements."[4] Rural facilities will have more time to adopt the requirements given the unique challenges that they face. Their phases will be as follows "Phase 1 — Within 90 days of the Final Rule publication, facilities must meet the facility assessment requirements. Phase 2 — Within three years of the Final Rule publication, facilities must meet the 3.48 HPRD total nurse staffing requirement and the 24/7 RN requirement. Phase 3 — Within five years of the Final Rule publication, facilities must meet the 0.55 RN and 2.45 NA HPRD requirements."[5]

The rule includes a hardship exemption, but it involves extensive criteria and is a burdensome process. The exemption is likely to be granted on a limited basis, especially since CMS expects the requirements to be just that: a new minimum. Facilities are expected to determine whether the resident acuity and individual care needs require more than the minimum.

CMS estimates that the total cost associated of the Final Rule will be $4.3 billion per (a total of $43 billion over 10 years) yet the Rule does not include any funding to facilities to help increase staffing and meet the new staffing requirements. CMS will use $75 million for scholarships and tuition reimbursement to help increase the workforce but facilities will still incur extensive costs associated with wage increases and other adjustments needed to fulfill the requirements.

Facilities that fail to meet the requirements may incur penalties including, but not be limited to, denial of payment for new admissions (DPNA), directed plan of correction (DPOC), directed in-service, civil monetary penalties, temporary management, state monitoring, transfer of residents, provider agreement termination.

Shortcomings and Implications of the Rule

While the rule stems from admirable intentions that LTC providers generally do not disagree with, thousands of comments were submitted by LTC providers about the shortcomings, oversights and negative implications of the rule. LTC providers have firsthand experience grappling with the growing patient population and the reality that the staff needed (and now mandated) is simply not available.

Overarchingly, the rule attempts to promote quality care by mandating staffing levels that facilities are knowingly unable to fulfill despite extensive financial

and recruitment efforts already made. It has been acknowledged that there is a historic workforce crisis worsened by the pandemic, which further strained existing staff, caused many staff to leave and others to choose to work elsewhere in healthcare. States like New York have even declared a statewide emergency and an acute labor supply shortage of nurses yet enacted their own minimum staffing requirements, which facilities are unable to fulfill despite heightened recruitment and retention efforts.

The rule was proposed in 2023 despite the extreme staffing shortage occurring at that time. The staffing shortage was so significant that, according to American Health Care Association and National Center for Assisted Living (AHCA/NCAL) advocates for more than 14,500 long term care and post-acute care facilities, 49% of urban facilities and 47% of rural facilities did not meet the 0.55 HPRD requirement for RNs and 73% of urban facilities and 69% of rural facilities did not meet the 2.45 HPRD requirement for nurse aides.[6] In terms of the 24/7 RN requirement, 77% of urban facilities and 92% of rural facilities did not meet the requirement.[7] CMS finalized the rule despite this reality. Facilities continue to deal with staffing shortages and a lack of people to hire and with this, facilities were essentially setup for failure as they are not close to adhering to the requirements.

The rule does not account for many hurdles and realities faced by facilities. For example, the rule does not provide funding to help facilities fund wage increases and bonuses necessary to obtain and retain staff. Some skilled nursing facilities (SNFs) have spent hundreds of thousands of dollars in additional annual bonuses, and unfortunately, still have difficulty meeting state requirements and/or the CMS requirements. Importantly, even if effective, such spending levels are not sustainable. While the rule includes funding for scholarships and reimbursement to help grow the workforce, the requirements will begin to be effective before the workforce grows and/or returns.

The rule also fails to give facilities some flexibility in how they fulfill the 24/7 RN requirement by allowing them to use telehealth and a remote RN. Without this flexibility, facilities will incur extensive additional costs and have difficulty fulfilling the role because it is already extremely difficult to hire RNs. As highlighted by LeadingAge President and CEO Katie Smith Sloan, RNs typically choose to work in settings other than LTC and are leaving the workforce and the profession as a whole at this time, and "the final rule does not include additional funds to pay RNs comparable or higher wages to [entice them to] work in long-term care."[8]

The proposed rule had overlooked the extensive role of LPNs by not counting their HPRD toward the requirements. Thankfully, the Final Rule allows them to be counted as LPNs are vital and helpful members of the clinical team and their role represents an opportunity for career growth in the eyes of many CNAs. Nonetheless, the Final Rule fails to allow facilities to fulfill staffing requirements by recognizing the role of other staff members such as activities directors, social workers, therapists etc. Meanwhile, these other staff members may serve the needs of residents in various ways and can help account for staffing shortages. The value of all staff was evident during the pandemic when the staff at many facilities did anything that they could to help and work as a team.

Accordingly, the minimum staffing requirements will add administrative and financial burdens and will not necessarily rectify the staffing issues because it is already known that it is very difficult to hire and retain staff despite extensive efforts. The stark nature of the market is evident in the ratio of job postings vs. applications. For example, facility job postings in a three-month time span may garner almost 25,000 views and 19,000 clicks. However, the facility may only receive 424 completed applications, which is a mere 2.2% of the clicks and only 1.7% of the views. This issue is not uncommon within the industry and these numbers are a glaring reminder of the competitive job market and the impact of the staffing shortage.

Facilities have already increasingly relied on agency staff to fulfill staffing needs, but some areas continue to struggle to obtain staff due to competitors nearby. Other facilities that meet important patient needs in rural areas have difficulty hiring staff even via agency because the area is less desirable for some candidates who need to move or drive long distances if they even have a car. While using agency staff can be helpful, it has not resolved the staffing issues in industry as the shortage lingers. Having more agency staff is also less advantageous for residents as the nature of having staff members work for random or brief periods of time makes it more difficult to foster a close-knit environment and reduces the relationships built with residents. Agency staff members also typically require higher pay rates, which cannot be sustained.

