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***The CMS 2016 Final Rule:
More of the Same for Skilled Nursing Facilities***

Amy Swinehart, MJ, BSN, RN-BC

I. INTRODUCTION

Before her death in 2014, 36-year-old Letasha Mims was a resident in six different nursing facilities.¹ In the months preceding Letasha's death, she developed a pressure ulcer which was so deep that the tailbone itself became infected, resulting in death.² When the Illinois Department of Public Health investigated the circumstances surrounding her pressure ulcer development, they concluded that the facility was in compliance with nursing home regulations.³ Letasha Mims is not alone. A study conducted by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) in 2014, found that 22% of Medicare beneficiaries experienced an adverse outcome during nursing home stays⁴. Of these incidents, 59% were considered preventable.⁵ When viewed in light of the notion that nursing homes are supposedly highly regulated⁶, the current regulatory system is broken, evidenced by patient outcomes like Letasha's that are not adequately addressed through regulatory compliance efforts.

Annually, and as needed in the event of complaints, state surveyors inspect nursing facilities to determine compliance with the federal rules for Medicare & Medicaid participation.⁷ As their guide, surveyors use the Centers for Medicare and Medicaid Services (CMS) State Operations Manual (SOM) which includes over 700 pages of interpretive guidelines to guide the inspection process.⁸ On October 4, 2016, CMS issued a Final Rule (2016 Final Rule) which revised and expanded the previous Requirements for Participation for Long-Term Care Facilities (ROP).⁹ This revision increased the number of existing citations included in the SOM from 150 to more than 200 potential citations. These citations are referred to as F-tags.¹⁰ When surveyors issue citations, they specify the *scope* and *severity* classification of the citation which categorizes the extent of the harm, or potential for harm, as well as the extent of the impact on residents whether such impact might be considered isolated, a pattern or widespread.¹¹ According to the 2016 Final Rule issued by CMS, the "intent" of the new requirements "was to improve the quality of care and quality of life for residents of long-term care facilities."¹² Analysis of the effect of the 2016 Final Rule now indicates that the regulators actually only produced "more of the same" with additional

¹ Ward, S. (2016). The Human Cost of Doing Business. ABA Journal, 102(8), 52-56,58-61; (pg.1)

² *Id.* at pg. 2.

³ *supra* note 1 at pg. 5.

⁴ Kapp, M., & Howard, Philip. (2014). Are Nursing Home Regulations Like Cobwebs? *The Gerontologist*, 54(5), 886-890. (pg. 887)

⁵ [Government Report: Office of Inspector General Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries, 2014; \(pg. 2\)](#)

⁶ Bowblis, J., & Lucas, R. (2012). The impact of state regulations on nursing home care practices. *Journal of Regulatory Economics*, 42(1), 52-72. (pg. 53)

⁷ 42 CFR Part 483, Subpart B-Requirements for Long-term Care Facilities; available at <https://www.govinfo.gov/app/details/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part483>

⁸ State Operations Manual: Appendix PP-Guidance to Surveyors for Long-term Care Facilities; available at: https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/som107ap_pp_guidelines_ltc.pdf

⁹ [CMS Final Rule for Long-Term Care Facilities; \(2016\) available at: https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf](#)

¹⁰ [CMS F-tags for Long-Term Care \(2014\); available at: https://surveyortraining.cms.hhs.gov/Preceptor/PManual/LTC/PreceptorBasics/LTC-App-PP-List.pdf](#)

¹¹ Castle, N., & Ferguson, J. (2010). What is nursing home quality and how is it measured? *The Gerontologist*, 50(4), 426-42. (pg. 440)

¹² *supra* note 4.

regulations.¹³ The prior regulations have proven to be ineffective in numerous respects. This is especially evident in the surge of nursing home negligence-related lawsuits.¹⁴

Nursing home regulations are necessary, in some respects, to monitor for minimum compliance with basic standards.¹⁵ Because regulatory compliance and oversight has not substantially prevented substandard quality of care, the 2016 Final Rule for nursing facilities is unlikely to effectuate substantial change in the long-term care industry.^{16,17} Moreover, these requirements fail to encourage and incentivize providers to *exceed* the minimum and push towards care excellence.¹⁸

This paper will discuss the regulatory landscape for United States nursing facilities. It will also discuss three types of burden experienced by nursing facilities that are not alleviated - - and could well be exacerbated - - through the 2016 Final Rule: (a) burden of compliance, (b) burden of enforcement, and (c) the burden of quality. Following these areas of discussion, recommendations will be offered to reduce specific burdens associated with nursing facility regulatory compliance.

II. BACKGROUND

a. Regulatory Landscape

The United States has over 15,000 nursing homes which provide care for approximately 1.4 million residents.¹⁹ Skilled nursing facilities, in particular, are subject to a multitude of regulations and regulatory agencies including: the Health Insurance Portability and Accountability Act (HIPAA), CMS regulations, Occupational Safety & Health Administration (OSHA) requirements, Office of Inspector General (OIG) oversight, and various state agencies oversight from Life Safety (fire and physical plant requirements) to pharmacy boards.²⁰ One author appropriately describes nursing facility regulatory forces as a "regulatory octopus."²¹ With the implementation of the Omnibus Budget Reconciliation Act (OBRA) of 1987, nursing facilities are required to meet minimum standards as set forth in the ROP in order to remain eligible for Medicare payments.²² These requirements cover multiple areas including quality of care, resident

¹³ 2016 CMS Final Rule Reform of Requirements; (pg. 68637); available at: <https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>

¹⁴ Stevenson, D., & Studdert, D. (2003). The rise of nursing home litigation: Findings from a national survey of attorneys. *Health Affairs (Project Hope)*, 22(2), 219-29.

¹⁵ "The Future Of Nursing Home Regulation: Time For A Conversation?", *Health Affairs Blog*, August 23, 2018. DOI: 10.1377/hblog20180820.660365

¹⁶ *supra* note 7.

¹⁷ *supra* note 6.

¹⁸ [Nursing Home F-Tag Citations, revised in 2017; available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf)

¹⁹ [Government Report: United States Government Accountability Office; Nursing Home Quality: Continued Improvements Needed in CMS's Data and Oversight; September 6, 2018](#)

²⁰ Kapp, M. (2005). Improving the Quality of Nursing Homes. *Journal of Legal Medicine*, 26(1), 1-8. (pg. 4)

²¹ Kapp, M. (1995). Medical Decision-Making for Older Adults in Institutional Settings - Is Beneficence Dead in an Age Of Risk Management. *Issues In Law & Medicine*, 11(1), 29-46. (pg. 30)

²² [supra note 16.](#)

rights, nursing services, and residents' quality of life.²³ According to the 2015 Nursing Home Data Compendium published by CMS, only 10.2% of facilities received deficiency-free surveys in 2014,²⁴ meaning that these facilities were noted to be in compliance with all of the federal requirements.

