NEXT CHALLENGE. NEXT LEVEL. NEXT SEN PRUET

Hot Summer News: Recent Legal and Regulatory Developments

Alice Harris and Chandler Martin, Nexsen Pruet



SC Health Care Association

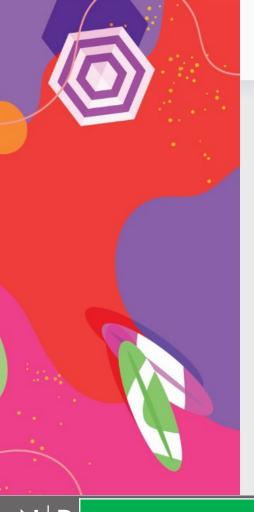
2022 Summer Splash



WHAT IS HOT NEWS IN THE POST-COVID ERA?

- New and developing legal and regulatory news
- Updates issued from state and federal agencies
- Recent audit targets gleaned from state and federal settlements and prosecutions
- "Lessons learned" the hard way by entities and individuals subject to audits and investigations (and how to avoid such missteps)
- Best practices for lowering risk through attention and compliance steps focused on newly developing agency news and enforcement topics

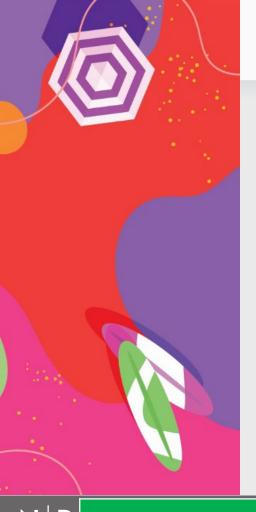




"The President believes we must improve the quality of our nursing homes so that seniors, people with disabilities, and others living in nursing homes get the reliable, high-quality care they deserve." 2/28/22

- Concern stems partly from Covid-19 Pandemic
- 1.4 million people live in 15,500 Medicare and Medicaid certified nursing homes
- More than 200,000 nursing home residents and staff died from COVID-19 in past two years – nearly 1/4 of all COVID-19 deaths in the United States
- The set of reforms will be developed by the Department of Health and Human Services (HHS) and CMS

https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniorsand-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/



Broad Agenda

- Ensuring Taxpayer Dollars Support Nursing Homes That Provide Safe, Adequate, and Dignified Care
- Enhancing Accountability and Oversight
- Increasing Transparency
- Creating Pathways to Good-paying Jobs with the Free and Fair Choice to Join a Union
- Ensuring Pandemic and Emergency Preparedness in Nursing Homes



Ensuring Taxpayer Dollars Support Nursing Homes That Provide Safe, Adequate, and Dignified Care

- Establish a Minimum Nursing Home Staffing Requirement
 - Reasoning: "Increasing registered nurse staffing by just 20 minutes per resident day was associated with 22% fewer confirmed cases of COVID-19 and 26% fewer COVID-19 deaths"
 - CMS intent to propose minimum standards
 - New <u>CMS</u> standards will be mandatory and enforced



- Establish a Minimum Nursing Home Staffing Requirement
 - *Current* CMS regulations: A nursing home must have "sufficient nursing staff" 42 C.F.R. § 483.35
 - *CMS State Operations Manual*. 24-hour licensed nursing, RN 8 consecutive hours a day, RN designated as DON
 - The State may waive these requirements (Note: SC DHEC licensing has more specific staffing requirements)



- Establish a Minimum Nursing Home Staffing Requirement
 - Staffing has been reported on <u>Nursing Home Compare</u> since 2003
 - January 2022 added weekend staffing and staff turnover measures
 - July 27, 2022 added four new measures:
 - Total nurse (RN, licensed practical nurses, and nurse aids) staffing hours per resident per day on weekends.
 - Total nurse staff turnover within a given year.
 - RN turnover with a given year.
 - Number of administrators who have left the nursing home within a given year

https://www.cms.gov/newsroom/fact-sheets/updates-care-compare-website-july-2022



- Establish a Minimum Nursing Home Staffing Requirement
 - 2022 Change in Survey Processes
 - "To begin helping address the staffing issue while the rulemaking process is underway, CMS added new requirements for surveyors to incorporate the use of Payroll Based Journal staffing data for their inspections. This will help better identify potential noncompliance with CMS's nurse staffing requirements, such as lack of a registered nurse for eight hours each day, or lack of licensed nursing for 24 hours a day. This guidance will help to uncover instances of insufficient staffing and yield higher quality care."

https://www.cms.gov/newsroom/press-releases/cms-issues-significant-updates-improvesafety-and-quality-care-long-term-care-residents-andcalls#:~:text=To%20begin%20helping%20address%20the,staffing%20data%20for%20th eir%20inspections



Establish a Minimum Nursing Home Staffing Requirement

April 11, 2022 SNF Proposed PPS Rule:

- Expressed intent to propose minimum federal standards for nursing home staffing
- Cites studies finding positive relationship between staffing and hospitalization - Higher RN staffing associated with better quality care
- Are conducting a new study to help inform policy decisions related to determining the level and type of staffing needed
- Intend to issue proposed staffing rules by April 2023
- Opportunity to comment: CMS requested input on many aspects of staffing



Establish a Minimum Nursing Home Staffing Requirement

July 29, 2022 Final Rule:

- CMS is reviewing comments "which the agency anticipates will be used to help inform future rulemaking on minimum staffing requirements for long-term care facilities."
- "The Biden-Harris Administration is committed to issuing the proposed rule within one year of President Biden's State of the Union announcement."



Staffing: *But what about the ongoing staffing crisis?*

- It is well known that nursing homes are finding it difficult to attract and retain staff
- The number of workers in long term care are still far below prepandemic levels
- Nursing homes are finding themselves competing with other nursing homes for staff – "We're all fighting for the same nurses"

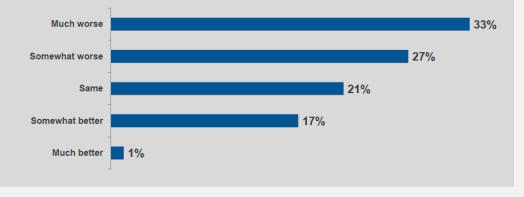
https://skillednursingnews.com/2022/07/competition-forfrontline-workers-heats-up-between-nursing-homes/





60% of nursing homes are experiencing worse staffing situations since the start of 2022.

Since January 2022, has your workforce situation gotten better or worse?

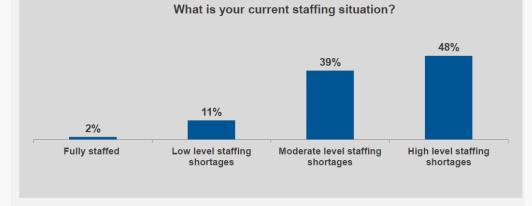


Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022





87% of nursing homes facing moderate or high staffing shortages.

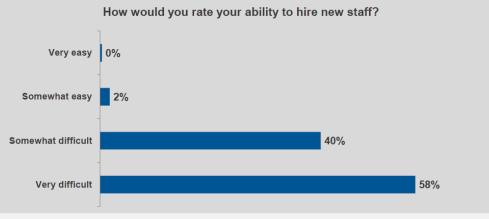


Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022





98% of nursing homes are experiencing difficulty hiring staff.



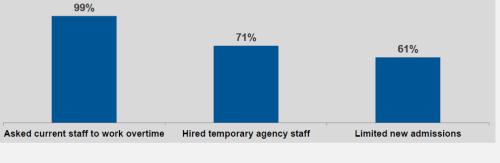
Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022





Nearly all nursing homes are asking staff to work more and 61% are limiting new admissions.

