KAHCF
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Bowling Green,, Kentucky

Surveys and Appeals: The Long and Winding Road to Justice

Alan C. Horowitz, Esq., RN

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Brief Overview

Significant Changes in Administrative Law and Their Impact on Litigation

Successfully Challenging CMS/Survey Allegations

Survey Reform: An Idea Whose Time Has Come

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Appeals of CMS Enforcement Actions

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- Administrative Law Judge ("ALJ") (within HHS)
- Departmental Appeals Board ("DAB" or "Board") (within HHS)
- U.S. District Court
- U.S. Court of Appeals
- U.S. Supreme Court (very rare)
- Note: IDR/IIDR results not binding on CMS or courts

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Administrative Law's Changing Landscape

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To the extent courts defer to agency interpretations of their regulations, such deference often places the agency in the role of "judge, jury and executioner." (*Elgin v. HHS*, Court reversed ALJ and DAB.)

Recent decisions from SCOTUS will likely level the legal playing field for providers.

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Deference to Agencies

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Chevron

courts defer to any reasonable agency interpretation of a statute

Chevron v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984)

Auer

deference to agency interpretation of its regulations whenever a rule is ambiguous ("Auer Deference")

Auer v. Robbins, 519 U.S. 452 (1997)

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Kisor v. Wilke, 139 S. Ct. 2400 (2019)

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Four justices described *Auer* deference as "maimed and enfeebled – in truth, zombified," asserting that *Auer* contradicts the APA's mandates.

Essentially, *Kisor* restricts the circumstances when a court may defer to an agency's interpretation of its regulation.

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Question

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- Surveyors come into your Center on an annual recert survey. They cite 3 deficiencies *based solely on the SOM's Interpretive Guidelines*.
- Without knowing anything else, are the survey citations valid and enforceable?

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The SOM is NOT Law

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Surveyors MAY NOT cite a deficiency based solely on the SOM

"Surveyors should refer to SOM Section 2712 "Use of Survey Protocols in the Survey Process" and Principle #5 in the Principles of Documentation found in Exhibit 7A for clarification in using information found in the interpretive guidelines. Both sources make it clear that surveyors must base all cited deficiencies on a violation of statutory and/or regulatory requirements, rather than sections of the interpretive guidelines. The deficiency citation must be written to explain how the entity fails to comply with the regulatory requirements, not how the facility fails to comply with the guidelines for the interpretation of those requirements."

"Use of Interpretive Guidance by Surveyors for Long Term Care Facilities" S & C Memo 08-10 January 18, 2008

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THE SOM IS NOT LAW

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- "Although surveyors must use the information in the Guidelines, they must be cautious in their use. Guidelines do not replace or supersede the law or regulation, and therefore, may not be used as the basis for a citation."
- *Use of Interpretive Guidance by Surveyors for Long Term Care Facilities*, CMS S & C Memo 08-10 January 18, 2008

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Golden Living Center - Mountain View v. HHS No. 19-3755 (6th Cir. 2020)

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"Nowhere in the regulations does CMS put nursing homes on notice that consideration of additional staffing will be dispositive. Instead, CMS argues that it is 'obvious.' Because this interpretation of this regulation arose through enforcement, rather than notice and comment, we do not give it the deference that we give substantive rules that went through the notice and comment process."

DAB determination vacated, case remanded

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Elgin Nursing & Rehab Center v. U.S. Dept. HHS, 718 F.3d 488 (5th Cir. 2013)

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Fifth Circuit reversed DAB and ALJ decisions regarding "runny eggs" and "sanitary conditions." CMS relied, in large part, on SOM and letter from CMS Dallas Regional Office.

"Affording deference to agency interpretations of ever more ambiguous regulations would allow the agency to function not only as judge, jury and executioner but also to do so while crafting new rules . . ."