The Federal Government retains responsibility for certifying nursing facilities. CMS is responsible for developing regulations governing any facility that participates in Medicare and/or Medicaid.²⁵ In order to assess compliance with the ROP, facilities are subject to survey inspections.²⁶ The respective state agencies are responsible for nursing home recertification surveys and management of the compliance surveys.²⁷ The respective states' departments of health are responsible for inspecting facilities to monitor compliance with the ROP.²⁸ When an area of non-compliance is identified, the respective state agency issues an F-tag.²⁹ Until 2016, during state agencies' facility inspections nursing homes were at risk of receiving 150 different F-tags.³⁰ The 2016 regulatory revisions included over 200 potential citations with plans to roll-out the changes in three phases for implementation, respectively, in 2016, 2017 and 2019.³¹ As previously stated, the nursing home industry is one of the most regulated sectors in all of healthcare.³² Karl Steinberg notes, "...the nursing home industry is either the most highly regulated industry in the country, or second only to the nuclear energy industry."³³

Despite the changes that CMS made to the ROP, in August 2017 the OIG issued a memorandum to the CMS Administrator, Seema Verma, citing concerns that CMS had *inadequate procedures* to ensure incidents of potential abuse or neglect were identified and reported.³⁴ Further, the United States Government Accounting Office (GAO) gave testimony in September of 2018 which indicated that CMS had failed to properly monitor how the modifications to government oversight of nursing homes was going to affect nursing home quality of care.³⁵ An earlier GAO report to Congress, highlighted the fact that surveys were "understating" serious care problems.³⁶ With all of the negative findings related to CMS' oversight of nursing homes, CMS

²³ [supra note 8.](#)

²⁴ 2015 Nursing Home Data Compendium; Centers for Medicare and Medicaid Services; (2015); available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/nursinghomedatacompendium_508-2015.pdf

²⁵ 42 CFR Part 488; Survey, Certification and Enforcement Procedures; Available at: <https://www.govinfo.gov/content/pkg/CFR-2018-title42-vol5/pdf/CFR-2018-title42-vol5-sec488-305.pdf>

²⁶ *Id.*

²⁷ *supra* note 24.

²⁸ *supra* note 24.

²⁹ Walshe, K. (2001). Regulating U.S. nursing homes: Are we learning from experience? *Health Affairs*, 20(6), 128-44. (pg. 130)

³⁰ [supra note 9.](#)

³¹ [supra note 17.](#)

³² Kapp, M., (2000) Quality of Care and Quality of Life In Nursing Facilities: What's Regulation Got to do with It?; *McGeorge Law Review* 31, no. 3; 707-731

³³ Steinberg, Karl; *Easing Regulations May Do More Good Than Harm*; *Caring for the Ages*, Volume 19, Issue 2, 2 (February 2018)

³⁴ [Office of Inspector General Letter to Centers for Medicare and Medicaid Re: Inadequate Procedures for Identifying and Reporting Abuse in Skilled Nursing Facilities; August 24, 2017](#)

³⁵ [supra note 18.](#)

³⁶ GAO Report to Congressional Requesters; *Nursing Homes: Federal Monitoring Surveys Demonstrate Continued Understatement of Serious Care Problems and CMS Oversight Weakness*; May 2008

made revisions to the interpretive guidelines and rolled out a Final Rule with "more of the same" in 2016.^{37,38}

Most stakeholders will agree that, in some respects, nursing home regulations are necessary.³⁹ CMS regulatory methods for improving quality include: setting and enforcing standards, promoting collaborations and providing information to consumers.⁴⁰ However, the requirements are minimum standards that are not designed to incentivize providers to go beyond the "minimum."⁴¹ The detailed rules offer little incentive for exceeding the minimum standards, thus having the effect to "stifle innovation."⁴² In fact, the burden of these regulations may even divert attention away from patient care in some respects because facility staff are engaged in compliance related activities that do not result in direct patient care.⁴³

b. Quality of Care

Nursing home quality is an ongoing concern for consumers and regulators.⁴⁴ "Quality of care" is not explicitly defined within the ROP. This said, in the 2016 Final Rule, quality of care is noted to be "...a fundamental principle that applies to all treatment and care provided to facility residents."⁴⁵ The regulations go on to say "...the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices..."⁴⁶ In 1990 a report from the Institute of Medicine defined quality of care as "...the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." ⁴⁷

To empower consumers, CMS implemented the Nursing Home Compare (NHC) website in 2001.⁴⁸ NHC is not part of the ROP, but it is a way for consumers to evaluate nursing home quality. This website rates nursing homes on a scale of 5-stars with individual star ratings in categories of health inspections, quality measures, staffing and fire safety inspections.⁴⁹ Consumers can search for individual facilities and see how they compare to competitor facilities. There are 15 quality indicators for short-stay residents and 16 indicators for long-stay residents.⁵⁰ These indicators include: percentage of residents with pressure ulcers, percentage of residents

³⁷ [supra note 8.](#)

³⁸ [supra note 16.](#)

³⁹ *supra* note 16.

⁴⁰ Nedza, S. (2005). Driving Improvement in Long-Term Care. *Journal of Legal Medicine*, 26(1), 61-68. (pg. 64-66)

⁴¹ *supra* note 16.

⁴² Wiener, J. (2003). An assessment of strategies for improving quality of care in nursing homes. *The Gerontologist*,

43 Spec No 2, 19-27. (pg. 20)

⁴³ *supra* note 32.

⁴⁴ *supra* note 10, at pg. 442.

⁴⁵ [supra note 8, at pg. 68860.](#)

⁴⁶ [supra note 8, at pg. 68860](#)

⁴⁷ Institute of Medicine (1990) Medicare: A Strategy for Quality Assurance; accessed via National Academy Press and National Academy of Sciences; available at: <https://www.napg.edu/catalog/1547/medicare-a-strategy-for-quality-assurance-volume-i> (pg. 4)

⁴⁸ www.Medicare.gov/nursinghomecompare/

⁴⁹ *Id.*

⁵⁰ *supra* note 47.

who are restrained, percentage of residents with urinary tract infections as well as what percentage of residents received a flu or pneumonia vaccine.⁵¹ The system can be somewhat unreliable, however, because the facilities self-report the quality indicator information via Minimum Data Set (MDS) submissions.⁵² Furthermore, a 2016 study showed that consumers had a degree of mistrust of the information being provided on the Nursing Home Compare Website.⁵³ Another study in 2003 concluded that the data was "unstable" in respect to quarterly data analysis and recommended that the process be improved by averaging measures over a longer period of time.⁵⁴ Another study, by Brauner, et al., showed that NHC is ineffective at assessing nursing facility safety measures.⁵⁵ In a recent Health Affairs article, CMS' Kate Goodrich responded to the Brauner study. She stated that CMS agreed that NHC only "captures a subset of harm" and that CMS is considering additional measures to offer insight into other safety measures.⁵⁶ Nursing Home Compare has the potential to impact facility revenue based on market competition; therefore, it is thought that facilities with good "star ratings" are motivated to maintain those ratings.

III. BURDENS OF COMPLIANCE

a. Financial Burden

The financial impact of nursing facility regulations has not been widely researched.^{57,58} One study, by Mukamel, et al., sought to evaluate the costs associated with regulatory stringency in nursing facilities.⁵⁹ This study found a positive correlation between increased stringency and associated facility costs.⁶⁰ That is, the stricter the regulations are, the more expensive the costs are for the facility.