Thus, unfortunately the requirements may be well intended but may not garner the desired benefit. The rule may actually create detriments by leading facilities that are already foreseeably unable to fulfill the mandates to have to halt or reduce admissions leaving many patients with fewer options of places to go for necessary care. Meanwhile members of the LTC industry agree with CMS that ensuring the health and safety of residents is a top priority. Many facilities have 4- and 5-star Nursing Home Compare (CMS) ratings, which are a testament to their commitment to providing quality care and maintaining such quality. While issuing the rule may technically promote quality care by mandating staffing, in reality, the rule may cripple many facilities already facing staffing difficulties due to no lack of desire or effort.

In response to CMS' affirmation of the rule, AHCA President and CEO Mark Parkinson highlighted these types of flaws and foreseeable risks associated with the "one-size-fits-all enforcement approach."[9] Mr. Parkinson said, "While it may be well intentioned, the federal staffing mandate is an unreasonable standard that only threatens to shut down more nursing homes, displace hundreds of thousands of residents, and restrict seniors' access to care."[10] He added that "It is unconscionable that the [Biden] Administration [] finaliz[ed] this rule given our nation's changing demographics and growing caregiver shortage. Issuing a final rule that demands hundreds of thousands of additional caregivers when there's a nationwide shortfall of nurses just creates an impossible task for providers. This unfunded mandate doesn't magically solve the nursing crisis."[11]

An Insurance Company Perspective

Several insurance companies providing professional and general liability insurance for senior care organizations shared their perspective on staffing concerns and senior care recently. According to Lynette Perkins, Underwriting Specialist with Liberty Mutual Insurance, "more often than not, insurance companies see a correlation between staffing, quality indicators and insurance claims."1 As a result, staffing is a crucial element in the underwriting process. It should be noted, however, that organizations are not evaluated solely based on staffing levels.

The insurance company submission review process is a collaboration between underwriting, claims, risk, and actuary, each providing their perspective of a particular risk. This allows for objective and subjective considerations in the evaluation.

To begin, the application provides basic data related to staffing including the employee screening process, total number of health care professionals, and turnover rates. This data is thoroughly analyzed in conjunction with loss data, state surveys, and other public information. Additional factors are considered including:

- Types of services and level of care provided
- Facility reputation (news articles, reviews, perception online)
- Financial condition of the organization
- Location of the risk
- Management and ownership (private equity backed)
- Experience of administrators and Director of Nursing

More than ever before, senior care facilities have heavily relied on agency staff to maintain appropriate staff-to-resident ratios. Although this may improve ratios, facilities with a high percentage of agency staff may be "flagged" for a number of reasons:

- Inconsistency of resident care
- Agency staff are not as invested in the facility
- Animosity between the agency and employed staff
- Potential financial impact

When initially queried if the underwriting process would change if the staffing mandate is passed, the consensus among the underwriters at that time is that they have a robust process in place and [did] not plan to make any changes. "As with all changes that broadly reach the Senior Care industry, we keep a close watch on the operational and legal impacts of any mandates." Said Benjamin Mack, head of Senior Care with Bowhead Specialty Underwriters. Similarly, there are no current plans to change policy language. The underwriters agreed the focus would be on asking the right questions rather than changing policy language initially. Will exclusionary language be introduced in the future? While not likely, this is not off the table.

Insurers noted several initiatives introduced by senior care operators to improve staffing and employee morale including student loan reimbursement, AI and remote patient monitoring, and employee recognition programs. While all positive, these initiatives come

with a cost, and many facilities cannot afford to implement them.

All insurers agreed that increasing staff will have a positive impact, however, there is no clear path to accomplish this. The estimated funding to comply with the mandate is $6.8B2. How will this be funded? Many operators are struggling financially and do not have the means to comply, nor will they be in a position to pay any fines for noncompliance. The fines may increase accountability, but will they improve care or cause an unneeded distraction for operators? The backlog created in hospitals trying to discharge patients who require a senior care setting for safe discharge demonstrates the systemic burdens the staffing mandate will likely have on the healthcare system. How will this be addressed?

While insurance companies recognize the link between staffing and quality care, concerns remain about the viability and impact of the staffing mandate. The financial burden on senior care facilities and the complexities of implementation raise questions about its effectiveness in actually improving resident care. Finding a sustainable solution that balances quality standards with realistic feasibility will require further collaboration between policymakers, insurers, and the healthcare industry.

Unintended Consequences

Clearly, the minimum staffing mandate released by the CMS has engendered pushback from skilled nursing providers and has given insurers reason for concern. The mandate may also have a significant unintended consequence: providing a playbook for plaintiff's attorneys. Anyone who has defended a skilled nursing provider already knows that the plaintiff recipe for success includes claims of understaffing, which often, are advanced in the abstract with no real correlation to the facts of a given case. However, in states such as New York and Pennsylvania, which do have staffing mandates, plaintiff attorneys often use data points to support their cases – particularly, CMS star ratings, where staffing and staffing turnover is a component of the ratings systems; or the Payroll Based Journal. The federal staffing mandate adds to these potential real-world data points. With a federal mandate in place, plaintiffs now argue that any failure to meet a statutory requirement should be evidence of negligence or negligence per se.

Claims about understaffing also skirt what should be readily obvious: SNFs are now offering more services to residents with higher acuity levels. Using the COVID crisis as an example, skilled nursing facilities were required in many states to admit residents with COVID to free up much needed hospital space, adding a level of complexity to care for such patients in the skilled nursing setting. As a result, SNFS accepted sicker patients which in turn, affected their case mix levels and in some instances, their star ratings. Moreover, persons are living longer and with advanced age comes advanced disease and comorbidities, which adds to SNF acuity and burdens on staff. Rising acuity then becomes one of the many dots defense attorneys need to connect and use to place surveys, starting ratings and other data points into proper context.