Take-away: Court rejected deference to CMS based on interpretations of interpretation of a regulation. Court noted the "three levels of interpretation" used by CMS – 42 CFR 483.35(i)(2); Appendix PP of SOM; CMS' interpretation of App. PP

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Hot Coffee Case

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- Background: Resident is AAO x 3, sitting in chair in room, adult caretaker beside him (caretaker brought cup of coffee to Resident), Resident seized, spilled coffee – "dime-sized wound on abdomen." (June) Classified as 2nd degree burn, fully healed.
- At annual survey in March of next year, surveyor reviews incident reports, sees report of coffee spill and cites immediate jeopardy (failure to provide adequate supervision (F325, now F689); administration, QAPI/QAA F-tags)
- Surveyor was unusually aggressive and inappropriate, resulting in some staff members actually crying and causing two staff to resign. (One left LTC nursing altogether based on surveyor's inappropriately aggressive manner)
- Astonishingly: "Don't you know the federal regulations regarding the temperature of hot coffee?" Surveyor berates and demeans staff.
- Note: There are no federal or state regulations regarding the temperature of hot coffee.

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Morrisons Cove Home v. CMS, DAB CRD CR1581 (2007)

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- 56 y/o woman admitted to SNF for short-term rehab following ORIF distal tibia
- Rx from hospital's orthopedic surgeon:
- Have pt. see me for follow-up bandage and staple removal on June 2nd
- Facility misses follow-up appointment, realizes that and sends resident to surgeon on June 11th, cellulitis present, resident febrile, debridement done and sent back to SNF with IV Cipro and Rx to "have nurses monitor wound for s/s of infection."
- No documentation of monitoring
- Resident get worse, sent to hospital, leg amputated, resident dies few days later.
- Key issue: was monitoring done by nursing, consistent with standards of care and Rx?

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Morrisons Cove Home: Outcome

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- Facility loses appeal, CMS CMP upheld, collateral litigation
- "The facility failed in contravention of the applicable standard of care to document the wound's appearance systematically."
- "There is a distinct need to document a wound's appearance at least daily."
- Key is Documentation

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Covington Manor v. CMS, DAB CRD No. 4706 (September 16, 2016)

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- Background:

- Female resident was assessed as a "safe smoker"
- Consistent with her functional capabilities and cognitive level, she was smoking independently on a designated area (back porch of Facility)
- Her sweater caught fire when the wind blew an ember from her cigarette
- Resident sustained 2nd degree burns and was promptly sent to ER
- Facility immediately reviewed and revised its Smoking Policy and implemented several interventions
- Surveyors reviewed an incident report – seven months later – at an annual survey and cited immediate jeopardy. CMS imposed a CMP over $700,000 (197 days of a per-day CMP) due to "unsafe smoking environment."

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Covington Manor v. CMS

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- Deficiencies and Related Allegations:

  - Lack of adequate supervision for residents who smoked
  - Hazardous and flammable materials (trash container liner)
  - Noncombustible Polyethylene liner in 3-foot ashtray
  - Wrong type of ashtrays (cup of water not acceptable)
  - Smoking materials were not "secure"
  - Fire extinguisher was more than 75 feet from front porch (smoking area)
  - Environment was not safe

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Covington Manor's Timely Interventions

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Smoking Policy and Procedure Reviewed and Revised

All smokers re-assessed (and documented)

Smoking aprons must be worn

Smoking only at designated times

Only smoking in designated area (front porch, concrete floor, sprinklers)

Signs on all doors to/from Facility

All cigarettes, tobacco products removed and placed behind nurse's station in box

All smoking must be supervised

All staff in serviced

KEY: ALL OF THE ABOVE WAS TIMELY DOCUMENTED

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Trial/Hearing

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- Testimony
  - Written statement in lieu of direct testimony
  - Video taken by owner and administrator (trash container liners)
  - Expert witnesses (fire safety experts)
- Cross-examination of surveyors
  - Did not know the difference between flammable and inflammable even though written-up in 2567
  - Could not explain why smoking materials in a locked tackle box behind Nurse's station were not "secure"
  - Forced to concede that not only did Covington Manor meet standards of care, it "exceeded the applicable standards of care"

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Is The Survey Process in Need of Reform?