What adjustments have you made in recent months due to staffing shortages? (Check all that apply)



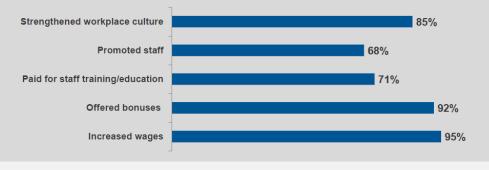
Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022





9 out of 10 nursing home providers have offered increased wages and bonuses.

In the past year, what strategies have you implemented to try to recruit and retain staff? (Check all that apply)

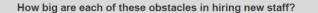


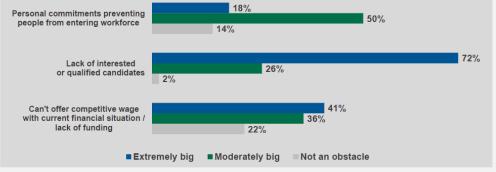
Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022





Lack of interested or qualified candidates is the top obstacle in hiring new staff.



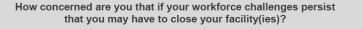


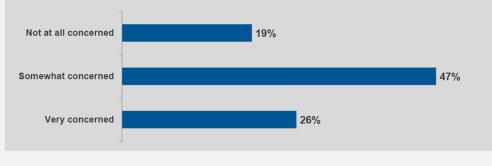
Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022





73% of nursing homes are concerned about having to close over staffing woes.





Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022

Ensuring Taxpayer Dollars Support Nursing Homes That Provide Safe, Adequate, and Dignified Care

- Preduce Resident Room Crowding
- Most nursing home residents prefer to have private rooms
- Shared rooms with one or more other residents remain the default option and increase residents' risk of contracting infectious diseases, including COVID-19
- CMS will explore ways to accelerate phasing out rooms with three or more residents and to promote single-occupancy rooms



Ensuring Taxpayer Dollars Support Nursing Homes That Provide Safe, Adequate, and Dignified Care

• Reduce Resident Room Crowding: June 29, 2022

- "As part of the Biden-Harris Administration call to reduce resident room crowding, CMS has highlighted the benefits of reducing the number of residents in each room for preventing infections and the importance of residents' rights to privacy and homelike environment.
- The pandemic has further proven the risk of contracting infection diseases in rooms with several residents.
- CMS is urging providers to consider making changes to their settings to allow for a maximum of double occupancy in each room and encouraging facilities to explore ways to allow for more single occupancy rooms for nursing home residents."

https://www.cms.gov/newsroom/press-releases/cms-issues-significant-updates-improvesafety-and-quality-care-long-term-care-residents-and-calls



Ensuring Taxpayer Dollars Support Nursing Homes That Provide Safe, Adequate, and Dignified Care

- Strengthen the Skilled Nursing Facility ("SNF") Value-Based Purchasing ("VBP") Program "CMS intends to propose new payment changes based on staffing adequacy, the resident experience, as well as how well facilities retain staff."
 - The Value-Based Purchasing program awards incentive payments to facilities for quality performance – based on just one all-cause hospital readmission measure.
- The 2023 SNF PPS final rule added three new VBP Program performance measures based on

 (i) total nursing hours per resident each day;
 (ii) the number infections requiring
 hospitalization; and (iii) the rate of successful discharges from the SNF.
- First two new measures will be effective in FY 2026, and the third is effective in FY 2027.
- CMS also requested feedback on a proposed **staffing turnover** measure based on the percent of total nurse staff that have left the SNF over the last year.



Ensuring Taxpayer Dollars Support Nursing Homes That Provide Safe, Adequate, and Dignified Care

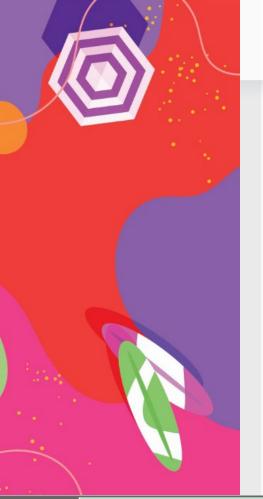
- Reinforce Safeguards against Unnecessary Medications and Treatments
- Biden administration the nation has seen a dramatic *decrease* in the use of antipsychotic drugs in nursing homes in recent years due to CMS' "National Partnership to Improve Dementia Care in Nursing Homes"
- BUT -- they are concerned that inappropriate diagnoses and prescribing of antipsychotic medications still occur at "too many" nursing homes.
- CMS will launch a new effort to identify problematic diagnoses and refocus efforts to continue to bring down the inappropriate use of antipsychotic medications.



Ensuring Taxpayer Dollars Support Nursing Homes That Provide Safe, Adequate, and Dignified Care

- Reinforce Safeguards against Unnecessary Medications and Treatments
- In June 2022, CMS announced updated conditions of participation and updated guidance to surveyors that address:
 - Unnecessary use of non-psychotropic drugs and antipsychotics (e.g., favoring gradual dose reduction for residents that may have already been on such medications)
 - Reiterating rights and available behavioral health services for residents with mental health needs or substance use disorder
 - Situations where a resident may have been inaccurately diagnosed or coded by providers or facilities (e.g. as having schizophrenia)

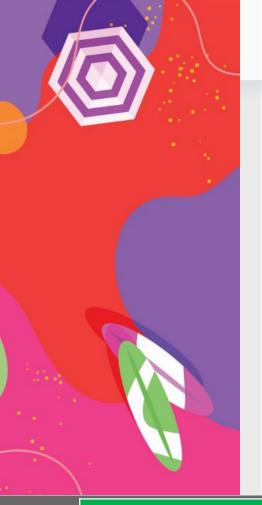




Enhancing Accountability and Oversight

- Adequately Fund Inspection Activities
 - Funding has remained flat for over 7 years
 - Biden to request almost \$500 million to CMS, a nearly 25% increase, to support health and safety inspections at nursing homes
 - "The annual appropriation for inspection and certification activities at nursing homes and other medical facilities has remained at just over \$397 million since fiscal year 2015, the agency reports. President Joe Biden's <u>budget</u> calls for hiking that amount by nearly \$97 million to \$494.3 million in FY 2023."

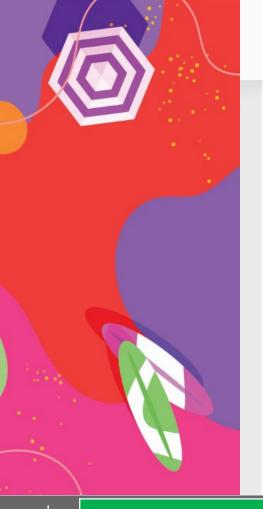
https://news.bloomberglaw.com/health-law-and-business/cash-influxaimed-at-tackling-nursing-home-inspection-woes



Enhancing Accountability and Oversight

Beef up Scrutiny on Poorest Performers

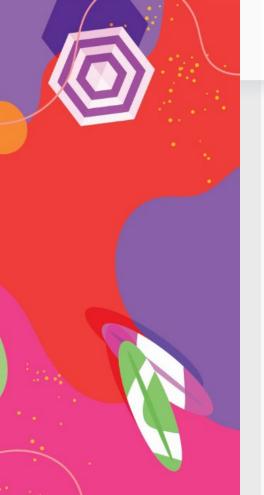
- CMS's Special Focus Facility (SFF) program identifies the poorest-performing nursing homes for increased scrutiny to immediately improve the care delivered
- The SFF program requires more frequent compliance surveys, which must pass two consecutive inspections to leave the SFF program
 - The SFF program will be overhauled to make its requirements tougher and more impactful
 - CMS will scrutinize more facilities, by moving facilities through the program more quickly
 - Facilities that fail to improve will face increasingly larger enforcement actions, including termination from participation in Medicare and Medicaid