Another unintended consequence of the staffing rule is that if a skilled nursing facility cannot meet it, patients may be displaced. New York providers a sobering tale. Under its mandate, passed in November 2021, facilities must provide 3.5 hours of care per resident per day; no less than 2.2 hours of care must be provided by a CNA or nurse aide, and at least 1.1 hours must be provided by an RN or LPN. After several providers and trade groups sued to block the law, it was temporarily suspended, but went into effect in April 2022.

Some facilities in New York have been unable to comply with the mandate and their solution was to limit or stop admissions. This in turn led to a bottleneck as hospitals could not discharge patients and hospitals were not reimbursed for patients occupying beds while awaiting discharge to a post-acute facility.

To assume that this bottleneck will not be felt by families of patients is erroneous. In litigation, families often testify that their loved one could not be placed in their preferred facility of choice due to the lack of available beds. The frustration of having their loved one being put in a facility which they did not choose is palpable and remains apparent years after the care at issue and often drives lawsuits. It is not inconceivable that staffing mandates will have the unintended consequence of making preferred placement choices even harder. Also, in New York, Governor Hochul has issued several Executive Orders declaring a state of emergency due to healthcare staffing shortages throughout regions of New York, underscoring the reality of staffing in the post-pandemic era.

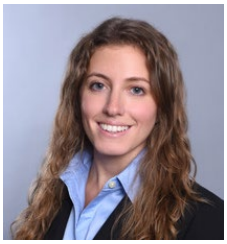
Staffing mandates do not recognize that care is multidisciplinary and involves critical employees such as contracted therapy providers, consultants, specialists and activity coordinators, amongst other professionals. Open up any SNF chart and there will be copious examples of wound care, podiatrist, speech therapists, social workers, and others providing hands-on direct care of great value to residents. In essence, reducing staffing to raw numbers does not tell the complete picture. Defending SNFs, now more so than ever, would require proof that facility operators are recruiting and retaining workers, offering competitive salaries, bonuses, and adopting strategies to attract, retain and educate their front-line staff – none of which is evident in a chart.

Staffing mandates also fail to understand that often, front line staff have a connection with their residents. As a defense attorney, one of the most gratifying things to hear when interviewing a nurse or an aide is that they knew the resident and can share a story about them. Even more gratifying is to hear that they respect the people they work with and entered nursing because they had a mission and purpose to care for people. Staffing mandates, by reducing people to mere numbers, completely loses the human element.

The staffing law has been challenged in multiple courts across 21 states. The key arguments are that the new minimum staffing requirements are "irrational" and "unattainable"; that CMS lacked statutory authority to issue the final staffing rule; and that the rule is arbitrary and capricious, in violation of the Administrative Procedure Act. The issue is likely to make its way to the United States Supreme Court where the viability of the Chevron doctrine will again be tested.

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About the Authors



Michelle A. Frankel is the Director, Legal Affairs & Counsel at National Health Care Associates, Inc, which is a provider of short-term rehabilitation, skilling nursing and post-hospital care. As the sole in-house attorney, Michelle assists about 40 affiliated facilities throughout the northeast with varied legal and compliance issues to ensure the provision of quality and compassionate care.

Michelle has a background in litigation and broad healthcare experience from working at a boutique healthcare law firm, the New York State Department of Health, and Pfizer. Michelle has lectured physicians at a renown NYC hospital and published more than 20 articles on diverse topics impacting the healthcare industry.



Sharon is a Senior Vice President in the National Healthcare Practice at Risk Strategies, a national specialty insurance brokerage firm, and serves as a producer and team leader. Her primary role is new business development and for managing client relationships and coordinating services and resources provided. Sharon has over 34 years of insurance brokerage and consulting experience. Her professional experience began as an Account Manager at a regional broker in the Midwest.

Sharon is a member of the American Society for Healthcare Risk Management (ASHRM), Association of Healthcare Risk Managers in NY (AHRMNY) and LeadingAge New Jersey & Delaware. Additionally, Sharon serves on the AHRMNY Board and the AHRMNY Publications Committee.



Mario C. Giannettino is a partner in the law office of Kaufman Borgeest & Ryan, LLP in the firm's Medical Malpractice, Nursing Home and Long Care and General Litigation practice groups. Throughout his career, Mr. Giannettino has represented a wide range of healthcare professionals and providers, including hospitals, physicians, nurses, residential healthcare and assisted living facilities, physician's assistants and home healthcare agencies. During his varied career, Mr. Giannettino has defended a myriad of suits, including class actions, from inception through trial. Mr. Giannettino serves as lead counsel for his firm's COVID-19 practice group and has been responsible for seminal decisions concerning pandemic-related legal immunities.

In addition to his litigation experience, Mr. Giannettino provides a broad spectrum of services to healthcare clients, including staff training, in-servicing, counseling on risk assessment issues, and assisting them in navigating privacy and security issues under both HIPAA and the HITECH Act and regulatory and compliance issues. Mr. Giannettino is also a Certified Professional in Health Care Risk Management through the American Hospital Association.



Submit your topic and speakers here by April 30th

State Survey Deficiencies and Claim Allegations in Assisted Living Facilities

Susan Lucot

Assisted living facilities (ALFs) were established to provide residential options for elderly individuals who find that living alone is no longer appropriate or practical. Often, the decision to move to an ALF is made when an elderly person needs help with everyday tasks, such as housekeeping, cooking, laundry, housing maintenance, and transportation. In addition, the elderly individual may need aid with personal care tasks, such as bathing, dressing, eating, managing medications, and toileting.

The model of living in these communities allows residents to possess some level of independence rather than being dependent on 24-hour skilled nursing care. Although this model is appealing to residents and their families, ALFs must balance a fine line between maintaining resident rights and keeping them safe.