A facility also incurs additional costs when new regulations are issued requiring additional areas of compliance, as was true with the 2016 Final Rule issued by CMS.⁶¹ When CMS issued the Final Rule for these regulatory changes, they estimated that the overall cost of these changes would be \$831 million in the first year and \$736 million in the subsequent years.⁶² Their estimates average to \$62,900 per facility in the first year of implementation and \$55,000 per facility for

⁵¹ *supra* note 47.

⁵² Mukamel, D., & Spector, W. (2003). Quality report cards and nursing home quality. *Gerontologist*, 43, 58-66.

⁵³ Konetzka, R., & Perrailon, M. (2016). Use Of Nursing Home Compare Website Appears Limited By Lack Of Awareness And Initial Mistrust Of The Data. *Health Affairs (Project Hope)*, 35(4), 706-13.

⁵⁴ Vincent Mor, Katherine Berg, Joseph Angelelli, David Gifford, John Morris, Terry Moore; The Quality of Quality Measurement in U.S. Nursing Homes, *The Gerontologist*, Volume 43, Issue suppl_2, 1 April 2003, Pages 37-46, https://doi.org/10.1093/geront/43.suppl_2.37 (pg. 37)

⁵⁵ Brauner, D., Werner, R., Shippee, T., Cursio, J., Sharma, H., & Konetzka, R. (2018). Does Nursing Home Compare Reflect Patient Safety In Nursing Homes? *Health Affairs (Project Hope)*, 37(11), 1770-1778.

⁵⁶ The Urgent Work of Patient Safety Improvement in Nursing Homes: CMS Responds to Brauner and Colleagues; (2019), available at: <https://www.healthaffairs.org/doi/10.1377/hblog20190125.451315/full/>

⁵⁷ Mukamel, D., Li, Y., Harrington, C., Spector, W., Weimer, D., & Bailey, L. (2011). Does state regulation of quality impose costs on nursing homes? *Medical Care*, 49(6), 529-34. (pg. 529)

⁵⁸ Bowblis, J. (2015). The cost of regulation: More stringent staff regulations and nursing home financial performance. *Journal of Regulatory Economics*, 47(3), 325-338. (pg. 325)

⁵⁹ *supra* note 56, at pg. 532.

⁶⁰ *supra* note 56, at pg. 532.

⁶¹ *supra* note 28, at pg. 132.

⁶² *supra* note 12, at pg.68690.

subsequent years.⁶³ The troubling reality of these increased costs is that the consequences are usually suffered by the residents of the facility.⁶⁴ While less likely to be monetary, these consequences may result in decreased quality due to lower staffing levels because of budget cutbacks.⁶⁵ Thus, when increasing regulations negatively impact the profitability of nursing facilities, there may be unintended consequences which negatively impact quality of care.⁶⁶

Additionally, the current regulatory system for nursing facilities involves both state and federal requirements.⁶⁷ Facilities must manage compliance with state requirements in addition to the extensive requirements laid out by the Federal Government. The result is a somewhat fragmented regulatory system which increases the complexity of implementation and enforcement.⁶⁸ This dual system also increases the cost of regulatory enforcement.⁶⁹

b. Time Burden

The State Operations Manual (SOM) has over 700-pages of interpretive guidelines. Karl Steinberg, a nursing facility medical director notes, "The sheer number of regulations and the culture in our facilities create a tendency to be hypercompliant with these regulations—sometimes at the expense of common sense, or worse yet, good patient care."⁷⁰ John and Valerie Braithwaite, Australian professors who conducted a study of nursing home regulations in the United States, note that due to the volume of regulations, some are simply *forgotten*.⁷¹ This tendency is not just an affectation of nursing home staff; during the study, they noted that a Midwest surveyor reported only using 10% of citations repeatedly due to being in the "habit" of citing the same ones over and over.⁷² In addition, facilities may be spending time focusing on compliance with regulations which the surveyors may not be in the "habit" of citing, thus contributing further to the time burden of the current regulations.

The burden of all of the nursing facility regulatory requirements has the potential to distract staff attention away from patient care. Another researcher comments on this detrimental possibility in saying, "those with the most training are often forced to preoccupy themselves with administrative responsibilities..." which takes away from "staff supervision, staff education and direct patient care activities."⁷³ The time-related burden of the regulations actually has the potential to detract from quality because staff are engaged in regulatory requirements that do not result in direct patient care activities.⁷⁴

⁶³ *supra* note 12, at pg. 68690.

⁶⁴ Kapp, Marshall B. (2000). Quality of care and quality of life in nursing facilities: What's regulation got to do with it? *McGeorge Law Review*, 31(3), 707-731 (pg. 716)

⁶⁵ *Id.* at pg. 716.

⁶⁶ *supra* note 57, at pg. 337.

⁶⁷ *supra* note 28, at pg. 136.

⁶⁸ *supra* note 28, at pg. 136.

⁶⁹ *supra* note 28, at pg. 136.

⁷⁰ *supra* note 32.

⁷¹ Braithwaite, John, & Braithwaite, Valerie. (1995). The Politics of Legalism : Rules Versus Standards in Nursing-Home Regulation. *Social & Legal Studies*, 4(3), 307-341. (pg. 320)

⁷² *Id.* at pg. 320.

⁷³ *supra* note 31, at pg. 720.

⁷⁴ Mor, V. (2011). Cost of nursing home regulation: Building a research agenda. *Medical Care*, 49(6), 535-7. (pg. 535)

One regulatory change made in the 2016 Final Rule was the "facility-wide assessment" requirement.⁷⁵ The regulation states, "A facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually."⁷⁶ In theory, this requirement sounds like a good idea; however, in the practical sense, this is a very detailed process that requires hours of labor on the part of the facility administrator. The initial facility-wide assessment is especially time-consuming, and the day-to-day revision of this plan based on the ever-changing needs of the resident population is burdensome. This new requirement is duplicative of other existing requirements like the Quality Assurance and Performance Improvement (QAPI), emergency preparedness and compliance requirements.⁷⁷

One of the risks with a regulation like the facility-wide assessment is that the facility will become "paper-compliant," rather than compliant in practice. That is, the facility *will go through the motions of completing the facility-wide assessment*, while missing the main objective of the regulation, which is to ensure that the facility has adequate resources to provide care. In discussing this type of regulatory phenomenon, Marshall B. Kapp wrote, "a major problem with these statutory commands (as with many other legal mandates) is the likelihood that they will inspire providers to comply far more faithfully with their letter than with their spirit, resulting in a triumph of documentation for its own sake..." rather than the intended purpose of the requirements.⁷⁸

In response to the 2016 Final Rule, various stakeholders sent feedback to CMS regarding the anticipated burden of some of the new regulations.⁷⁹ CMS identified three themes as potentially burdensome for facility staff.⁸⁰ CMS issued statements indicating that further evaluation of the requirements would be completed including evaluation of the grievance process, QAPI changes and discharge notice requirements.⁸¹ Essentially, before these requirements were even in full-effect, CMS had received enough feedback to make regulators second-guess the requirements.