Enhancing Accountability and Oversight

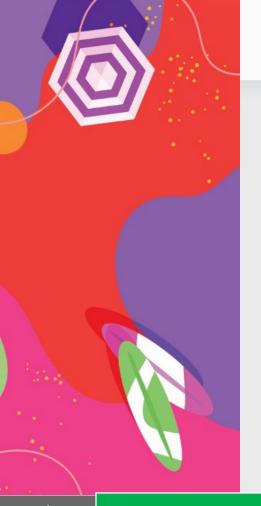
Expand Financial Penalties and Enforcement Sanctions

- CMS will expand the instances in which it takes enforcement actions against poor-performing facilities based on desk reviews and on-site inspections
- In July 2021, CMS rescinded a Trump Administration change that lowered penalty amounts for deficiencies by imposing only a one-time fine, instead of per-day fines. CMS is exploring making per-day penalties the default penalty for non-compliance
- CMS will also use data, predictive analytics, and other information processing tools to improve enforcement
- President Biden is also calling on Congress to raise the dollar limit on per-instance financial penalties levied on poor-performing facilities, from \$21,000 to \$1,000,000



Enhancing Accountability and Oversight

- Increase Accountability for Chain Owners of Substandard Facilities
- President Biden asking Congress to give CMS authority to require minimum corporate competency to participate in Medicare and Medicaid programs allowing CMS to prohibit an individual or entity from obtaining a Medicare or Medicaid provider agreement for a nursing home (new or existing) based on the Medicare compliance history of other owned or operated facilities
- **President Biden is asking Congress to expand CMS enforcement authority at the ownership level** – allowing CMS to impose enforcement actions on owners and operators (even if a facility closes)



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PRESIDENT BIDEN'S SNF AGENDA

Enhancing Accountability and Oversight

- Provide Technical Assistance to Nursing Homes
- CMS current contracts with Quality Improvement Organizations (QIOs)
- CMS will ensure that improving nursing home care is a core mission for QIOS
 - Expand on-demand trainings and information sharing around best practices
 - Expand individualized, evidence-based assistance related to issues exacerbated by the pandemic

Increasing Transparency

Biden's view: "For too long, <u>corporate</u> owners and operators have not been held to account for poor nursing home performance. CMS will improve the **public transparency of facility ownership** and safeguard nursing home residents."

Create a Database of Nursing Home Owners and Operators; Improve Transparency of Ownership

- CMS will collect and publicly report more detailed corporate ownership and operating data using a new database that identifies and tracks owners and operators
 - Using info collected through provider enrollment and health and safety inspections
 - Will provide more information to states about prospective owners and operators
- Goal: Give public a resource to better understand owners' and operators' previous violations and empower states to better protect the health and safety of residents.
 - Seeks to highlight "previous problems with promoting resident health and safety"



Increasing Transparency

<u>Updates</u> Regarding Ownership-Related Agenda Items

- CMS has published a data set on its website that includes ownership information for all active SNFs: <u>https://data.cms.gov/provider-data/dataset/y2hd-n93e</u>
- More comprehensive ownership data has also been added to CMS' *Nursing Home Care Compare* website. Each facility now has an "Ownership Details" tab that lists owner info.
- In April 2022, CMS also began publishing data related to changes of ownership and similar transactions for nursing homes enrolled in Medicare, starting with 2016.
 - The database lists CHOWs and ownership information for the buyers/sellers involved in the CHOW transactions:
 - https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/skilled-nursing-facilitychange-of-ownership-owner-information
 - https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/skilled-nursing-facilitychange-of-ownership



Increasing Transparency

Examine the Role of Private Equity

- Private equity investors are playing a growing role in the nursing home industry.
- According to Biden's SNF Agenda, research indicates that facility ownership by "investment groups" leads to worse outcomes while costing taxpayers more.
 - The Agenda Fact Sheet notes that these owners have cut expenses at the cost of patient health and safety, including during the COVID-19 pandemic
- HHS and other federal agencies will examine the role of private equity, real estate investment trusts (REITs), and other investment ownership to determine when corporate entities are not serving their residents' best interests.
- These agencies will seek to inform the public when "corporate entities" are not serving their residents' best interests.



Increasing Transparency

Enhance Nursing Home Care Compare

- CMS will implement a range of initiatives to improve Nursing Home Care Compare, the rating website designed to help families pick a facility for their loved ones.
 - Improve the readability and usability of the information displayed on Care Compare
 - Easier to find, more comprehensive facility ownership data
 - ldentify whether a facility is meeting any new minimum staffing requirements, once effective
- CMS has already published new measures on Care Compare, including nursing home staff turnover, weekend staffing levels, and other factors.
- CMS relies in part on self-reported data for Care Compare. Biden is seeking authority for CMS to validate data and take enforcement action against facilities that submit incorrect information





Creating Pathways to Good-paying Jobs with the Free and Fair Choice to Join a Union

Ensure Nurse Aide Training is Affordable

- Lowering financial barriers to nurse aide training and certification
- CMS will establish new requirements to ensure nurse aide trainees are notified about their potential entitlement to training reimbursement upon employment
- CMS will further work with states to ensure reimbursement is being distributed and that free training opportunities are widely publicized



Creating Pathways to Good-paying Jobs with the Free and Fair Choice to Join a Union

Support State Efforts to Improve Staffing and Workforce Sustainability.

- Strengthening the nursing home workforce requires adequate compensation
- CMS will develop a template to encourage States to tie Medicaid payments to clinical staff wages and benefits, including additional pay for experience and specialization



Creating Pathways to Good-paying Jobs with the Free and Fair Choice to Join a Union

Launch National Nursing Career Pathways Campaign

 CMS, in collaboration with the Department of Labor, will work with external entities—including training intermediaries, registered apprenticeship programs, labor-management training programs, and labor unions—to conduct a nationwide campaign to recruit, train, retain, and transition workers into long-term care careers, including health-care careers like registered and licensed nurses

Ensuring Pandemic and Emergency Preparedness in Nursing Homes

Continued COVID-19 Testing in Long-term Care Facilities

- During the pandemic, the Biden Administration provided approximately 3 million tests per week to nursing homes and assisted living facilities
- Nursing homes are required to ensure staff are vaccinated and more than 87.1% of residents have received their primary series
- DC continues to offer all facilities the ability to be matched with a federal pharmacy partner to host an on-site vaccination clinic
- The Agency for Healthcare Research and Quality has made a wide set of tools available



COVID-19 Vaccinations Fraud Settlement

- MorseLife Nursing Home Health System Agrees to Pay \$1.75 Million to Settle False Claims Act Allegations for Facilitating COVID-19 Vaccinations of Ineligible Donors and Prospective Donors
- MorseLife is a not-for-profit corporation located in West Palm Beach, Florida, that oversees health care facilities on its campus, including a nursing home and an assisted living facility
- MorseLife participated in a Pharmacy Partnership for Long-Term Care Program (LTC PPP), a program specifically designed to vaccinate long-term care facility (LTCF) residents and staff when doses of COVID-19 vaccine were in limited supply
- Morselife allegedly knew that the LTC PPP covered only LTCF residents and staff but invited and facilitated the vaccination of hundreds of ineligible persons at the clinic by characterizing them as "staff" and "volunteers"
- Many of the ineligible persons were targeted for donations the United States alleged that MorseLife (1) characterized board members as "staff," (2) directed the organization's fundraising arm to invite donors and potential donors to the vaccination clinic, and (3) allowed the Vice Chairman of the MorseLife Health Systems Inc. Board and his brother to invite close to 300 ineligible individuals to receive the vaccine

https://www.justice.gov/opa/pr/morselife-nursing-home-health-system-agrees-pay-175-million-settle-false-claims-act