Thus, the following issues often are identified as deficiencies in assisted living state surveys and are noted in legal claim allegations. Each issue is presented along with one or more risk-mitigation strategies to help ALF owners, operators, community management, and staff improve their practices.

Issue: Marketing Advertisements

Example: False or misleading advertising, such as claims of 24-hour nursing care when no trained and licensed nurse — e.g., registered nurse (RN), licensed practical nurse (LPN), or licensed vocational nurse (LVN) — is onsite or on shift.

Mitigation strategy: Use truthful advertising; for example, if appropriate, advertise that the facility has 24-hour *resident* care rather than nursing care.

Issue: Misleading Staff-to-Resident Ratios

Example: Advertising or promising a 1:1 staff-to-resident ratio that does not reflect direct resident care staff.

Mitigation strategy: Be transparent regarding direct staff-to-resident ratios. Ancillary staff members — such as those in administrative management, housekeeping, laundry, dietary, and maintenance — are not direct resident care staff and should not be counted toward the 1:1 staff-to-resident ratio.

Issue: Inappropriate Level of Resident Care

Example: Admitting or retaining residents who have physical and/or mental deficits at a location (i.e., community, unit, etc.) that is not equipped or no longer able to provide safe and effective care.

More information: Sometimes the practice referenced in the example is due to marketing/sales staff making resident admission decisions rather than a qualified and licensed nurse or provider. These decisions can lead to allegations of profits over resident safety. In addition, hiring private duty nursing services for ALF residents may potentially increase facility liability if that service is not available on a given day or days for a multitude of reasons.

Mitigation strategies: The following recommendations can help ensure that residents are receiving the proper level of care:

- Conduct thorough and frequent assessments, including preadmission assessments. Trained and experienced nursing staff should conduct the assessments to ensure proper placement and retention of all residents.
- Establish and maintain open and transparent dialogue with each resident's power of attorney (POA) and family members so that they are actively engaged in the decision-making process.
- Inform residents' POAs and family members of the ALF's policy regarding scope of services and the need to comply with transfer requests for residents who have needs the facility cannot meet. This includes residents who have advancing dementia, residents who have escalating aggressive behaviors, or residents whose physical conditions have worsened and require a higher level of care.

- Develop and maintain working relationships with other facilities to procure easier resident transfers and allay resident and family anxieties.

Issue: Admission of Dangerous Residents

Example: Admitting residents without conducting full state and federal criminal background checks, including screening for sex offenders and residents who have behavioral health diagnoses.

More information: Lack of vetting residents has resulted in resident-on-resident cases of criminal and sexual assault, including death.

Mitigation strategy: Conduct full state and federal criminal background and sex offender checks, and screen residents for previous behavioral health diagnoses.

Issue: Staff Qualifications and Training

Example: Hiring untrained and unlicensed personnel to serve as direct resident caregivers.

More information: Many states in the United States do not require trained and licensed nurses (i.e., RNs, LPNs, and LVNs) to provide care in ALF settings, which has led to the practice of using untrained caregivers. Also, on-the-job training is often inadequate for various tasks, such as:

- Performance of routine resident assessments
- Development of, and compliance with, individual resident care plans
- Identification of subtle changes in residents' physical, mental, and behavioral status
- Administration of medications or notification of residents to take medications
- Notification of management, providers, and family regarding changes in residents' conditions
- Documentation of assessments, treatments, monitoring, notifications, and care plan revisions
- Submission of incident reports for unsafe conditions, near misses, and adverse events
- Compliance with policies and procedures, including HIPAA

Mitigation strategies: If hiring trained and licensed nursing staff is not an option, ensure that proper and continuous training is provided to all direct resident caregivers. Initial and continuous training should include, but not be limited to:

- Review of policies and procedures (i.e., operational and clinical, including chain of command)
- Resident assessments/evaluations (upon admission, daily, and when changes in resident status are observed)
- Documentation (assessments, changes in resident status, notifications, care and treatment provided, interventions to maintain safety, etc.)
- Care plans (development, compliance, and revisions as needed)
- Medications (generic and brand names, purpose, most common and serious side effects, complications due to over- or under-administration, and notification of nursing management and providers)
- Incident reporting for unsafe conditions, near misses, and adverse events
- Notifications (management, providers, and POA/family)

Issue: Policies and Procedures

Example: Having lack of, or inadequate, policies and procedures with little to no management oversight to ensure compliance.

Mitigation strategies: The following recommendations can help ensure a consistent approach to resident care, organizational protocols, and legal and regulatory compliance:

- Develop and implement well-constructed policies and procedures for chain of command; HIPAA compliance; assessments, care plans, and resident wellness checks; notifications to management, providers, and family members; disclosure of adverse events; etc.
- Conduct routine management compliance audits and provide ongoing coaching for staff as noncompliance issues arise.

Issue: Assessments, Care Plans, and Management Oversight

Example: Inadequate or inconsistent execution of resident assessments and care plans, and failure to properly monitor residents.

More information: ALFs are required to have fall, pressure injury, and wandering/elopement prevention programs. Problems occur when assessments are not performed as needed, care plans are not revised to

reflect deficits identified through assessments, and management does not provide oversight. In addition, resident monitoring often is lacking, resulting in injuries. For example, residents have been harmed by being left unattended in courtyards, smoking areas, and at offsite activities.

Mitigation strategies: The following recommendations can help support a more robust assessment approach and improve quality of life for residents:

- Increase assessment frequency to include physical, cognitive, behavioral, and socialization aspects.
- Establish management expectations for routine oversight of assessments and care plans.
- Hire additional staff if feasible.
- Increase engagement activities for residents, such as soliciting volunteers in the local community, getting involved with local community groups or charities, and offering reading and arts sessions to local children.
- Adjust staffing to enhance engagement opportunities.