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All stakeholders agree that the survey process needs to be reformed but the devil is in the details.

Does regulatory compliance necessarily translate to better resident outcomes?

Do higher CMPs result in improved resident care?
(If so, what valid evidence supports those premises?)

Note: The author is not aware of a single, credible study that correlates better resident outcomes with higher CMPs and other enforcement actions.

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To What End Surveys?

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Surveys *may* increase regulatory compliance

Evidence that surveys (and enforcement actions) improve quality of care is lacking

Survey results do not necessarily correlate with quality improvement

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AMDA'S POTENTIAL ALTERNATIVES*

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1. "Instead of focusing on deficiencies only, surveyors should also account for superior performance, using a net score to determine overall quality
2. Any financial penalties should be reinvested in a formal quality improvement initiative for that NH in partnership with accredited quality improvement consultants
3. 'Deficiency amnesty' for a first-time deficiency for a NH that has historically done well, like a warning instead of a traffic citation

**Time for an Upgrade in the Nursing Home Survey Process: A Position Statement From the Society of Post-Acute and Long-Term Care Medicine,* Arif Nazir MD, CMD, AGSF, FACP Karl Steinberg MD, CMD, HMDC,

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AMDA'S POTENTIAL ALTERNATIVES

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4. Different survey approaches based on 5-star rating; for example, less frequent surveys for 5-star SNFs and more hands-on (but supportive) surveys for 1-star SNFs
5. Survey processes should be informed and supplemented by proven supportive approaches, e.g., Baldrige process that creates a dynamic environment with focus on strategy-driven performance to achieve customer and workforce engagement, and improve governance and ethics, competitiveness, and long-term sustainability (https://www.nist.gov/baldrige/how-baldrige-works)
6. Utilize behavioral economic principles of internal motivation and engagement rather than financial incentives for promoting behavior change
7. Perform customer service surveys after each survey, with facility staff providing feedback regarding each surveyor/team on their performance"

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Carrots or Sticks?

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Non-punitive

Directed In-service

Directed Plan of Care

Funds dedicated to Quality Improvement Account

SIA

Punitive

Higher CMPs

DPNA

SFF Status

Termination

Have increasingly harsh enforcement actions resulted in improved quality of care? (Where's the evidence?)

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The Lesson of St. Agnes Medical Center, Philadelphia, PA

Arnall Golden Gregory LLP

Two patients died of intracranial hemorrhage occurring "as a complication of Coumadin therapy which was improperly administered because of laboratory error," according to the Philadelphia Medical Examiner.

Hospital president holds press conference: "Mea Culpa"

CMS and PA Department of Health Want CMPs

Department of Health fined St. Agnes Medical Center $447,500

After suggestions by OGC with CMS agreement, St. Agnes was allowed to use the $447.5K for quality improvement (e.g., community health initiatives)

Take-away: a non-punitive approach may represent a win-win.

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Editorial

Time for an Upgrade in the Nursing Home Survey Process: A Position Statement From the Society of Post-Acute and Long-Term Care Medicine

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A few weeks after getting hit by the first known cases of COVID-19 in the United States, Life Care Center of Kirkland received 3 "immediate jeopardy" deficiencies (with a civil monetary penalty of $611,323): (1) a failure to have emergency physician services available 24 hours a day or to have an alternative emergency plan when the primary care physician, who is also the Medical Director, is unavailable; (2) a failure to have an appropriate infection control surveillance program; and (3) a failure to provide quality care and services for residents during a respiratory outbreak.[1]

Should this nursing home (NH), previously a 5-star facility, receive commendation for its courageous conduct during an unprecedented, sudden disaster, or be penalized for the tragic yet inescapable bad outcomes involving a previously unknown virus? Or something in between? Should accountability necessarily equate to punishment, and how often does punishment translate into improved quality in the future? COVID-19 gives us a prime opportunity to pose these questions and develop a framework within which to respond to them.