Ensuring Pandemic and Emergency Preparedness in Nursing Homes

Strengthen Requirements for On-site Infection Preventionists

 CMS will clarify and increase the standards for nursing homes on-site infection prevention employees



Strengthen Requirements for On-site Infection Preventionists

June 29, 2022 Updated Infection Control Guidance:

- Requires facilities have a part-time Infection Preventionist.
- While the requirement is to have <u>at least</u> a part-time IP, the IP must meet the needs of the facility.
- The IP must physically work onsite and cannot be an off-site consultant or work at a separate location.
- IP role is critical to mitigating infectious diseases through an effective infection prevention and control program.
- IP specialized Training is required and available.

https://www.cms.gov/newsroom/fact-sheets/updated-guidance-nursing-





Ensuring Pandemic and Emergency Preparedness in Nursing Homes

Enhance Requirements for Pandemic and Emergency Preparedness

- The pandemic and increase in natural disasters have demonstrated how critical need for proactive emergency preparedness
- CMS is considering changes to emergency preparedness requirements
- <u>CMS QS0-20-41</u> May 22, 2022 Providers are exempt from Full Scale Exercise for 2021 and 2022 if they are operating under an activated / reactivated emergency plan
 - This exemption only applies to one of two require annual exercises <u>https://www.ahcancal.org/News-and-Communications/Blog/Pages/Review-Updated-CMS-Emergency-Preparedness-Exercise-Exemption-Released-on-May-26.aspx</u> and <u>https://www.cms.gov/files/document/gso-20-41-all-revised-05262022.pdf</u>



July 2022 OIG Audit – Eight States Noncompliant with Nursing Home Life Safety and Emergency Preparedness

- Visited 154 nursing homes found noncompliance at 150 with 2,233 areas of noncompliance – Life Safety and Emergency Preparedness
- Alleged deficiencies occurred because of inadequate oversight by management, staff turnover, inadequate oversight by State survey agencies, and a lack of any requirement for mandatory participation in standardized life safety training programs
- https://oig.hhs.gov/oas/reports/region2/22101010.pdf



July 2022 OIG Audit – CMS Response:

- Will consider proposing regulation requiring nursing homes to notify State survey agencies when fire alarm and sprinkler systems are not working
- Will consider proposing regulation requiring nursing homes to have carbon monoxide detectors to be installed for all fuel-burning appliances
- Will consider proposing regulation requiring nursing home staff to participate in standardized life safety training

https://oig.hhs.gov/oas/reports/region2/22101010.pdf





STATUS OF PANDEMIC WAIVERS

- In April 2022, CMS phased out some of its temporary waivers : https://www.cms.gov/files/document/qso-22-15-nh-nltc-lsc.pdf
- Temporary waivers suspended certain CMS requirements to provide facilities with flexibility to respond to the extraordinary circumstances of the pandemic.
 - Waiver examples Nurse aid training, in-person assessments by providers, life-safety codes, etc.
 - Now -- According to CMS, on-site surveys have begun to reveal "*significant concerns* with resident care that are unrelated to infection control."
 - Increases in abuse, weight-loss, depression, pressure ulcers, etc.
 - CMS believes the waivers contributed to these outcomes: "*CMS is very concerned about how residents' health and safety has been impacted by the regulations that have been waived, and the length of time for which they have been waived.*"



STATUS OF PANDEMIC WAIVERS

CMS now wants facilities to "*redirect efforts back to meeting the regulatory requirements aimed at ensuring each resident's physical, mental, and psychosocial needs are met.*"

Emergency Declaration Blanket Waivers That Ended May 7, 2022:

- **Resident Groups 42 CFR §483.10(f)(5):** waiver of requirements ensuring that residents can participate in-person in resident groups.
 - **Physician Visits and Delegation of Tasks 42 CFR §483.30:** three waivers related to physicians delegating a task when regulations specify that the physician must perform it personally; physicians visits being made by collaborating/supervised non-physicians clinicians instead of the physician; and use of telehealth options as appropriate instead of mandatory in-person visits.
 - **Quality Assurance and Performance Improvement (QAPI) 42 CFR §483.75:** Waiver modifying certain requirements for facilities' QAPI programs that permitted a narrower focus on issues associated with COVID-19.
 - **Detailed Information Sharing for Discharge Planning- 42 CFR §483.21(c)(1)(viii):** Waiver of the discharge planning requirement that facilities assist residents in selecting a post-acute care provider using certain data.
 - **Clinical Records 42 CFR §483.10(g)(2)(ii):** Waiver modifying the requirement that facilities provide a resident a copy of their records within two working days (when requested by the resident) to provide more time.



Emergency Declaration Blanket Waivers That Ended June 5, 2022:

- Physical Environment; Safety 42 CFR §483.90: Three waivers of certain physical environment requirements to allow temporary certification and use of facilities, buildings, and rooms due to a need for isolating and treating COVID-19 residents, including requirements to have outside doors and windows in every room and fire safety requirements (e.g., fire drills).
- Inspection, Testing & Maintenance 42 CFR § 483.90: Two waivers of certain inspection, testing and maintenance requirements for facility and medical equipment that sought to reduce disruption of patient care and potential exposure/transmission of COVID-19.
- Paid Feeding Assistants 42 CFR §483.60(h)(1)(i):Waiver modifying the requirements regarding required training of paid feeding assistants to permit training of a minimum of one hour in length.
- In-Service Training for Nurse Aides 42 CFR §483.95(g)(1): Waiver modifying nurse aide training requirements for nursing assistants to receive at least 12 hours of in-service training annually.
- **Training and Certification of Nurse Aides 42 CFR §483.35(d):** Waiver of requirements to not employ nursing aides for longer than four months unless they meet the training and certification requirements under §483.35(d).



OWNERSHIP TRENDS

Trends for SNF Transactions and Ownership are Fluid

According to the Journal of American Health Association (JAMA) and Skilled Nursing News:

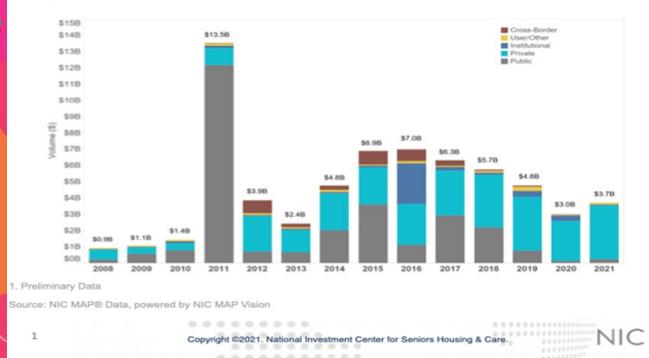
- Real estate investment trusts (REITs) owned about 12% of all SNFs as of 2021 (about 1,870 facilities). Major healthcare-oriented REITs seem to be receding in the SNF space for now.
- Private equity firms owned about 5% of all SNFs as of 2020 and remain very active into 2022.
 SNF is ownership rising, along with AL and IL where private equity is more active historically.
- According to the National Investment Center for Seniors Housing & Care (NIC), in 2021
 - **\$3.7 billion** spent in skilled nursing transactions
 - 89% of the buyers "private"
 - Publicly traded companies and REITs remain mostly out of SNF transactions for now

https://skillednursingnews.com/2022/05/reits-owned-12-of-us-skilled-nursing-assets-in-2021-ownership-trends-changing/ https://jamanetwork.com/journals/jama-health-forum/fullarticle/2792403 https://skillednursingnews.com/2022/03/rhetoric-vsreality-nursing-home-leaders-denounce-staffing-private-equity-aspects-of-reform-package/

OWNERSHIP TRENDS

Private Buyers Remain Very Active

Closed Transactions Skilled Nursing Care Volume by Buyer Type¹ U.S. | 1Q08 – 4Q21



- According to an April 2022 report from the American Health Care Association 1,103 nursing homes have closed since 2015.
- The AHCA data shows that nursing homes that close tend to be
 - Smaller facilities (less than 100 beds)
 - In urban settings
 - Majority of residents rely on Medicaid
- During the pandemic, nearly half of nursing homes that closed received 4- or 5-Star ratings from CMS.
- The closure numbers on the whole don't differ too much before the pandemic vs. during the pandemic – but AHCA projects that could change substantially in 2022 with over 400 closures in one year.