Issue: Security

Example: Inadequate security of the building and campus results in an environment where residents might wander, or outside intruders might gain access to resident living quarters.

Mitigation strategies: Security for residents and staff is the responsibility of all employees. The following recommendations can help improve safety inside the building and on campus:

- Install surveillance cameras inside and outside of the building to track who is entering and exiting and from which areas.
- Monitor main entrance doors at all times.
- Ensure external doors are locked at all times to prevent outside intruders from gaining access inside.
- Introduce residents and family members to all staff members.
- Implement a system to identify and monitor all vendors, contractors, and surveyors while they are in the building and on campus.
- If using agency staffing, implement a system to vet their criminal and sex offender history, identify them as staff members, and track their assignments and whereabouts in the building.

Issue: Culture of Safety

Example: Poor communication and teamwork result in an unsafe environment for residents and staff members.

More information: Lack of staff and management retention across the senior care industry creates hurdles for establishing a culture of safety in ALFs. Ineffective communication and lack of teamwork combined with unlicensed and untrained direct resident care staff can significantly increase risk exposures and lead to poor resident outcomes.

Mitigation strategies: Investing in facility management and staff is essential to improve employee retention and resident safety. The following recommendations can help reinforce a strong culture of safety:

- Examine current job descriptions. Do they align with the credentials and qualifications needed for the position? Is the salary based on local and national job averages? Is the salary appropriate for the skills and experience needed to fill the position?
- Examine current hiring practices. How are job applicants recruited? Are recruitment efforts effective in attracting high-quality and compassionate management and staff? Are thorough state and federal criminal background and sex offender checks conducted? Are previous work experiences reviewed?
- Examine current onboarding processes. Are new staff and managers given appropriate time and training to understand and learn the skills needed for their positions? Do new hires receive mentoring? Are new hires surveyed to assess the effectiveness of the organization's orientation process?
- Evaluate daily processes. Do managers and staff conduct daily briefings about the current work situation (e.g., staffing issues, building maintenance, supply inventory, and status of residents within the facility)? Are team huddles activated when changes with staff, residents, or facility operations occur during the shift? Are adverse event debriefings conducted to capture details leading up to and during the event as well as how the staff responded?
- Consider training opportunities. Has the facility implemented the teamwork elements of the Agency for Healthcare Research and Quality's TeamSTEPPS® program? The elements include

communication, leadership, mutual support, and situation monitoring.
- Learn from errors and near misses. Has the facility implemented a comprehensive root cause analysis program that includes reviewing potential system and process gaps?

Issue: Corporate Leaders and Facility Management

Example: Inconsistent leadership and high turnover of facility management compromise resident care and overall management of the ALF.

More information: Because ALFs are limited in federal and state regulatory oversight, the model of resident care varies from one facility to another. The lack of consistent leadership, facility support (i.e., collaboration, decision-making, and finance), and corporate oversight has a tremendous impact on risk exposures.

More involved corporate leaders with proper training and trust in facility management can decrease the risks that often lead to state survey deficiency citations and legal claim allegations. Some of these risks include lack of:

- Oversight, monitoring, and problem solving
- Notification to providers regarding changes in resident status (e.g., advancing dementia that requires hospice care)
- Legal and regulatory compliance
- Financial oversight
- Equipment upgrades, infrastructure maintenance, and repairs
- Adequate staffing
- Response to facility needs and requests
- Experienced facility management and staff members who meet the hiring policies and job descriptions

Mitigation strategies: The following recommendations can help establish a solid corporate culture as well as a qualified and well-supported workforce:

- Prioritize investments in facility management, staff, and infrastructure. Having an aesthetically pleasing resident environment means little if the facility management and staff are unstable due to constant turnover and lack of empathy and compassion.
- Establish high-quality hiring and management processes, such as adhering to job description standards; offering comparable industry salaries and benefits; supporting a culture of safety, trust, fairness, and respect; responding to facility requests in a timely manner; and adopting a realistic work–life balance for all employees (management and nonmanagement).

Learn More

Visit the National Institute on Aging to learn more about **residential facilities, assisted living, and nursing homes**.

About the Author



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The Impact of Staffing Shortages in Senior Care, and Strategies to Improve Recruitment and Retention

Marcy A. Metzgar

In 2023, LeadingAge (a community of more than 5,000 nonprofit aging services providers and other mission-driven organizations) found that 92 percent of its nursing home provider members and 70 percent of assisted living providers reported a significant or severe workforce shortage. Additionally, 64 percent noted no improvement in staffing shortages in the past year.[1]

In 2024, an American Health Care Association (AHCA) survey of 441 nursing homes revealed that two-thirds of nursing homes reported that ongoing staffing shortages may require them to close.[2] Nearly half of them have had to turn some residents away, yet more than half of them maintain a waiting list for new residents. Seven of 10 nursing homes report to have fewer employees than before COVID-19.[3] To manage these challenges, 97 percent of these organizations have asked staff members to work overtime or extra shifts; 73 percent have hired temporary staff members; 46 percent have limited new admissions; and 19 percent have closed a wing, unit, or floor.[4]

These sobering statistics reveal the critical state of employment in the senior care field. Staffing shortages, which were highlighted and exacerbated by COVID-19, are still very much prevalent. They are often a cause for burnout, turnover, unsafe staff-to-resident ratios, dangerous working conditions, and higher workloads and more overtime hours.[5] Staff members have reported leaving their jobs because they experienced burnout, worked long hours, received poor pay and benefits, had limited advancement opportunities, and felt a lack of respect.[6]

Although nearly every nursing home in the United States is hiring, many of these organizations find recruiting difficult, and it takes months for most to hire qualified employees.[7]