Accountability entails the procedures and processes by which one party justifies and takes responsibility for its activities.[2] The analytical framework of accountability stands on 3 principles: (1) control the misuse and abuse of public resources and/or authority (financial); (2) ensure that resources are used and authority is exercised according to appropriate and legal procedures, professional standards, and societal values (compliance); and (3) enhance performance through feedback and learning (performance improvement).[3]

Creating accountability in complex health systems in accordance with the 3 principles offers challenges and can result in conflicting behaviors. For example, setting financial and authority accountability can result in blame, that may conflict with accountability for performance improvement, which emphasizes *embracing* error as a source of learning.[3] Also, institutional capacity limitations may undermine efforts to enhance accountability for all 3 purposes. The Institute of Medicine has emphasized the necessity of a "just culture," one that promotes safety by viewing errors as learning opportunities rather than focusing on the blame of individuals.[4]

Accountability programs in NHs need to be cautiously constructed, as they represent complex adaptive systems, composed of semi-autonomous individuals who interact frequently and in a nonlinear way. These individuals are constantly faced with and respond to external stressors (patients' medical status, insurance, regulations, available evidence, and legal issues) and internal stressors (financial stress, personal health, ethical concerns), and attempts to rigidly control these systems may worsen problems.[5]

The Omnibus Budget Reconciliation Act of 1987 (OBRA '87) enacted by Congress set the foundation of the NH quality assurance program and associated regulatory standards.[6] The impact of these standards on NH quality has been debated for decades and the jury is still out on them. Even though research shows an association between regulatory compliance and decrease in specific care areas such as polypharmacy and restraint use, the impact of the survey processes on holistic quality outcomes, such as hospitalizations and mortality, and quality of life is less clear.[7–9]

As survey results are a component of the NH 5-star ratings and other metrics, could a relation between star ratings and quality represent a positive association between surveys and quality? In general, studies showing a correlation between 5-star ratings and better quality are limited, but even for those, it is unknown if such a correlation represents a causal relationship vs merely an association. At the very least there is evidence that the 5-star rating doesn't correlate with consumer ratings of quality.[10]

Several GAO and academic research reports have highlighted limitations of the federal survey system, for example, state-to-state variations, wide interpretive variations between surveyors, and inadequate funding.[11,12] Other factors are also known to impact survey

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1525-8610/

Table 1
Potential Solutions From the AMDA Taskforce to Upgrade the Survey Process

1. Instead of focusing on deficiencies only, surveyors should also account for superior performance, using a net score to determine overall quality
2. Any financial penalties should be reinvested in a formal quality improvement initiative for that NH in partnership with accredited quality improvement consultants
3. "Deficiency amnesty" for a first-time deficiency for a NH that has historically done well, like a warning instead of a traffic citation
4. Different survey approaches based on 5-star rating; for example, less frequent surveys for 5-star SNFs and more hands-on (but supportive) surveys for 1-star SNFs
5. Survey processes should be informed and supplemented by proven supportive approaches, eg, Baldrige process that creates a dynamic environment with focus on strategy-driven performance to achieve customer and workforce engagement, and improve governance and ethics, competitiveness, and long-term sustainability (https://www.nist.gov/baldrige/how-baldrige-works)
6. Utilize behavioral economic principles of internal motivation and engagement rather than financial incentives for promoting behavior change
7. Perform customer service surveys after each survey, with facility staff providing feedback regarding each surveyor/team on their performance

SNFs, skilled nursing facilities.

findings, for example, average age and case mix of residents, for-profit vs nonprofit status, chain vs independent ownership, occupancy rates, and state political leadership.[13] Moreover, there are concerns that NHs "staff up" for expected surveys and merely write a Plan of Correction (usually in the nature of nursing education via in-service presentations), then go back to business as usual.

Previously, AMDA and other organizations have cautioned on the adversarial and punitive tone of federal survey processes, but little has changed.[14] Current survey processes continue to fly in the face of proven principles of internal motivation for promoting performance, instead assigning individual blame, focusing on punishments and impinging on provider autonomy. The updated SNF Requirements of Participation have yet again resulted in a conversation about the survey process, polarizing consumer advocates and providers with diverging opinions.[15] It is important that we take a fresh look at the approach and value of the survey process and how it should be improved.

