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Failing to Care: How Effective Compliance Prevents Institutional Elder Neglect

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FAILING TO CARE: HOW EFFECTIVE COMPLIANCE PREVENTS INSTITUTIONAL ELDER NEGLECT

David R. Hoffman*

"A society's quality and durability can best be measured by the respect and care given its elder citizens."

—President John F. Kennedy[1]

INTRODUCTION

In 1963, President John F. Kennedy noted the importance of caring for our older population by measuring society's quality based on care afforded the elderly.[2] Measuring the quality of care provided to older adults residing in nursing homes, hospitals, and assisted living facilities is no easy task, but from any objective observation, America as a nation has failed miserably. Institutional elder neglect exacts an enormous toll on us individually and on our society as a whole.[3] The failure to provide necessary goods and services to frail and vulnerable populations, such as the elderly who are hospitalized or are residing in long-term care facilities, is a violation not only of regulatory requirements but also of our moral obligation to care

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1. President John F. Kennedy, Special Message to the Congress on the Needs of the Nation's Senior Citizens (Feb. 21, 1963), http://www.presidency.ucsb.edu/ws/print.php?pid=9572 (last visited Oct. 24, 2008).

2. *Id.*

3. David R. Hoffman, *The Role of the Federal Government in Ensuring Quality of Care in Long-Term Facilities*, 6 ANNALS HEALTH L. 147, 156 (1997).

for those less fortunate and most at risk for harm.[4] Yet, sadly, neglect of older adults often goes unnoticed, under-reported, and unpunished.[5] While health care providers typically do not set out to do harm, a lack of internal checks and balances on care delivery systems may lead to unintended consequences such as significant resident clinical compromise and the imposition of unspeakable harm to those who cannot protect themselves. Over the last decade, the federal government has developed criminal and civil fraud theories associated with providers' conduct that causes harm to this vulnerable population.[6] These theories have been created, in part, because there is no federal patient or resident abuse and neglect statute.[7] This article will explain some of the government's fraud theories and discuss how effective compliance can prevent institutional elder neglect and the need for government investigation and prosecution.

INSTITUTIONAL ELDER NEGLECT

What is institutional elder neglect? Neglect is defined in the federal regulations governing long-term care facilities to mean "[the] failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness."[8] While neglect is referenced elsewhere in federal law and regulation, it goes undefined in many contexts, thereby leading to legal interpretations based on the plain meaning of the word.[9] From a clinical perspective, the American Medical Association has

4. *See generally* Hoffman, *supra* note 3; Press Release, U.S. Dep't of Justice, U.S. Attorney Announces First Settlement Involving Personal Care Homes (June 10, 2008) *available at* http://www.ssa.gov/oig/communications/pressreleases/press06102008.pdf (last visited Oct. 23, 2008).

5. *See generally* Hoffman, *supra* note 3.

6. *See generally id.*

7. *See generally id.*

8. 42 C.F.R. § 488.301 (2007).

9. The Departmental Appeals Board for the Department of Health and Human Services used the definition of neglect from Webster's Third New International Dictionary, 1976 Edition, as "1: to give little or no attention or respect to . . . 2: to carelessly omit doing (something that should be done) either altogether or almost altogether . . . Thomas M. Cook, CR No. 51 (1989) (*quoting* WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1976)).

defined neglect to mean "the failure to provide the goods or services necessary for functioning or to avoid harm."[10] It is important that health care providers and government enforcement agencies be on the same page and, therefore, the need for a standardized and operational definition of neglect (in federal law) is patently obvious.[11]

Interestingly, regardless of what definition is applied, there is no intent standard associated with neglect.[12] Obviously, not every failure by facility staff to avoid harm constitutes neglect or we would see neglect cited much more frequently by state and federal surveyors in institutional settings.[13] Instead, neglectful conduct is cited under other types of violations such as quality of care or pressure ulcers or other specific deficiency tags.[14] However, we should be demanding that regulators call a facility's systemic failure to provide goods or services neglectful when the facility knew or should have known about a resident's clinical condition, failed to respond in a timely fashion (whether intentionally or not), and thereby caused harm to the resident.[15]