One of these areas of concern was the "notice of discharge" requirement, which requires facilities to send a notice of discharge to the State Ombudsman prior to each discharge or transfer.⁸² This creates an unnecessary burden for facilities to ensure that the Ombudsman is notified with every transfer and discharge. Furthermore, it creates excess activity in the Ombudsman office with an "overload of information" which might distract from legitimate cases of involuntary discharges.⁸³ In response to stakeholder feedback, CMS agreed that the Ombudsman notification

⁷⁵ 42 CFR § 483.70(e)

⁷⁶ 42 CFR § 483.70(e)

⁷⁷ LeadingAge Calls for Delay, Revision of Nursing Home Requirements of Participation; (2017); available at: <https://leadingage.org/regulation/leadingage-calls-delay-revision-nursing-home-requirements-participation>

⁷⁸ Marshall B. Kapp, Medical Decisionmaking for Older Adults in Institutional Settings: Is Beneficence Dead in an Age of Risk Management, 11 Issues L. & Med. 29(1995) (pg.8)

⁷⁹ Federal Register; Volume 82; No. 85 (May 4, 2017); "Possible Burden Reduction in the Long-Term Care Requirements; available at: <https://www.govinfo.gov/content/pkg/FR-2017-05-04/pdf/2017-08521.pdf> (pg. 21088)

⁸⁰*Id.* at pg. 21088.

⁸¹ *supra* note 79, at pg. 21088.

⁸² 42 CFR § 483.15(c)(3)(i)

⁸³ *supra* note 77.

requirement needed to be reevaluated to ensure it was achieving the intended purpose of reducing inappropriate and/or involuntary discharges.⁸⁴ CMS also acknowledged that respective Ombudsman offices may lack the capacity to handle all of the discharge notices.⁸⁵

Another theme in stakeholder feedback addressed the changes made to the Quality Assurance and Performance Improvement (QAPI) requirements. While there was already a QAPI requirement in place, the 2016 Final Rule expanded upon this to include additional QAPI requirements. One of those QAPI changes was to require that facilities produce QAPI documentation to surveyors for review during annual recertification surveys.⁸⁶ Stakeholders reported that the requirement was too prescriptive and lacked flexibility.⁸⁷ In response, CMS committed to reevaluating the requirement to possibly make revisions which would increase the flexibility of the requirement, thereby enabling facilities to tailor the requirement to the specific needs of the individual facility.⁸⁸

The third area which raised concerns with stakeholders was related to the grievance process.⁸⁹ The new requirement mandates that the existing grievance process be expanded by requiring the appointment of a grievance officer to oversee the process.⁹⁰ This prompted concerns from stakeholders about additional costs involved in employing a grievance officer.⁹¹ Stakeholders also voiced concerns over a new mandate which requires facilities to maintain records of grievances for three years.⁹² CMS responded by indicating that they are considering ways to reduce the associated burden with this regulation to ensure that facilities have greater flexibility in how they manage the grievance process.⁹³

IV. BURDENS OF ENFORCEMENT

a. Survey Process

As indicated previously, CMS has tasked the respective state surveyors with enforcing the ROP's.⁹⁴ The culture between facility operators and state surveyors has been plagued with anxiety and distrust because of the perceived punitive nature of surveyors' visits to facilities.⁹⁵ The facility staff live in fear of regulatory reprisal by the surveyors, who can greatly influence every aspect of nursing facility care.⁹⁶ In her 2005 article, *The American Geri-Wars*, Dr. Rebecca Elon (a former facility medical director) tells the story of a nursing facility administrator who suffered through increased regulatory oversight of a nursing facility that was in the process of decertification in

⁸⁴ *supra* note 79, at pg. 21088.

⁸⁵ *supra* note 79, at pg. 21088.

⁸⁶ *supra* note 12, at pg. 68867.

⁸⁷ *supra* note 79, at pg. 21088.

⁸⁸ *supra* note 79, at pg. 21088.

⁸⁹ *supra* note 79, at pg. 21088.

⁹⁰ *supra* note 79, at pg. 21088.

⁹¹ *supra* note 79, at pg. 21088.

⁹² *supra* note 79, at pg. 21088.

⁹³ *supra* note 79, at pg. 21088.

⁹⁴ *supra* note 24.

⁹⁵ Kapp, M. (2003). Resident Safety and Medical Errors in Nursing Homes. *Journal of Legal Medicine*, 24(1), 51-76. (pg. 61)

⁹⁶ Elon, R. (2005). The American Geri-Wars. *Journal of Legal Medicine*, 26(1), 69-83. (pg. 76)

Maryland in 1999.⁹⁷ The administrator had also served as a flight nurse during a period of active war in Iraq in 2003.⁹⁸ Dr. Elon notes, "She (the administrator) bears witness to the fact that living through the period of facility decertification in Maryland in 1999 was more stressful than her active duty during war."⁹⁹ While this is the opinion of only one facility administrator, who was subject to a heightened degree of regulatory scrutiny due to facility decertification, this experience speaks to the oppressive culture that can exist among facility staff and State surveyors.

One study sought to evaluate nursing home administrators' (NHA) job satisfaction in the context of the survey process.¹⁰⁰ The study surveyed 135 facility administrators, with a 41% response rate, and found that 64% of administrators viewed the survey process as negative.¹⁰¹ It also found that only 38% of respondents perceived the survey process as a good indicator of quality.¹⁰² Another concerning result was that only 8% of administrators reported that the survey process was fair and consistent.¹⁰³ Twenty-three percent of these respondents also reported that the survey process caused them to consider leaving their current positions.¹⁰⁴

The potential for staff turnover due to the adversarial and oppressive nature of regulatory enforcement needs to be considered when, in the present era, regulators are implementing "more of the same." One study by Nicholas Castle sought to evaluate the impact of nursing home administrator turnover on the quality of care in nursing facilities.¹⁰⁵ He found that quality measures were negatively impacted by administrator turnover and recommended that further research be done in this area.¹⁰⁶ That is, the higher the turnover rate, the more the patients suffered from adverse clinical outcomes.¹⁰⁷

b. Financial Impact of Non-Compliance

When a facility is non-compliant with a regulation, CMS has authority to impose various penalties.¹⁰⁸ These penalties can include: installing temporary management, denial of payment for all residents, denial of payment for new residents, civil money penalties, state monitoring, transfer of residents, closure of the facility, directed plan of correction, directed in-service training or alternative state remedies approved by CMS.¹⁰⁹ If a facility is subject to denial of payment, the resources available to provide adequate care to the residents will quite likely be limited in the absence of emergency financial reserves. This can also be true when a facility is subject to civil money penalties. The apparent logic is that facilities will remain compliant with regulations to

⁹⁷ *Id.* at pg. 77.

⁹⁸ *supra* note 96, at pg. 76.

⁹⁹ *supra* note 96, at pg. 76.

¹⁰⁰ Holecek, T., Dellmann-Jenkins, M., & Curry, D. (2010). Exploring the Influence of the Regulatory Survey Process on Nursing Home Administrator Job Satisfaction and Job Seeking. *Journal of Applied Gerontology*, 29(2), 215-230.

¹⁰¹ *Id.* at pg. 224.