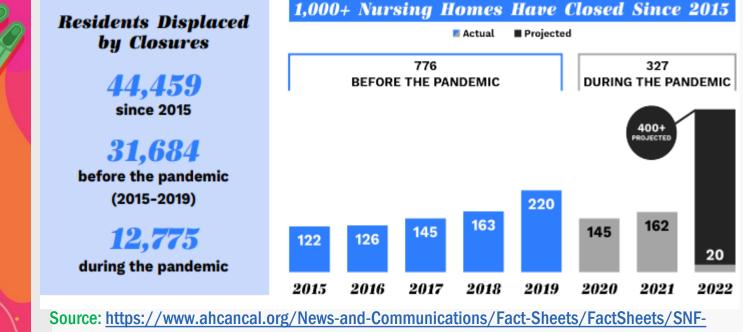


According to AHCA's April 2022 report:

	<i>Before COVID</i> (2015-2019)	<i>During COVID</i> (2020-present)
Average size (beds)	72	77
Average Medicaid occupancy	62%	60%
Average operating margin	-12%	-12%
% Urban	66%	73%
% Rural	34%	27%
Five-Star Facility Ratings: 4 and 5 Stars	43%	46%
Not-for-Profit	25%	29%

Source: <u>https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/SNF-</u> <u>Closures-Report.pdf</u>

According to AHCA's April 2022 report:



Closures-Report.pdf

- AHCA data projects an alarming number of closures for 2022 at 400+.
 - Basis for projection is not entirely clear in the report
 - Due in part to decreased financial support from federal and state governments (compared to 2020 and 2021), continuing COVID-19 safety measures, and drastically increased costs and operational difficulties (e.g., staffing).
- The trend of closures actually slowed during the pandemic thus far, showing that support measures worked in the short-term, but the long-term trend of increased closures remains, with added risk of a "cliff" year in 2022.
- AHCA's data and reporting is in the context of advocating against proposed payment cuts for SNFs, but projections seem to match the reality.
- AHCA also published survey data in June 2022 that is consistent with its concerning projections for 2022.

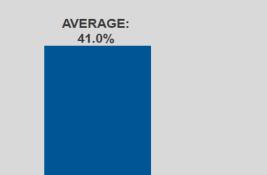


NURSING HOME COSTS



Nursing home providers estimate their costs have increased by 41% in one year.

By what percentage have your operational costs increased since this time last year?



Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022

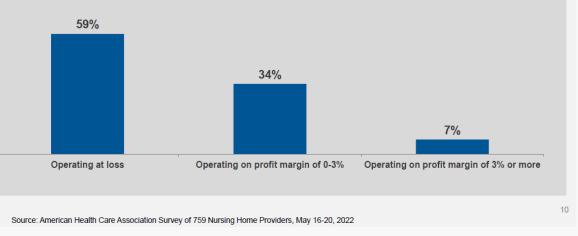
https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/SNF-Survey-June2022.pdf



NURSING HOME COSTS



Nearly 6 out of 10 nursing home providers are operating at a loss.



What is your current operating situation relative to your budget?

https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/SNF-Survey-June2022.pdf

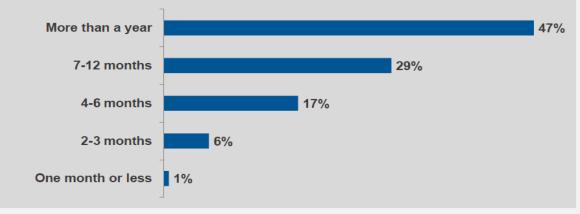


NURSING HOME COSTS



More than half of nursing homes can't sustain their current pace more than one year.

How long can you sustain operating at its current pace?



Source: American Health Care Association Survey of 759 Nursing Home Providers, May 16-20, 2022

https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/SNF-Survey-June2022.pdf

TELEHEALTH IN NURSING HOMES – PROS AND CONS

2021 Study

PROS

- The benefits of avoiding travel for the nursing home resident.
- Saved organizational resources.
- Improved access to care.
- Enhanced communication

• CONS

- Preference for in-person encounters.
- Worsening social isolation.
- Difficulty for residents with cognitive impairment.
- Workflow and tech-usability challenges.
- Increased burden on staff or infrastructure

https://www.healthcareitnews.com/news/rapid-telehealth-rollout-was-beneficialnursing-homes-had-downsides-too



TELEHEALTH – RECENT OIG REPORTS

- Pre-COVID April 1, 2020 OIG Report
- Analyzed 100 South Carolina Medicaid, Fee-for-Service Telemedicine Claims
 - Sample of 100 claims from \$2.3 million in payments from 7/1/14 to 6/20/17- <u>Only 3 payments of 100 were allowable</u>
 - *95 payments not payable:*
 - Providers did not document the start / stop times
 - Providers did not document the consulting site location of the medical <u>service</u>
 - OIG blames State of South Carolina for not training providers or adequately monitoring compliance



TELEHEALTH – AUDIT COMPLIANCE BEST PRACTICES

Consider Baseline Audit

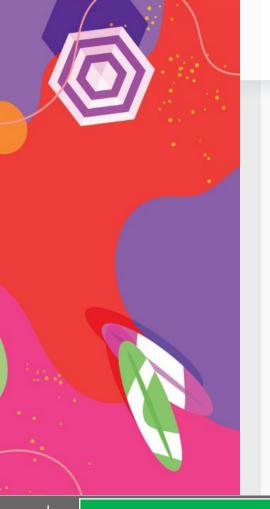
- Areas to explore during baseline audit: Telehealth
 - Do you have the appropriate documentation in the file to support timebased codes?
 - Do you have the appropriate documentation in the file to the requisite level of decision making?
 - Do your records meet the specific payor billing requirements for telehealth?
 - Does your documentation capture elements like means of communication between provider and patient?



TELEHEALTH – AUDIT COMPLIANCE BEST PRACTICES

- Areas to explore during baseline audit: Telehealth
 - Do your claims meet the specific payor's specified technical requirements?
 - Are there potential individual provider issues, such as
 - Enrollment
 - Licensing
 - Scope of practice
 - DEA registration requirements





SAMPLE CURRENT POST-ACUTE AUDIT TOPICS

Example Current Medicare RAC Topics:

- Medical Necessity and Documentation
- Ambulance Transfer between SNFs Unbundling
- E&M in SNFs
- Excessive Units of Therapy and SNF Services
- Duplicate Claims
- E&M Same Day as Admission to Nursing Facilities
- Consolidated Billing for Therapies Unbundling

AUDIT DEFENSE – LESSONS LEARNED AND BEST PRACTICES

- Compliance Infrastructure
 - Designated response team
 - Conduct ongoing risk assessments
 - Conduct risk-based and baseline audits and routine auditing and monitoring
 - Across the board education
 - Billing/coding staffing and skills assessment



AUDIT DEFENSE – LESSONS LEARNED AND BEST PRACTICES

Audit Response

- Arrival of Request for Records / Information
- Initial Analysis of Request
- Responding to the Request
- Analysis of Materials Produced
- The Appeals and Repayment Processes
- Clinical Arguments and Witnesses
- Legal Arguments and Witnesses