AMDA Survey Taskforce to Facilitate Rethinking of an Upgraded Survey Process.

The Society approved a task force (authors included) to explore the performance of the survey process by drawing on literature, governmental reports and opinions of policy and regulatory experts, and to use this information to provide recommendations and facilitate conversation to rethink the survey process. The task force convened in early 2019 and since have met 10 times, putting forth the following opinions:

1. The survey process improves regulatory compliance, but evidence for improvement in quality of care is lacking and more research is needed; that is, compliance does not equate with better quality of care.
2. Lack of adequate funding impacts the consistency and quality of the survey program.
3. Statewide variability and surveyor biases impact validity of deficiencies.
4. The survey process has evolved with a heightened focus on adversarial and punitive practices.
5. The survey process is not conducive to person-centered care and innovations in care delivery, but more to maintaining status quo and susceptibility to gaming.
6. The survey process, at least anecdotally, negatively affects team morale; this needs to be researched.
7. Civil monetary penalties that siphon money from NH operations cannot improve quality of care in already financially strapped NH operations.
8. Other approaches to accountability in long-term care (eg, Joint Commission) may provide lessons for improving the survey process, for example, the Joint Commission's approach to use Donabedian's framework of structure, process, and outcome and to use evidence-based measures of performance as part of their quality improvement programs.[16]
9. The survey process should recognize high-performing and innovative facilities. It should shed the blame approach and incorporate constructive feedback—stimulating NHs to seek collaboration with credible quality improvement partners.
10. The survey process needs to engage geriatric experts in assessing NH performance. For example, redefine medical director participation in quality assessments and problem solving.
11. The survey process should incorporate lessons from behavioral economics to improve staff motivation (eg, nudge theory that employs indirect suggestions to try to achieve nonforced compliance and to influence the decision making and behavior).[17,18] Such approaches have shown to improve compliance in healthcare, for example, shared decision making.[19]
12. Previously, questioning the survey process has been perceived as ignoring poor quality of care by many stakeholders (eg, consumer advocates). Any solutions to survey improvement will require sincere collaboration among stakeholders with a conviction to improve patient care without loosening accountability for NHs that are negligent.

Although a complete redesign of the survey process was beyond the scope of the task force's initial assignment, the conversations did result in many potential solutions to positively modify the survey process (see Table 1).

The COVID-19 pandemic highlights the opportunity for a better accountability framework. The negative outcomes at the Life Care Center of Kirkland were multifactorial and probably inevitable. For surveyors to simply blame the hardworking and courageous staff is unacceptable, as is the recent announcement by federal government to "enhance[ing] the penalties for noncompliance with infection control to provide greater accountability," particularly when research fails to show a relationship between quality and COVID-19 outbreaks.[20] It is high time that we push for a survey process that not only assesses performance in a no-blame fashion but also facilitates person-centered care and innovations in care delivery, while continuing to fairly account for deficient practices and negligence. This may be a tall order, but NH residents and the staff who serve them deserve nothing less.

Acknowledgment

The authors acknowledge the other members of the Survey think-tank including Cheryl Philips MD, CMDR; Christopher E. Laxton, CAE, Executive Director, AMDA, The Society for Post-Acute and Long-term Care Medicine; and Alice Bonner, PhD, RN, FAAN, Senior Advisor for Aging Institute for Healthcare Improvement, for their contributions to the discussions and to the recommendations shared in this publication.

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Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-08-10

DATE: **January 18, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Interpretive Guidance by Surveyors for Long Term Care Facilities

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) has been asked to clarify the use of the Interpretive Guidance to Surveyors for Long Term Care Facilities in reviewing for compliance with the regulatory requirements for nursing homes.
- Surveyors must cite all deficiencies based on a violation of statutory and/or regulatory requirements.