¹⁰² *supra* note 100, at pg. 224.

¹⁰³ *supra* note 100, at pg. 224.

¹⁰⁴ *supra* note 100, at pg. 223.

¹⁰⁵ Castle, N. (2001). Administrator turnover and quality of care in nursing homes. *The Gerontologist*, 41(6), 757-67.

¹⁰⁶ *Id.* at pg. 757.

¹⁰⁷ *supra* note 105, at pg. 757.

¹⁰⁸ 42 CFR § 488.406

¹⁰⁹ 42 CFR § 488.406

avoid being subject to financial penalties. However, in the long run these penalties may just produce additional areas of quality concerns due to decreased financial resources. Civil Money Penalty (CMP) amounts can range from \$50 to \$20,628 per day depending on the nature and degree of non-compliance identified.¹¹⁰ A 2006 study by Harrington, et al. revealed that over \$21,000,000 in CMPs had been collected from nursing facilities across the United States in 2004.¹¹¹ These CMPs were issued for 2% of the overall citations.¹¹²

V. BURDENS OF QUALITY

a. Regulations and Quality of Care

The question as to whether nursing facility regulations have been successful in improving quality of care remains somewhat uncertain due to the lack of available research.¹¹³ In fact, one author describes the available research as "relatively sparse."¹¹⁴ A study published by the Institute of Medicine in 2001 indicated that the issue of quality of care in nursing homes continues to be "problematic" despite regulatory "improvements."¹¹⁵ In another report the GAO noted that facility surveys used to monitor nursing home quality were "limited in their scope and effectiveness."¹¹⁶ The same study showed that 1 out of every 4 nursing homes had deficiencies that caused actual harm or potential for harm or death.¹¹⁷ Tragically, 40% of those same facilities had repeated deficiencies which indicated that the initial citation was not sufficient in correcting the deficient practice.¹¹⁸ A February 2019 OIG report highlighted failures on the part of state agencies in following-up on facility citations once issued.¹¹⁹ This OIG study found that several state agencies (7 of the 9 sampled) failed to verify that deficiencies were corrected in respect to nearly half of the sampled deficiencies.¹²⁰ The report further stated that the safety and health of nursing facility residents could be placed at risk due to this lack of follow-up.¹²¹

¹¹⁰ Federal Register; Volume 81; No 172 (2016); available at: <https://www.federalregister.gov/documents/2016/09/06/2016-18680/adjustment-of-civil-monetary-penalties-for-inflation>

¹¹¹ Theodore Tsoukalas, Cynthia Rudder, Richard J. Mollot, Meghan Shineman, Hyang Yuol Lee, Charlene Harrington; The Collection and Use of Funds From Civil Money Penalties and Fines From Nursing Homes, *The Gerontologist*, Volume 46, Issue 6, 1 December 2006, Pages 759–771, (pg. 763)

¹¹² Charlene Harrington, Theodore Tsoukalas, Cynthia Rudder, Richard J. Mollot, Helen Carrillo; Variation in the Use of Federal and State Civil Money Penalties for Nursing Homes, *The Gerontologist*, Volume 48, Issue 5, 1 October 2008, Pages 679–691, <https://doi.org/10.1093/geront/48.5.679> (pg. 679)

¹¹³ Hilliard, J. (2005). The Nursing Home Quality Initiative. *Journal of Legal Medicine*, 26(1), 41-60. (pg. 43)

¹¹⁴ *supra* note 31, at pg. 708

¹¹⁵ Institute of Medicine (2001) Improving the Quality of Long-Term Care; accessed via National Academy Press and National Academy of Sciences; available at: <https://www.napg.edu/read/9611/chapter/1> (pg. 1)

¹¹⁶ GAO Report to Congressional Requesters; Nursing Homes: Sustained Efforts are Essential to Realize Potential of the Quality Initiatives; September 2000 (pg. 5)

¹¹⁷ *supra* note 115, at pg. 77.

¹¹⁸ *supra* note 115, at pg. 77.

¹¹⁹ Office of Inspector General (February 2019); CMS Guidance to State Survey Agencies on Verifying Correction of Deficiencies Needs to be Improved to Help Ensure the Health and Safety of Nursing Home Residents; available at: <https://oig.hhs.gov/oas/reports/region9/91802000.pdf> (pg. 4)

¹²⁰ *Id.* at pg. 4.

¹²¹ *supra* note 119, at pg. 4.

CMS has answered these multiple reports with "more of the same"—more regulations—even though they have proven ineffective at accomplishing the main objective: improving quality of care. Those who are critical of the current regulatory landscape argue that the regulations do not measure what is most important and that those who enforce the regulations are not consistently applying them.¹²² One survey of long-term care specialists (persons with demonstrable experience in at least one aspect of long-term care) found that only 15% of respondents believed that the Federal Government was doing *well or very well* in their enforcement of quality standards for nursing facilities.¹²³ This same survey showed that only 6.1% of respondents believed the Federal Government was consistent in its application of the regulations.¹²⁴ In fact, regulations have been noted to be inconsistently applied from one state to another due to the subjectivity employed by surveyors in their interpretation of the regulations.¹²⁵

Another concern with increased regulations is a concept referred to as *offsetting behavior* which is discussed in a 2012 article.¹²⁶ When regulators are more focused on one particular area of care, the facility personnel change their focus to align with regulators.¹²⁷ This leads to decreased attention on other care areas which results in the "opposite effect on quality in other dimensions."¹²⁸ When a nursing facility is tasked with managing compliance in 200 different areas, there is an obvious increased risk for offsetting behavior. Beyond the offsetting behavior, there are resource constraints which may prevent operators for devoting enough resources to each area of compliance.¹²⁹ While regulations may be effective at improving quality in certain targeted care areas, there is a risk of deteriorating quality in untargeted areas.¹³⁰ In his book, *The Rule of Nobody: Saving America from Dead Laws and Broken Government*, Phillip K. Howard discussed the effect that compliance in many different areas can have on an individual.¹³¹ He noted the cognitive limits of humans in writing: "if required to focus on complying with numerous rules, they cannot at the same time think about the regulatory goal."¹³²

Studies about the impact of regulations on quality of care are limited because of the lack of a control group, as most nursing homes are the subject of regulations.¹³³ An article published in 2001 titled "Regulating U.S. Nursing Homes: Are We Learning from Experience?" by Kieran Walshe, notes opposing views on the issue of regulatory oversight.¹³⁴ On one hand, since nursing home quality is such an obvious issue, the nursing home industry needs tougher standards.¹³⁵ On

¹²² *supra* note 41, at pg. 20.

¹²³ Miller, E., Mor, V., & Clark, M. (2010). Reforming long-term care in the United States: Findings from a national survey of specialists. *The Gerontologist*, 50(2), 238-52.

¹²⁴ *Id.*

¹²⁵ Miller, E., & Mor, V. (2008). Balancing Regulatory Controls and Incentives: Toward Smarter and More Transparent Oversight in Long-Term Care. *Journal of Health Politics, Policy and Law*, 33(2), 249-280. (pg. 253)

¹²⁶ *supra* note 5, at pg. 53.

¹²⁷ *supra* note 5, at pg. 70.