Federal Staffing Requirements for Nursing Homes

Since staffing shortages in nursing homes can compromise resident safety and lower care quality, the U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), issued a proposed rule in September 2023 aimed to create comprehensive staffing requirements for nursing homes, including the introduction of national minimum nurse staffing standards.[8]

According to the AHCA survey, most nursing homes are concerned about meeting the proposed federal staffing mandate, which would require them to have a registered nurse (RN) on staff 24 hours per day, 7 days per week. (Current law requires nursing homes to have an RN on duty for 8 consecutive hours per day, 7 days a week. They also must have a licensed nurse — either an RN or licensed practical nurse — on duty 24 hours per day).[9]

The new rule would also require nursing homes to provide at least 3 hours of direct care per resident, per day, including at least 33 minutes from a registered nurse. A nursing home would need about 10 nurse aides per each 8-hour shift in a facility with 100 residents.[10]

The rule was finalized on April 22, 2024, and implementation of the regulations will occur in phases over several years.[11]

Strategies to Recruit, Educate, and Retain Staff Members

With changes in federal staffing requirements as well as the ever-increasing demand for healthcare workers, it remains challenging for senior care organizations to recruit new staff. Thus, it is imperative that senior care organizations commit to recruiting, educating, and retaining their nurses and other staff. Below are some strategies to help guide these efforts:

- Develop comprehensive onboarding and orientation programs, or review existing programs to determine areas for improvement.
- Integrate staff between care levels to facilitate employee collaboration and empowerment.
- Designate lighter workloads for new nurses and then add duties over time.
- Assign mentors as part of a mentorship program to foster a team culture and provide feedback to staff members.

- Have flexibility in scheduling options, such as staggering shifts where organizational tasks can be accomplished while staff members are given time to address personal and family needs (promoting positive work–life balance).
- Offer continuing education and other career growth opportunities to staff members.
- Initiate an incentive program to recognize and reward staff members who go above and beyond in caring for residents and assisting the organization to further its goals.
- Promote staff members and provide advancement opportunities.[12]

Some longer-term approaches may include:

- Reexamining and enhancing the organization's benefits package to make it more appealing to attract staff members
- Using alternative scheduling and care models
- Creating nurse retention programs
- Partnering with local nursing schools and providing internships/apprentice programs for their students
- Designing respectful and purposeful roles for aging frontline healthcare workers so they can transition into a position that serves a social purpose in the organization[13]

Having a highly effective director of nursing (DON) championing these staff-retention efforts is integral to success, team building, and morale. The DON should value staff input, encourage skill building and leadership efforts among the staff, and hold staff accountable for high-quality performance and care delivery. All employees at the organization should feel that they are part of a highly skilled and recognized team. The increased focus on team building, communication, and respect will reinforce a positive culture and support staff recruitment and retention at the organization.

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Taking Action to Address Drug Shortages

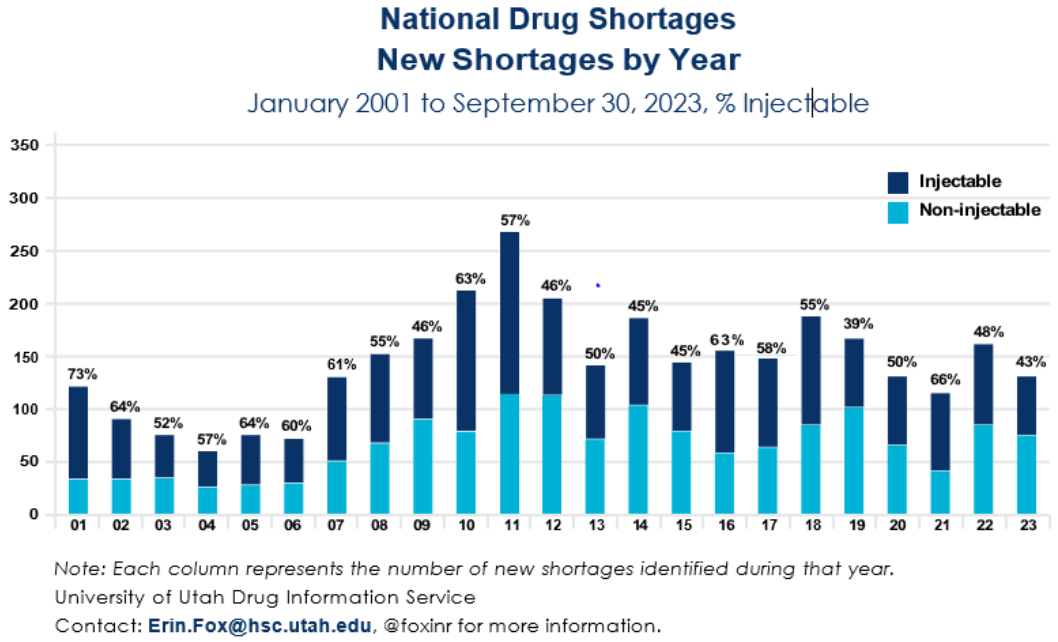
Shelly Kriete

The current resource challenges facing healthcare organizations are unprecedented. Issues related to limited resources, including drugs, supplies, and labor, impact overall costs, access to products and services, and, ultimately, patient health outcomes. As a long-standing problem for healthcare providers, our focus in this article will be drug shortages, which can have a negative impact on appropriate therapy regimes and access to needed surgical procedures and also may contribute to medication-related errors and poor patient outcomes.