SURVEY F-TAGS AND ARBITRATION AGREEMENTS

- New F-Tags For Entering into Arbitration Agreements
 - Requirements went into place in 2019
 - New F-Tags F847: Must comply with Regulation 42. C.F.R 483.709(n) if a facility asks a resident to enter into an agreement for binding arbitration
- Link to updated survey guidance: <u>https://www.cms.gov/files/document/appendix-pp-guidance-</u> <u>surveyor-long-term-care-facilities.pdf</u>

https://skillednursingnews.com/2022/07/nursing-home-operators-could-face-fines-citations-tied-toarbitration-agreements-as-part-of-new-cms-requirements/?itm_source=parsely-api

SURVEY F-TAGS AND ARBITRATION AGREEMENTS

- New F-Tags For Entering into Arbitration Agreements
- The Facility:
 - Must not require agreement as condition of admission
 - Must explain the terms of the agreement to the resident or his or her representative in a form and manner (including language) that he or she understands
 - Must inform the resident or representative they have the right to rescind or terminate the agreement within 30 calendar days of signing
 - The Agreement may not contain language that prohibits discourages the resident or his or her representative from communicating with federal, state, or local officials

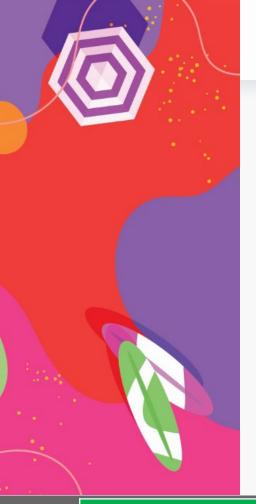
<u>https://www.cms.gov/files/document/appendix-pp-guidance-surveyor-long-term-care-</u> <u>facilities.pdf</u>

FEDERAL PHE EXTENDED

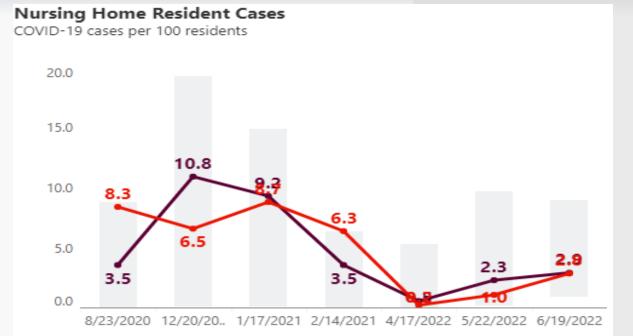
- HHS extended the federal Public Health Emergency on July 15, 2022, extending it for another 90 days.
- PHE is critical gives rise to numerous pandemic-related support measures like the remaining blanket waivers, additional reimbursement, etc.
- Industry analysts project that the PHE will continue at least through the end of 2022.
- HHS has indicated that it would give stakeholders 60 days notice if the PHE will not be continued.

Source: <u>https://aspr.hhs.gov/legal/PHE/Pages/covid19-15jul2022.aspx</u>; https://skillednursingnews.com/2022/07/hhs-extends-public-health-emergency-another-90-days/



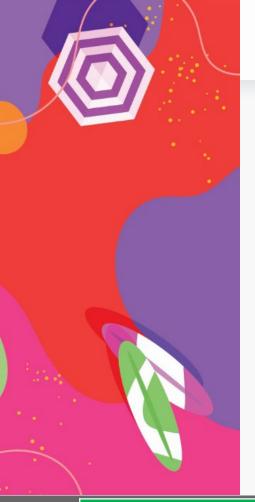


CURRENT COVID CASES IN NURSING HOMES – ON THE RISE, RELATIVELY



In the last month (four weeks ending 6/19/2022) in South Carolina, there were 2.8 COVID-19 cases per 100 nursing home residents.

Source: https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-dashboard.html



CURRENT COVID DEATHS IN NURSING HOMES

Nursing Home Resident Deaths



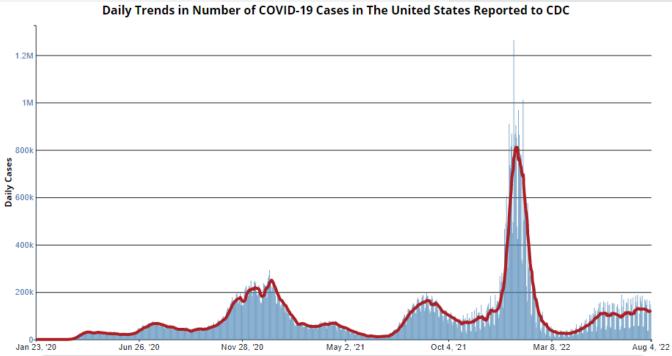
8/23/2020 12/20/20.. 1/17/2021 2/14/2021 4/17/2022 5/22/2022 6/19/2022

In the last month (four weeks ending 6/19/2022) in South Carolina, there were 0.04 COVID-19 deaths per 100 nursing home residents.

Source: https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-dashboard.html



CURRENT COVID CASES IN NURSING HOMES



Source: https://covid.cdc.gov/covid-data-tracker/#trends_dailycases_select_00

COVID RELATED ENFORCEMENT - UPDATE

- DOJ established a COVID-19 Fraud Enforcement Task Force in 2021
- In March 2022, DOJ appointed a Director for COVID-19 Fraud Enforcement to lead DOJ's efforts to combat and prevent COVID-19 related fraud
- DOJ also provided an update on its enforcement actions for **fraud related to pandemic relief funds** as of March 2022:
 - Enforcement actions involving **\$8 billion** in pandemic relief funds
 - Criminal charges against over 1,000 defendants related to over \$1 billion in loans
 - Over **240 civil investigations** into more than **1,800 individuals and entities** for alleged misconduct involving more than **\$6 billion** in pandemic relief funds
 - Seizure of over **\$1 billion** in EIDL proceeds

Source: https://www.justice.gov/opa/pr/justice-department-announces-director-covid-19-fraud-enforcement





COVID RELATED ENFORCEMENT

Active Areas for COVID related enforcement:

- LOTS of fake vaccine card charges and settlements not a good idea!
- DOJ cases and investigations involving CARES Act relief programs:
 - Loans obtained through the SBA's Paycheck Protection Program (PPP)
 - Economic Injury Disaster Loan (EIDL) program
 - Provider Relief Fund payments
- False Claims Act violations related to false statements and information in applications, attestations, and data submissions under these programs.
- False Claims Act violations related to the impermissible use of funds under these programs



COVID RELATED ENFORCEMENT - EXAMPLES

- In March of 2022, a former Seattle doctor was sentenced to <u>4 years in prison</u> and \$1,438,000 in restitution for fraudulently seeking over \$3.5 million in COVID-19 relief funds under the PPP and EIDL program. Severe sentence was due to "the blatant nature of the fraud and its size" involving 26 fraudulent PPP applications and 13 EIDL loan applications for companies that had no operations and based on employees and costs that did not exist.
- A California physician and his practice paid \$70,000 to resolve allegations under the FCA that they falsely certified in an application for a second PPP loan that they had not received a first PPP loan. Additionally, the practice paid back the second loan with interest = \$430,000.
- A California physician recently entered into a \$18,846.61 settlement agreement with the OIG to resolve allegations that he knowingly made a false statement in a document submitted to retain Provider Relief Fund payments under the CARES Act.
- A Florida nursing home system recently agreed to pay \$1.75 million to resolve FCA liability for facilitating COVID-19 vaccinations for hundreds of individuals ineligible to participate in the CDC's Pharmacy Partnership for Long-Term Care Program (LTC PPP), a program designed to vaccinate eligible long-term care facility residents and staff when vaccines were sparse.