¹²⁸ *supra* note 5, at pg. 53.

¹²⁹ *supra* note 5, at pg. 53.

¹³⁰ *supra* note 5, at pg. 70.

¹³¹ Howard, Phillip K. (2014). *The Rule of Nobody: Saving America from Dead Laws and Broken Government*. W.W. Norton New York (pg. 39)

¹³² *Id.* at pg. 39.

¹³³ *supra* note 28, at pg. 131.

¹³⁴ *supra* note 28, at pg. 132.

¹³⁵ *supra* note 28, at pg. 132.

the other, the current regulatory landscape is so burdensome that regulators have created an "adversarial" climate that impedes quality improvement.¹³⁶ The climate is one of "command and control."¹³⁷ The current model is one of policing rather than empowering.¹³⁸ Thus, continuing to address substandard quality with more policing (more of the same) is unlikely to effectuate substantial change in the industry.

b. Nursing Home Negligence Lawsuits

If nursing home regulations were working, one would expect negligence and related lawsuits to be decreasing. Instead, in response to poor nursing home quality, negligence-related lawsuits have been increasing.¹³⁹ Negligence litigation has become an attempt to correct substandard nursing facility care.¹⁴⁰ In the process of litigation, a facility's adherences to and/or departures from minimum standards of care are used to establish a proximate cause related to the alleged injuries suffered by the resident.¹⁴¹ A 2004 article written by Pat Iyer, a legal nurse consultant, indicated that nursing home litigation was one of the "fastest growing areas of medical malpractice."¹⁴² In a more recent article, from 2014, Muqet, et al. write, "Nursing home neglect/abuse is growing fast, and so is related litigation."¹⁴³ A 2003 survey of 464 attorneys was conducted with a response rate of 60% (278 attorneys) and found that those attorneys were personally involved in 4,677 nursing home negligence claims filed in 2001.¹⁴⁴ Those attorneys' firms reported having handled 8,256 nursing home negligence claims during that same year.¹⁴⁵ Although the exact reason for the increase in nursing home negligence litigation is not known, the authors speculate that the increase is due, in part, to "unacceptable care in nursing homes and potential failures of regulatory oversight."¹⁴⁶ The most commonly alleged injuries in nursing home negligence cases include pressure ulcers, falls, dehydration or weight loss.¹⁴⁷ Interestingly, there are regulations in place for all four of these care areas; yet, the rate of lawsuits related to these types of injuries is growing.¹⁴⁸ The 2017 AON Long Term Care Actuarial Analysis report notes increasing liability costs for long term care profession.¹⁴⁹ In Kentucky, for example, the cost to defend and settle nursing home liability suits was \$1,480 per bed in 2007; ten-years later, this

¹³⁶ *supra* note 28, at pg. 132.

¹³⁷ *supra* note 113, at pg. 41.

¹³⁸ *supra* note 19, at pg. 6.

¹³⁹ Peterson, A. (2002). Overview of the nursing home litigation process. *Geriatric Nursing*, 23(1), 37-42. (pg. 1)

¹⁴⁰ *supra* note 19, at pg. 3.

¹⁴¹ *supra* note 139, at pg. 2.

¹⁴² Iyer, PG. (2004). Liability in the Care of the Elderly. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, 33(1), 124-131. (pg. 124)

¹⁴³ Adnan, Mohammed Muqet, Adnan, Huma, Amer, Syed, & Bhutta, Usman. (2014). Nursing home litigation: A vicious cycle. *The Journal of Family Practice*, 63(9), 493.

¹⁴⁴ *supra* note 13, at pg. 219.

¹⁴⁵ *supra* note 13, at pg. 219.

¹⁴⁶ *supra* note 13, at pg. 225.

¹⁴⁷ *supra* note 139, at pg. 1.

¹⁴⁸ *supra* note 6.

¹⁴⁹ AON Long Term Care Actuarial Benchmark Report; 2017 Long Term Care General Liability and Professional Liability Actuarial Analysis; available at: <https://www.aon.com/risk-services/thought-leadership/report-2017-long-term-care.jsp>

number grew more than four times.¹⁵⁰ This shows that quality of care regulations are not working to substantially prevent nursing home negligence.¹⁵¹

The fact remains that facility surveys do not promote enough quality to discourage negligence-related lawsuits.¹⁵² In fact, one study showed that regulatory compliance does not substantially reduce a facility's risk of lawsuit.¹⁵³

When patients and families receive poor care from nursing facilities, they sometimes resort to lawsuits to recover damages. In fact, since the implementation of the public sector regulatory system, nursing home negligence lawsuits have been on the rise.¹⁵⁴ While some believe that lawsuits promote nursing home quality, others believe that lawsuits divert resources in the defense of the nursing facility, thus diverting resources from resident care.¹⁵⁵ Therefore, it is believed that lawsuits can be counterproductive in promoting improved quality.¹⁵⁶

Another study, by Konetzka, et al., sought to evaluate the effectiveness of lawsuits in deterring facilities from the deficient practices that led to the lawsuit.¹⁵⁷ This study found that the deterrence effect was low and "unlikely to lead to widespread improvement in quality."¹⁵⁸ All the more concerning, another study found that good survey outcomes did not significantly reduce a facility's rate of lawsuits.¹⁵⁹ It was noted that those facilities who received the least amount of citations during State inspections were subject to lawsuits only "marginally" less frequently than the worse performing facilities.¹⁶⁰

Stevenson, et al. conducted a study to evaluate whether nursing home litigation increases or decreases quality of care.¹⁶¹ The study looked at 6,471 negligence claims which were filed against 1,514 nursing facilities between 1998 and 2010.¹⁶² They found that higher litigation costs were associated with a decrease in care quality.¹⁶³

¹⁵⁰ Flynn, Maggie; (2018) Nursing Home Operators Face Uphill Battle Against Lawsuits in Kentucky; Skilled Nursing News; available at: <https://skillednursingnews.com/2018/03/nursing-home-providers-face-uphill-battle-lawsuits-kentucky/>

¹⁵¹ *supra* note 41, at pg. 19.

¹⁵² Troyer, J., & Thompson, H. (2004). The Impact of Litigation on Nursing Home Quality. *Journal of Health Politics, Policy and Law*, 29(1), 11-42. (pg. 37)

¹⁵³ Studdert, D., Spittal, M., Mello, M., O'Malley, A., & Stevenson, D. (2011). Relationship between Quality of Care and Negligence Litigation in Nursing Homes. *The New England Journal of Medicine*, 364(13), 1243-1250.

¹⁵⁴ *supra* note 153, at pg. 12.

¹⁵⁵ *supra* note 13, at pg. 219.

¹⁵⁶ *supra* note 153, at pg. 12.

¹⁵⁷ Konetzka, R., Park, J., Ellis, R., & Abbo, E. (2013). Malpractice Litigation and Nursing Home Quality of Care. *Health Services Research*, 48(6pt1), 1920-1938. (pg. 1920)

¹⁵⁸ *Id.* at pg. 1936.

¹⁵⁹ *supra* note 154, at pg. 1243.

¹⁶⁰ *supra* note 154, at pg. 1243.