History

While drug shortages have been a systemic problem for over 20 years, they have become a recent hot topic for patient safety. In 2013, the FDA published its first annual drug shortages report following the enactment of the **Food and Drug Administration Safety and Innovation Act (FDASIA)**, which effectively requires an annual report to Congress on drug shortages. Concerns related to drug and drug product shortages continue: a post on August 18, 2023, titled **Reforms Needed to Alleviate Persistent Drug Shortages**, notes that "the AMA Council on Science and Public Health (CSAPH) is charged with evaluating the factors driving national drug shortages and reporting on progress toward solutions…" The Council's 2022 report on this subject found that, while the number of new drug shortages has trended downward in recent years, the overall number of active drug shortages has remained relatively steady, suggesting that individual shortages are taking more time to resolve.

Unfortunately, a surge in new drug shortages in 2023, combined with the complexity of resolving even a single drug shortage, has resulted in severe stress to the supply chain. **The University of Utah Drug Information Service**, which has tracked drug shortages since 2001, reported that active drug shortages in 2023 were at their highest level in a decade. Its data on real-time shortages are posted regularly on a **website** hosted by the **American Society of Health-System Pharmacists** (ASHP), the largest professional association of pharmacists in support of safe medication practices. The five classes of drugs most frequently in short supply are central nervous system drugs, fluids and electrolytes, antimicrobials, chemotherapies, and hormones." [1]



Note: Each column represents the number of new shortages identified during that year.
University of Utah Drug Information Service
Contact: **Erin.Fox@hsc.utah.edu**, @foxinr for more information.

As of December 28, 2023, ASHP's website listed 248 items on the drug shortage list. In a recent MLMIC-moderated panel discussion at the Association for Healthcare Risk Management of New York's Fall Conference, one of the panelists stated that her facility's pharmacist mentioned that he had not seen shortages like we are currently experiencing in the last 20 years.

Factors Contributing to Drug Shortages

Pharmaceutical production and distribution is a complex, worldwide system that faces many variables for supply volume. Given these variables, to solely describe drug shortages as supply not meeting demand would be an oversimplification. All areas along the vast continuum of the pharmaceutical supply chain have ample opportunity to contribute to the risk of supply imperfections, reductions, production losses, or distribution delays. One or more of these aspects of supply can impact drugs and drug products reaching the patient. Some examples include:

- Production of raw material
- Technical and quality issues in the manufacturing systems
- New or modified regulation(s)
- Distribution processes
- Vendors and/or group purchasing organizations
- Healthcare organizations' procurement practices
- Unique attributes of the drug product market, such as the specific challenges of the generic drug sector

Each of these areas offer potential complications with product availability and quality, production capacity (including labor force availability), distribution, and business decision-making (e.g., budget constraints), which can be exacerbated by natural disasters or other public health emergencies, such as the recent coronavirus pandemic.

As we will note later, being aware of the the potential for shortages and being proactive in assessments are key to effective medication management programs. Assisting in that preemptive approach is the 2012 FDASIA requirement that manufacturers notify the FDA of production changes for some drugs and biologicals. The elements to be reported include interruptions or the permanent discontinuation of drugs or biologicals, any of the active pharmaceutical ingredients necessary, and the reason for the interruption. The notification to the FDA should occur 6 months prior to changes or as soon as possible if less than 6 months. This requirement was updated by the Coronavirus Aid, Relief, and Economic Security Act Act in 2020 to further mitigate the effects of shortages.

Concerns and Risk for Patient Safety

Not only do providers and their practices and facilities need to be concerned with disruptions to the operational workflows and administrative burdens when planning for current or anticipated drug shortages, the potential negative impacts related to clinical patient safety should be at the forefront. It is well known that patient safety and medication management initiatives are directly related, and changes to medication management processes, from procurement to administration, can increase medication error rates.

In October of 2023, ECRI, a patient safety organization, and the Institute for Safe Medication Practices, both associates in patient safety, announced information from a survey on the supply shortages and their impact on harm to patients. As noted in the report, "most respondents reported that shortages have compromised patient care, with half saying shortages have delayed patient treatments and one- third reporting they were unable to provide patients with optimally recommended drugs or treatments. A quarter of respondents said they were aware of at least one error related to a drug, supply, or device shortage."[2]

Additionally, changes in available drug substitutes may impact treatment routines by creating delays or complete interruptions in planned care; making errors in instructions to patients or caregivers more likely; and making prescribing errors more frequent as prescribers are forced to use dosing parameters they are not accustomed to.

In addition to process risks, clinical risks related to shortages and alternative therapies must always be considered. Much uncertainty and the potential for liability concerns come with choosing an alternate medication regime. Is there an alternative option available? Will the new therapy be as effective and meet the current standards of care? Will patients be able to tolerate the available substitution drug? These issues may not only affect the care provided but may also have a tremendous impact on the patient's overall mental well-being, particularly if life-saving treatment is at stake.

Although not directly clinical, the potential negative impacts on clinical treatment plans due to the possibility of a payor not covering the costs of available alternative therapies; the ethical dilemmas and emotional struggles created for patients, their families, and staff stemming from distribution or rationing parameters; and issues surrounding the informed consent (e.g., drug alternatives now being considered may warrant an update or a totally new consent process and form) should be concerning.

Strategies for Managing Drug Shortages

On a national level, both the FDA and AMA are leading supporters in reducing the negative effects drug shortages have on patient care through proactive reporting requirements, exploring options to expand investment in production capacity, early notification of impending shortages, ongoing regulatory review, and analysis of contracting practices related to organizations in competition (e.g., GPOs). A November 14, 2023, article in *Medical Economics*, **AMA Pushes for Action on Drug Shortages**, is calling the shortage of drugs a "growing public health crisis."[3]

Even with their continuous efforts to find longer-term solutions, healthcare organizations must be actively vigilant and prepared by establishing a well-defined plan to inform their management of impending or actual disruptions in the drug or drug product supply chain. It is not "if" but "when" the next shortage will occur.