COVID RELATED ENFORCEMENT – LESSONS LEARNED

- The detailed requirements on eligibility and use of funds matter for the COVID-19 relief programs under the CARES Act.
- Applications, attestations, certifications, etc. must be accurate and complete.
- Consequences for noncompliance can be severe.
- DOJ is committed to enforcement.



ENFORCEMENT RELATED TO POORLY EXECUTED EMERGENCY RESPONSE

- Thomasville, NC nursing home "put its 98 residents at risk when it had just three staff members working during a snowstorm in January, a Department of Health and Human Services investigation found"
 - A resident at the Pine Ridge Health and Rehabilitation Center called 911 during the Jan. 16 snowstorm and said she had not seen any staff at the facility, according to the report
 - When first responders got to Pine Ridge, they found two residents dead and two in critical condition, and many had not had food or medication, DHHS said.
 - "Every resident of the facility was placed at risk of severe harm," DHHS said in the report
- The report faults the nursing home for not following an emergency preparedness plan when a winter storm dropped about 3 inches of snow in Thomasville and put residents in "immediate jeopardy" <u>https://spectrumlocalnews.com/nc/charlotte/news/2022/03/15/report--</u> nursing-home-put-residents-in-jeopardy-during-storm



ENFORCEMENT RELATED TO POORLY EXECUTED EMERGENCY RESPONSE

Louisiana Shuts Down Seven Nursing Homes

- During Hurricane Ida, 843 nursing home residents from the seven facilities were transferred to a warehouse
- Residents were placed close together on cots or floor mattresses, in damp filthy conditions and rising temperatures
- Seven died and dozens more hospitalized
- The owner had represented to the State that the warehouse was wellstaffed, with about 150 well-paid employees on site, and food catered by a nearby church – but issues arose post-storm and the facilities failed to provide essential care and services

https://www.nola.com/news/healthcare_hospitals/article_c0e3fe6c-1001-11ec-904b-838ad8570726.html and https://www.wwltv.com/article/news/investigations/the-warehouse/state-pulls-licenses-of-nursing-homes-that-sentresidents-to-warehouse-where-6-died/289-bec186e0-8c14-4600-99c2-a97af7a65527



POORLY EXECUTED EMERGENCY RESPONSE – LESSONS LEARNED

Focus on Development and Execution of Emergency Plan

- **From Louisiana Department of Health Secretary Dr. Courtney N. Phillips:**
 - *An emergency preparedness plan is more than just a form of paper compliance. The implementation must accomplish the goals it is designed to meet. Some of those goals include the delivery of essential care and services to residents, the procedures for ensuring that all residents have access to licensed nursing staff, and that services are provided, during all phases of the evacuation, including transporting of residents. [...] it is clear that the facility failed in this regard," reads the notice to nursing facilities of the revocation of their licenses.
 - "All of these nursing facilities clearly failed to execute their emergency preparedness plans to provide essential care and services to their residents. When issues arose post-storm, we now know the level of care for these residents plummeted."

https://www.wwltv.com/article/news/investigations/the-warehouse/state-pulls-licenses-of-nursing-homes-thatsent-residents-to-warehouse-where-6-died/289-bec186e0-8c14-4600-99c2-a97af7a65527



OSHA EXTENDS COVID-RELATED INSPECTION PROGRAM, TARGETING SNFS

- On March 7, 2022, OSHA announced an enforcement memorandum for a short-term increase in highly focused inspections directed at hospitals and skilled nursing care facilities that treat or handle COVID-19 patients
 - The agency will initiated focused inspections to emphasize monitoring for current and future readiness to protect workers from COVID-19
 - Follow-up inspections will be conducted at sites that were previously issued citations, as well as where complaints were received but the agency did not conduct in-person inspections.
 - The inspections ran from March 9, 2022 to June 9, 2022.
- This program ended but OSHA has stated it will continue to conduct surveys and use every tool to ensure employers are protecting workers
- As of June, 2022, OSHA inspected more hospitals and nursing homes than it did for all of 2021
- https://www.osha.gov/news/newsreleases/trade/03072022-0

https://news.bloomberglaw.com/safety/health-care-osha-inspections-for-covid-surge-past-2021-levels

RECENT POST-ACUTE FRAUD ENFORCEMENT

- HHS Office of Inspector General has made clear that healthcare fraud in the nursing home context specifically is an area of emphasis for the OIG in 2022 and beyond.
 Consider some of these recent fraud and abuse enforcements as examples.
- March 2022 Georgia nursing home settled with the United States DOJ for <u>\$400,000</u> to resolve allegations that the nursing home billed Medicare for services that were not necessary, reasonable, or skilled. Settlement relates to therapy services from 2011 to 2014.
 - Allegations -- (1) presumptively placing patients at higher therapy levels, rather than relying on individualized evaluations to determine the level of care most suitable for each patient's clinical needs; (2) providing the minimum therapy minutes required to bill at a given reimbursement level while discouraging the provision of additional services beyond that minimum threshold; and (3) pressuring therapists and patients to complete the planned minutes of therapy regardless of patient need/safety.
 - U.S. Attorneys Office: "This settlement demonstrates our continuing efforts to protect patients and taxpayers by ensuring the that the care provided to beneficiaries of government-funded health care programs is dictated by clinical needs, not a provider's fiscal interests."

RECENT POST-ACUTE FRAUD ENFORCEMENT

- <u>\$7.85 million</u> settlement with a New York nursing home alleged to have fraudulently switched residents' Medicare Advantage coverage to Original Medicare to get higher reimbursement.
- The changes were made by facility staff without the residents' or their family members' knowledge or consent.
- The change to Medicare Advantage plans impacted the residents' out-of-pocket payments, the scope of covered services, and their drug plans, all without any discussions with residents or their authorized representatives.
- Staff used the Medicare.gov website to enter residents' personal information and make the disenrollment from Medicare Advantage and enrollment into Original Medicare by misrepresenting themselves on the Medicare.gov website as enrollees, persons assisting enrollees, or persons authorized to act on behalf of enrollees.

Source: https://www.jdsupra.com/legalnews/continued-summary-of-fraud-and-abuse-6005418/

RECENT POST-ACUTE FRAUD SETTLEMENTS

- U.S. DOJ filed a complaint in June 2022 against an Ohio operator of nursing home facilities alleging False Claims Act violations stemming from the facilities' provision of **"grossly substandard services" that failed to meet required standards of care.**
 - Failed to follow appropriate infection control protocols and did not maintain adequate staffing levels;
 - Housed its residents in a dirty, pest-infested building;
 - Gave its residents unnecessary medications, including antibiotic, antipsychotic, anti-anxiety and hypnotic drugs, while failing to make sure residents had prescriptions they actually needed.
 - Subjected residents to abuse and neglected to provide residents with activities or stimulation; and
 - Failed to create and maintain appropriate medical records.
- The United States' complaint stems from an investigation that the DOJ initiated as part of its **National Nursing Home Initiative**. The department launched the initiative in March 2020 to identify and investigate nursing homes that provide grossly substandard care.