Background: The Social Security Act mandates the establishment of minimum health and safety standards that providers and suppliers must meet in order to participate in the Medicare and/or Medicaid programs. Specific provision of the nursing home regulations at 42 C.F.R. Part 483 further refine this statutory obligation. CMS' authoritative interpretation of the regulatory language is found in the State Operations Manual (SOM). The SOM specifies that the interpretive guidelines serve as, and also provide surveyors with, specific survey protocols such as investigative protocols, definitions of regulatory terms, and interview probes that they can use during surveys to evaluate compliance with the regulations.

Discussion: The survey process is the best assurance we have that protections set forth in the nursing home requirements are being met and that residents are receiving quality services. CMS continuously investigates ways to improve the long term care survey process with the goal of improving the quality of care and quality of life of nursing home residents. Providing updated interpretive guidance to nursing home surveyors is one method used by CMS to improve the survey process. The interpretive guidance facilitates surveyors' consistent regulatory interpretation and determination of the gravity and pervasiveness of identified deficiencies; ultimately providing a consistent approach to the manner in which surveyors assess a nursing home's compliance with the requirements.

In providing new interpretive guidance, CMS is careful not to prescribe new requirements. Instead, the focus is on relaying to surveyors information consistent with the regulations and accepted standards of care. There are portions of the interpretive guidelines that specify such things as permissive duties or tools that facilities may be using to care for residents. Permissive duties are not requirements, and the lack of use of any particular tool does not, by itself, constitute sufficient grounds for the citation of a deficiency.

An example of a permissive duty is found in the guidance for 42 C.F.R. § 483.25(c) Pressure Sores. One section of this Guidance refers to repositioning as a common and effective intervention for individuals with a pressure sore or who are at risk of developing one. The Guidance provides, "The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning." This sentence indicates a permissive action by the facility but does not create a requirement that facilities use lift devices in order to prevent pressure sores, as the facility may have other interventions in place to avoid shearing and friction. The lack of use, by itself, does not create a deficient practice for a facility. Words like "should" or "may" create permissive standards, vs. words like "shall" and "must" that indicate requirements.

Conclusion: Surveyors should refer to SOM Section 2712 "Use of Survey Protocols in the Survey Process"[1] and Principle #5 in the Principles of Documentation[2] found in Exhibit 7A for clarification in using information found in the interpretive guidelines. Both sources make it clear that surveyors must base all cited deficiencies on a violation of statutory and/or regulatory requirements, rather than sections of the interpretive guidelines. The deficiency citation must be written to explain how the entity fails to comply with the regulatory requirements, not how the facility fails to comply with the guidelines for the interpretation of those requirements.

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[1] State Operations Manual, § 2712 reads, in part, "Included in the survey protocols are interpretive guidelines that serve to interpret and clarify the CoPs, conditions for coverage, and requirements of participation for specific types of entities. The interpretive guidelines contain authoritative interpretations and clarification of statutory and regulatory requirements and are to be used to make determinations about a provider's compliance with requirements. These interpretative guidelines define or explain the relevant statutes and regulations and do not impose requirements that are not otherwise set forth in statute or regulation.

The SA conducts the surveys in accordance with the appropriate protocols, and looks to the substantive requirements in the statute and regulations to determine whether a citation of noncompliance is appropriate. The SA bases any deficiency on a violation of the statute or the regulations. The decision of whether there is a violation of the statute or regulations must be based upon observations of the facility's performance, practices, or conditions in the facility."

[2] Principles of Documentation, Principle #5 reads, in part, "The deficiency citation demonstrates how the entity fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for the interpretation of those requirements. These Guidelines were designed to assist surveyors to develop a better understanding of the requirements, to apply these requirements in a consistent manner across entities, and to suggest pathways for inquiry.

Although surveyors must use the information in Guidelines, they must be cautious in their use. Guidelines do not replace or supersede the law or regulation, and therefore, may not be used as the basis for a citation. However, they do contain authoritative interpretations and clarifications of statutory and regulatory requirements...Surveyors should carefully consider how the practice of the entity relate to the illustrations within the Interpretive Guidelines, and then compare the entity's practice to the specific language and requirement of the regulation before determining that a deficiency exists."

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management