As recent as December 31, 2023, an article titled **Lessons From The Chemotherapy Shortages: Invest in Generics**, authored by Elenora Teplinsky, M.D., a medical oncologist, reflected on the 2023 shortages of chemotherapy agents and the difficulties in managing lifesaving therapy regimes for many cancer patients. She, too, indicated the need for the early identification of potential/imminent shortages, clear paths to address actual shortages, and improvements in production and pricing for the generic drug sectors.

What COVID Taught Us

As we have heard multiple times, if we've learned anything from the COVID pandemic, it is that we have to be prepared for the next one. The variables are complicated, with many along the drug and drug product supply chain continuum requiring proactive and ongoing attention and investment, both financial and from a human capital perspective.

Creating a management plan and structure involving a multidisciplinary team with decision-making authority is critical to an organization's success in navigating the challenges created by interruptions and shortages in the supply chain. Preemptively addressing the following areas and proactively monitoring for impending shortages are essential as ongoing organizational assessments could identify actions to be taken prior to the formal announcement of a shortage, which could then reduce the stress on an already burdened system.

Oversight

A multidisciplinary team reviewing the impact of drug shortages should have decision-making capabilities from:

- **Purchasing and Finance** — to leverage relationships with vendors and also have the liquidity to act quickly when necessary to secure resources as they become available.
- **Pharmacy Processes** — to secure the appropriate physical space and environmental requirements related to storage and preparation needs.
- **Information Technology (IT) and Security** — to manage data collection and monitoring that includes medication error rates before, during, and after shortage activities. Information gained from data analysis can be helpful in anticipating future requirements or addressing issues that may arise during a shortage.
- **Risk Management** — to address impacts on patient safety.
- **Nursing** — to provide insight into workflow, staffing, and training needs.
- **Communications & Education** — to expedite cross-functional training plans and provide all stakeholders with contemporaneous situational updates related to the shortage and process changes made in response to the shortage.

Distribution

Drug shortages that require decisions related to rationing limited pharmaceutical resources may necessitate a collaborative group specifically focused on managing drug and drug product distribution as well as determining the clinical stratification parameters needed to prioritize distribution. These decisions are complicated and, in many instances, emotionally charged.

The group established should be multidisciplinary, with delegates from pharmacy, nursing, social services/care management, medical expertise, patient advocates, ethics, human resources, and legal/risk management, and other disciplines, if necessary.

Communication and Documentation

Effective communication skills for both internal and external conversations related to drug shortages are a critical part of setting and managing realistic expectations and fostering a culture of collaboration and will assist in leveraging existing relationships. Internally, sharing information with practitioners may alleviate stress by reducing the number of unknowns related to shortage details, such as current inventory status and active substitutions or alternative treatments, what the distribution priorities and rationing protocols are, and any cancellations of or changes to routine operations.

Outside of the organization, plans to communicate with patients and their families, including conversations about difficult situations, must be considered, in addition to how an organization will respond to the local community or media with an appropriate spokesperson.

As always, detailed documentation related to patient care, treatment, and services, as well as other processes related to business interruption, will be necessary to accurately reflect and "tell the story" in a detailed and accurate manner, regardless of the subject matter.

How the patients respond to alternate therapies, as well as details of the informed consent discussion resulting in the chosen care plan, must be reflected in the medical record. Dates and details of decisions related to changes in services, protocol adjustments, or any new clinical practices implemented should be archived for future reference, accompanied by evidence of staff education related to these changes. Tracking the specifics of actions is an important part of accountability and responsibility and will always be your best defense in a legal action.

Looking Ahead

While large-scale efforts to support changes to drug manufacturing, supply chain processes, and issues with the generic drug market are in progress, there are no real solutions in the immediate future. With that, we must enhance our organizational framework, allowing for proactive monitoring, and foster nimble, creative, and collaborative decision-making related to our pharmaceutical products and supplies.

Thorough documentation of attempts to address drug shortages, as well as communication to patients and staff of these efforts, will be essential should a patient experience an untoward outcome related to care due to the shortage of essential drugs.

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AHRMNY Half-Day Conference Summary

March 13, 2025 – DeMatteis Conference Center

Patient Safety Awareness Week

The AHRMNY Half-Day Educational Conference on March 13, 2025, held at the DeMatteis Conference Center on Long Island during Patient Safety Week, was an absolute success! Our incredible speakers delivered engaging and impactful presentations on a range of critical topics focused on patient safety and improving the quality of care.

We kicked off the day with Deanna Mirro Altmann, RNC, and Mirsade Markovic, Esq. from MLMIC Insurance Company, who gave an outstanding presentation on **"Leveraging Opportunities: The Role of the Nurse Practitioner and Physician Assistant."** They skillfully navigated the complexities of the differing scopes of practice for nurse practitioners and physician assistants, highlighted key claims trends in New York, and discussed common allegations against them. They wrapped up their session with valuable risk management strategies that can reduce risks and enhance patient safety across the board.

Next, **Josh Hyatt, DHS DFASHRM** of ASHRM captivated us with his thought-provoking talk on **"Patients without Families: Ethical and Legal Considerations."** He dove deep into the ethical and legal challenges faced when caring for patients without capacity, providing essential insights on how facilities can manage unrepresented patients. His session emphasized the critical importance of proper documentation to protect patient rights and minimize risk.

To wrap up the event, **Greg Prentiss, CAPT, USN (Ret), MS** from Press Ganey delivered a dynamic presentation on **"Applying Human Factors Design to Safety Events."** He brought us a deeper understanding of human factors engineering, explained the top human factors challenges in healthcare, and highlighted the importance of applying human-centered corrective actions to improve processes and enhance patient safety.

We want to extend a heartfelt thank you to our exceptional speakers for their insightful and inspiring presentations, as well as to all the attendees and sponsors who made this conference such a resounding success. Your participation and enthusiasm made this event truly memorable! Here's to continuing our commitment to improving patient care and safety!



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