¹⁶¹ Stevenson, D., Spittal, M., & Studdert, D. (2013). Does litigation increase or decrease health care quality?: A national study of negligence claims against nursing homes. *Medical Care*, 51(5), 430-6.

¹⁶² *Id.* at pg. 430.

¹⁶³ *supra* note 162, at pg. 434.

VI. DISCUSSION

Nursing facility operators and their direct-care staff function under a multitude of regulatory forces and consequently, suffer from multiple burdens associated with regulatory compliance. Associated costs of maintaining compliance include employment of individuals tasked with compliance-related activities as well as the costs associated with regulatory mandated programs.¹⁶⁴ Dollars spent in the pursuit of regulatory compliance are diverted from staff wages and labor budgets and ultimately have the potential to negatively impact patient care. While the intention of the 2016 Final Rule was "to improve the quality of care and quality of life for residents of long-term care facilities,"¹⁶⁵ the financial impact of these regulatory changes can produce unintended consequences which negatively impact quality of care.¹⁶⁶

Another consequence of regulatory compliance is the amount of time spent by staff engaged in compliance-related activities that do not impact direct patient care. These activities include obligations to notify the local Ombudsman for each transfer and discharge and requirements to perpetually revise the facility-wide assessment. The interpretive guidelines (SOM) are voluminous and make it difficult for facilities to pay proper attention to all of these regulatory expectations at the same time.¹⁶⁷ The regulatory changes, though well-intended, could actually be having a negative impact on quality by detracting attention away from direct patient care activities.¹⁶⁸

The survey process itself is burdensome and stressful to facility operators and direct-care staff.¹⁶⁹ Some will argue that the survey should not be a burden if the facility is engaged in regulatory compliance year-round with a "business as usual" mentality during survey proceedings. However, surveyors have become known for entering facilities with the intention of finding every mistake a facility has made in the months since the prior survey. Facility staff live in fear of these punitive responses from surveyors.¹⁷⁰ This stress, in and of itself, can negatively impact quality because of the distraction that the survey itself produces. The relationship between surveyors and facility staff is strained, even pushing facility administrators into resignation due to the stress of the enforcement process and relationship burden. Losing facility administrators after a "bad survey" is not an uncommon theme in the industry.¹⁷¹ This leads to the logical finding that turnover in the administrator position has been linked to decreased quality outcomes for patients.¹⁷²

Depending on the severity of non-compliance, there is a risk of financial penalties as well,¹⁷³ hence raising the potential that funds will be diverted from direct patient care activities in the payment of CMP's or denial of payment for new admissions.¹⁷⁴ Any time the facility's operating

¹⁶⁴ *supra* note 56, at pg. 532.

¹⁶⁵ *supra* note 12, at pg. 5.

¹⁶⁶ *supra* note 57, at pg. 337.

¹⁶⁷ *supra* note 32.

¹⁶⁸ *supra* note 74, at pg. 535.

¹⁶⁹ *supra* note 95, at pg. 61.

¹⁷⁰ *supra* note 96, at pg. 76.

¹⁷¹ *supra* note 100, at pg. 223.

¹⁷² *supra* note 105.

¹⁷³ 42 CFR § 488.406

¹⁷⁴ *supra* note 110.

budget is subject to losses due to these penalties, there is a risk for deterioration in the caliber of patient care because of potential for labor cutbacks to offset the financial losses.¹⁷⁵

The purpose of the 2016 Final Rule came as an attempt to improve quality because prior regulations were perceived to be lacking in their ability to substantially improve quality for residents of nursing facilities. However, it is unreasonable to think that *more of the same*,¹⁷⁶ while previously ineffective in a lot of ways, will now be the sole answer to resolve quality of care issues.

VII. RECOMMENDATIONS

This section will propose recommendations to address problems with of regulatory burdens. Although multiple areas of potential burden have been identified, recommendations will be made to address three of these areas including: the financial burden, the time burden and enforcement-related burdens.

a. Financial Incentives

Further research needs to be conducted to evaluate the cost of regulatory compliance, including cost/benefit analysis of various proposals. One option for reducing the financial burden of nursing facility regulations is to offer financial incentives for improved patient outcomes.¹⁷⁷ In a national survey of long-term care providers, a majority of providers ranked financial incentives (pay-for-performance) as an effective strategy for improving the quality of care in nursing facilities.¹⁷⁸ The pay-for-performance concept has been proposed in the belief that it has the potential to produce healthier patients and improve quality of life.¹⁷⁹ With pay-for-performance, payers (in this case, CMS) offer incentives to facilities in the form of performance measures and reaching quality benchmarks.¹⁸⁰ At present, one pay-for-performance type incentive is in effect for nursing facilities which was rolled out in 2016 to incentivize facilities to reduce rehospitalization rates.¹⁸¹ Nursing facilities would experience a sense of relief related to the burden of regulations if the regulations were positively associated with financial incentives for meeting various metrics. Rather than a "command and control" type of approach¹⁸², the government could offer positive reinforcement of improved outcomes instead of focusing on negative reinforcement of negative outcomes as in the current regulatory climate.

¹⁷⁵ *supra* note 63, at pg. 716.

¹⁷⁶ [supra note 16](#).

¹⁷⁷ *supra* note 123, at pg. 248.

¹⁷⁸ *supra* note 123, at pg. 247.

¹⁷⁹ Greene, S., & Nash, D. (2009). Pay for Performance: An Overview of the Literature. *American Journal of Medical Quality*, 24(2), 140-163. (pg. 140)

¹⁸⁰ *Id.* at pg. 144.

¹⁸¹ Federal Register (2015); Final Rule: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program and Staffing Data Collection; available at: <https://www.govinfo.gov/content/pkg/FR-2015-08-04/pdf/2015-18950.pdf>

¹⁸² *supra* note 113, at pg. 41.

b. Reduction of Non-Patient Care Activities

There is a lack of research in respect to the relative time burden of regulatory requirements in nursing facilities. Further research needs to be done to evaluate the amount of time associated with individual regulations. More importantly, the regulations should be evaluated to determine which regulations have a direct impact on improving quality of care and which regulations are either of questionable benefit or actually detract from patient care. In nursing facilities, there are certain roles which are heavily oriented towards regulatory compliance. Specifically, nurse managers (i.e. directors of nursing and unit managers) are engaged in daily auditing and follow-up to ensure compliance with regulations. The nursing facility industry would benefit from further research as to how much of these individuals' days are wrapped up in compliance-related activities that may or may not directly impact patient care. While the goal of regulations is to improve the quality of care, there are some regulatory requirements for nursing facilities that result in only marginally beneficial or abjectly counterproductive time spent away from direct patient care activities. Further research should be conducted to streamline the regulatory requirements to improve the regulatory focus on activities that enhance direct-patient care interactions and, thus, improve care quality.

c. Relationship Reform

Another key aspect which would benefit from regulatory reform is the adversarial relationship that exists between regulators and operators. One way of accomplishing this relationship reform would be to modify the role of state agencies to allow surveyors to function in a consultant-type capacity.¹⁸³ This concept was discussed by Miller, et al. in a 2008 article by looking at "lessons learned" from Hurricane Katrina.¹⁸⁴ The authors evaluated the tragic account of St. Rita's Nursing Home in St. Bernard's Parish in New Orleans.¹⁸⁵ During the hurricane, 34 residents were abandoned and drowned.¹⁸⁶ The facility failed these residents in their inability to safely evacuate, but the government agencies also failed these 34 residents with their lack of intervention in the years prior to Katrina when it was clear that the facility was reducing staff while, at the same time, caring for a more acutely ill population.¹⁸⁷ The article referenced a 2003 OIG report which recommended that the state agencies remain in a "non-consultative" capacity when interacting with facilities.^{188,189} However, facilities could benefit from open dialogue from state agencies in the exchange of best practices to improve quality.¹⁹⁰ After all, the intended purpose of nursing facility regulations is to ensure quality of care; why not foster a more open relationship between operators and regulators if there is a potential for improved quality in the end?