Source: https://www.justice.gov/opa/pr/justice-department-sues-american-health-foundation-and-its-affiliates-providing-grossly

CMS, DHEC, AHRQ, AHCA COVID-19 RESOURCES

- CMS Best Practices Toolkit for Nursing Homes
 - Updated March 2022
 - Covers State Actions and Requirements <u>https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf</u>
- DHEC Long Term Care webpage: <u>https://scdhec.gov/covid19/guidance-healthcare-professionals-covid-19/long-term-care-facilities-covid-19</u>
- AHRQ Best Practices Summaries: <u>https://www.ahrq.gov/nursing-home/best-practices/index.html</u>
- AHCA/NCAL Coronvirus page: <u>https://www.ahcancal.org/Survey-Regulatory-</u> Legal/Emergency-Preparedness/pages/coronavirus.aspx





TREND TO TRACK: "SNF AT HOME"

- Recent trend is to look for ways to serve hospital and nursing home patients "at home"
- Pilot Study March 2022
- 10 patients, discharged from hospital for "rehabilitation at home"
- Short, 14 day stays
- Less cost, \$8,404 versus \$9,215
- Greater functional status, patient experience
- More studies are needed, but this is on the radar watch out for home health and hospitals vying for opportunities

https://journals.sagepub.com/doi/abs/10.1177/07334648221077092?journalC ode=jaga

TREND: EXPANDING BEHAVIORAL HEALTH SERVICES

- Example: NHC opens 64-bed psychiatric hospital in Knoxville in April 2022, and a 16 bed hospital in Osage Beach, Missouri in 2021
 - NHC VP Sawyna Nymeyer: "Nearly 50% of Americans will be diagnosed with a mental health problem in their lifetime. Our geriatric population is at risk of experiencing a mental health crisis when they have a diagnosis of dementia, Alzheimer's or even depression."
- Example: Responding to "great need for acute senior behavioral health," Catholic Care Center is developing a new acute care, senior behavioral health unit along with a memory care unit. The two units are expected to go "hand in hand."

https://skillednursingnews.com/2022/07/nursing-home-operators-make-infrastructurestaffing-changes-to-meet-behavioral-health-needs/



CURRENT CMS VIEW ON VISITORS

- "In general, visitation should be allowed for all residents at all times."
 - * While CMS is concerned about the rise of COVID-19 cases due to the Omicron variant, we're also concerned about the effects of isolation and separation of residents from their loved ones.
 - Earlier in the pandemic we issued guidance for certain limits to visitation, but we've learned a few key things since then. Isolation and limited visitation can be traumatic for residents, resulting in physical and psychosocial decline. So, we know it can lead to worse outcomes for people in nursing homes.
 - Furthermore, we know visitation can occur in a manner that doesn't place other residents at increased risk for COVID-19 by adhering to the practices for infection prevention, such as physical distancing, masking, and frequent hand hygiene."

March 10, 2022 FAQ <u>https://www.cms.gov/files/document/nursing-home-visitation-faq-1223.pdf</u>

CMS Infographic: https://www.cms.gov/files/document/how-safely-visit-nursing-homes.pdf



CURRENT SOUTH CAROLINA VIEW ON VISITORS

Most recent guidance 9/24/2021

- All facilities are required to allow visitation.
- Compassionate care visits continue to be required at all times, and include residents suffering mental, physical, and emotional decline due to prolonged separation from loved ones.
- Outdoor visits, window visits, and virtual visits also remain permitted in all scenarios, though the outdoor visits may be hindered by weather considerations or an individual resident's health status (e.g., medical condition(s), COVID-19 status).
- Compassionate care visits, outdoor visits, window visits, and virtual visits do not relieve facilities of the obligation to allow indoor visitation at all times and for all residents in accordance with these guidelines

https://scdhec.gov/sites/default/files/media/document/LTCF-Visitation-Guidelines-09.24.2021.pdf



CURRENT SOUTH CAROLINA VIEW ON VISITORS

Most recent guidance - 9/24/2021

- Facilities are required to allow indoor visitation at all times and for all residents. However, there are circumstances involving a high risk of COVID-19 transmission when facilities should limit indoor visitation for specific residents. Facilities should limit indoor visitation for the following residents:
- Unvaccinated residents, if the facility's COVID-19 county positivity rate is greater than 10% and less than 70% of residents in the facility are fully vaccinated (note: these guidelines continue the utilization of DHEC's county positivity rate, available at the link above and here)
- Residents with confirmed COVID-19 infection, whether vaccinated or unvaccinated, until they have met the criteria to discontinue Transmission-Based Precautions; or
- Residents in quarantine, whether vaccinated or unvaccinated, until they have met criteria for release from quarantine.
- Recognizes there may be pauses in indoor visitation during an outbreak (when there is a new COVID-19 case among residents or staff)

https://scdhec.gov/sites/default/files/media/document/LTCF-Visitation-Guidelines-09.24.2021.pdf



TREND TO TRACK: FLORIDA AND CHANGING VISITOR LAWS

Florida "No Patient Left Alone Act" April 6, 2022

- Health care facilities must allow in-person visitation in all of the following circumstances, unless the resident, client, or patient objects:
 - End-of-life situations.
 - A resident, client, or patient who was living with family before being admitted to the provider's care is struggling with the change in environment and lack of in-person family support.
 - A resident, client, or patient is making one or more major medical decisions.
 - A resident, client, or patient is experiencing emotional distress or grieving the loss of a friend or family member who recently died.
 - A resident, client, or patient needs cueing or encouragement to eat or drink which was previously provided by a family member or caregiver.
 - A resident, client, or patient who used to talk and interact with others is seldom speaking.
 - For hospitals, childbirth, including labor and delivery.
 - Pediatric patients.

Additionally, the bill allows a resident, client, or patient the option to designate a visitor who is a family member, friend, guardian, or other individual as an essential caregiver. The provider must allow in-person visitation by the essential caregiver for at least 2 hours daily in addition to any other visitation authorized by the provider. <u>https://flgov.com/2022/04/06/governor-ron-desantis-signs-bill-to-guarantee-visitation-rights-for-patients-and-their-families/</u>



SUPREME COURT DECISION ON PHYSICIAN OPIOID PRESCRIBING

Ruan v. United States, decided 6/27/2022

- Consolidated Case involving Doctors with pain management clinics across the Country two physicians licensed to prescribe controlled substances
- Each was tried for prescribing in an unauthorized manner
- A federal regulation authorizes registered doctors to dispense controlled substances but only if the prescription is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR §1306.04(a)
- At issue in physicians trials was the mens rea required to convict under §841 for distributing controlled substances not "as authorized"
- Once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner
 - "Prohibited conduct (issuing invalid prescriptions) is "often difficult to distinguish" from acceptable conduct (issuing valid prescriptions)"
 - Requires finding that physician "subjectively believed" they were wrongly dispensing to be convicted



RADONDA VAUGHT CASE

- Former Vanderbilt Nurse RaDonda Vaught Sentenced to Three Years Probation, May 2022
 - Worked at Vanderbilt University Medical Center
 - Made a fatal medication error in 2017 that resulted in the death of one of her patients
 - Vaught was an RN. The patient (Charlene Murphy) was a 75-year-old woman who was in the hospital for a subdural hematoma. Two days after she was admitted, Vaught was instructed to administer Versed (sedative) but instead administered Vecuronium (paralytic)
 - Vaught attempted to withdraw Versed from an automatic dispensing cabinet but was unsuccessful. She used an override to access a larger selection of medications.
- Patient was left braindead and died within a day

https://www.wspa.com/news/local-news/upstate-nurse-pleads-guilty-to-stealing-prescription-drugsfrom-nursing-home/



RADONDA VAUGHT CASE

- Hospital also failed to report the error to federal or state regulators and instead reported to the county medical examiner that she died of natural causes
- Hospital negotiated a settlement with Murphy's family--- Amount undisclosed
- Vanderbilt also allegedly instructed nurses to use their override systems regularly (every time they retrieved a medication)
- Hospital not prosecuted, but Vaught was convicted of gross neglect of an impaired adult & negligent homicide
- Sentenced to 3 years of probation—no prison time
- There has been a great deal of discussion about potential follow on effects of criminalizing medical mistakes - worry about a chilling effect that will discourage honest reporting of mistakes or even discouraging individuals from entering the medical field in fear of liability