¹⁸³ *supra* note 125, at pg. 249.

¹⁸⁴ *supra* note 125, at pg. 262.

¹⁸⁵ *supra* note 125, at pg. 262.

¹⁸⁶ *supra* note 125, at pg. 262.

¹⁸⁷ *supra* note 125; at pg. 262.

¹⁸⁸ Office of Inspector General (March 2003); Nursing Home Deficiency Trends and Survey and Certification Process Consistency; available at: <https://oig.hhs.gov/oei/reports/oei-02-01-00600.pdf> (pg. iii)

¹⁸⁹ *supra* note 125, pg. 271.

¹⁹⁰ *supra* note 125, pg. 272.

When facility staff remain focused on the consequences of non-compliance, resident care can be negatively impacted, particularly when facility policy and procedure are guided by the "letter" of the regulation rather than the "spirit."¹⁹¹ A study by Colon-Emeric, et al. sought to evaluate the regulatory effect on nursing home management's "mindfulness,"¹⁹² meaning the staff's ability to process information in an attentive manner that facilitates meaning and responsiveness in their day-to-day activities.¹⁹³ The authors sought to evaluate the effect that regulation has on mindfulness, having predicted that a high level of mindfulness would be beneficial in identifying changes in patients' health status.¹⁹⁴ This study found that regulations helped facilitate mindfulness in some respects but inhibited mindfulness in other respects.¹⁹⁵ Specifically, the authors found that mindfulness decreased when staff remained focused on the compliance and punitive aspects of regulations.¹⁹⁶ Alternatively, the study found an increase in mindfulness *when the regulations were framed in terms of the intended purpose versus the consequences of non-compliance.*¹⁹⁷

In the previously mentioned study which surveyed facility administrators' job satisfaction as it related to the survey process, 37% of respondents suggested that the survey process be more collaborative and/or educational.¹⁹⁸ The administrators offered their suggestions to open ended questions such as: "Share best practices" and "The process should be a chance to improve facilities' practices as opposed to finding what is wrong."¹⁹⁹ In his book, *The Rule of Nobody*, Phillip K. Howard suggests that regulators focus their attention on results instead of punishment.²⁰⁰ He further suggests that regulators focus their efforts on ways to help improve issues rather than only offering ways to punish those who have been unsuccessful in achieving compliance.²⁰¹ Regulations should have the ability to discriminate between poor performing facilities and those that are providing good care rather than taking a "cookie-cutter" approach which fails to adequately address the needs of facilities which are performing poorly.²⁰²

¹⁹¹ *supra* note 78, at pg.8.

¹⁹² Colón-Emeric, C. S., Plowman, D., Bailey, D., Corazzini, K., Utley-Smith, Q., Ammarell, N., Anderson, R. (2010). Regulation and Mindful Resident Care in Nursing Homes. *Qualitative Health Research*, 20(9), 1283–1294. <https://doi.org/10.1177/1049732310369337> (pg. 1284)

¹⁹³ *Id.*

¹⁹⁴ *supra* note 193, at pg. 1284.

¹⁹⁵ *supra* note 193, at pg. 1290.

¹⁹⁶ *supra* note 193, at pg. 1290.

¹⁹⁷ *supra* note 193, at pg. 1291.

¹⁹⁸ *supra* note 100, at pg. 225.

¹⁹⁹ *supra* note 100, at pg. 226.

²⁰⁰ *supra* note 131, at pg. 57.

²⁰¹ *supra* note 131, at pg. 57.

²⁰² *supra* note 28, at pg. 135.

VIII. CONCLUSION

On March 6, 2019, the Senate Finance Committee convened to discuss the current crisis of abuse and neglect in nursing facilities.²⁰³ David C. Grabowski, professor of health care policy at Harvard University, testified that the United States spends \$170 billion annually on nursing home care.²⁰⁴ He highlighted current issues with nursing facility staffing, care practices, outcomes, resident safety and quality of life.²⁰⁵ In discussing the reasons for these issues, he noted insufficient reimbursement, as well as problems with regulatory oversight, which is *extensive* but *inconsistent*.²⁰⁶ Furthermore, during her testimony at this Senate hearing, Dr. Kate Goodrich, Chief Medical Officer for CMS, admitted that *reducing provider burden* can allow operators to dedicate more resources to improving patient care.²⁰⁷ However, she also indicated that CMS has been committed to *strengthening requirements* [more of the same] for nursing homes. Now is the time for regulators to take a different approach on improving nursing home quality.

Dr. Rebecca Elon, an experienced nursing facility medical director once wrote, "What I have witnessed in nursing homes over the past 20 years leads me to believe that the current process of federal regulatory enforcement is more a part of our collective failure than a path to healing."²⁰⁸ Another expert noted that the punitive approach to regulations is "burdensome to the industry and ineffective in protecting consumers."²⁰⁹ Yes, regulations are necessary to monitor for compliance with minimum standards.²¹⁰ However, regulations, alone, are insufficient in substantially improving the quality of care.²¹¹ If history is our teacher, the 2016 Final Rule for nursing facilities is unlikely to be the answer for quality of care concerns. The industry needs regulatory reform to reduce the burden of the current regulatory "octopus."²¹² Changes should be made to enable and incentivize facility staff to spend more time at the bedside performing direct patient care activities rather than continuing to operate in an environment of fear, blame and paper-compliance.²¹³

²⁰³ Senate Finance Committee Hearing; "Not Forgotten: Protecting Americans From Abuse and Neglect in Nursing Homes;" (March 6, 2019); testimony transcripts available at: <https://www.finance.senate.gov/hearings/not-forgotten-protecting-americans-from-abuse-and-neglect-in-nursing-homes>

²⁰⁴ *Id.*

²⁰⁵ *supra* note 204.

²⁰⁶ *supra* note 204.

²⁰⁷ *supra* note 205.

²⁰⁸ *supra* note 96, at pg. 81.

²⁰⁹ Hovey, W. (2000). The Worst of Both Worlds: Nursing Home Regulation in the United States. *Review of Policy Research*, 17(4), 43-59. (pg. 43)

²¹⁰ *supra* note 16.

²¹¹ *supra* note 96, at pg. 81.

²¹² *supra* note 20, at pg. 30.

²¹³ *supra* note 96, at pg. 82.