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10. Carmel Bitondo Dyer, Marie-Therese Connolly, & Patricia McFeeley, *The Clinical and Medical Forensics of Elder Abuse and Neglect, in* ELDER MISTREATMENT: ABUSE, NEGLECT, AND EXPLOITATION IN AN AGING AMERICA 339, 342 (Richard J. Bonnie & Robert B. Wallace eds., Nat'l Academies Press 2002).

11. This article, however, addresses institutional neglect and not the issue of self-neglect.

12. 42 C.F.R. § 488.301.

13. *See id.; see also* Dyer et al., *supra* note 10, at 342-44.

14. *See generally* Dyer et al., *supra* note 10, at 342-44.

15. *But see* Amie E. Schaadt, Note, *Applying the False Claims Act to Chemical and Physical Restraint Cases: Is the Government Going Too Far?*, 68 U. PITT. L. REV. 763 (2006-2007) (arguing that the improper use of chemical and physical restraints by a hospital should not serve as the basis for government enforcement actions). The author's argument is based on an erroneous analysis of the government's theory employed in pursuing this matter. It is the failure to comply with promises made to the government that is the basis for liability, not the improper use of restraints. The notion that the improper use of chemical and physical restraints, with its attendant potential for serious bodily injury, should not be the basis for civil prosecution under the False Claims Act is simply misguided and, from a patient safety perspective, indefensible. For way too long, physical and chemical restraints have served as an unacceptable substitute for appropriate and lawful care delivery, and this misuse has been the essence of what neglectful care is all about.

THE BASIS FOR TRUST

Imagine you are deciding on whether to facilitate a loved one's placement in an assisted living facility or a nursing home. What are your expectations regarding the quality of care that will be rendered to your loved one? Certainly, it is reasonable for potential residents to expect that the facility entrusted with providing care has policies and procedures that will ensure that neglect does not occur and that, at a minimum, these policies, procedures, and protocols address adequate supervision, staff training and competency, clinical practices based on best clinical evidence, and ownership support for all levels of those providing care.[16]

There are many institutions that are delivering care to the elderly, including hospitals, nursing homes, assisted living homes, and personal care homes. In the nursing home context, the crux of the arrangement includes skilled nursing care, medical oversight of care rendered, assessment and care planning, pharmaceutical services and proper medication administration, dietary services, social services, and rehabilitation services. Needless to say, the regulatory requirements governing the operation of nursing homes are very extensive.[17] These regulations attempt to fulfill the mandate set forth in the Nursing Home Reform Act to "provide services and activities to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident in accordance with a written plan of care . . . ."[18] Implicit in that mandate is the notion that facilities must take steps to prevent causing any harm to residents.[19] For example, pressure ulcers are for the most part preventable. The failure to prevent pressure ulcers from developing is as much a concern as the

16. *See* 42 U.S.C. § 1396r(b)(1-2) (2003).

17. 42 C.F.R. § 483.1(a-b) (2003).

18. 42 U.S.C. § 1396r(b)(2). Over twenty years have passed since this law was enacted and some still view this mandate as a noble goal and not a statutory requirement.

19. *See id.*

failure to treat them.

In a civil case brought in the Western District of Missouri, a complaint alleged that residents were provided grossly inadequate care and, as a result, suffered weight loss, developed pressure ulcers, and suffered other harm as a result of a company's knowing maintenance of inadequate staffing and supplies.[20] The court, in *United States v. NHC Health Care Corporation*, held that:

> NHC agreed to provide the quality of care that promotes the maintenance and enhancement of quality of life. At some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient's quality of life. When the provider reaches that point, and still presents claims for reimbursement to Medicare, the provider has simply committed fraud against the United States.[21]

How and when this blurry point is reached are the important questions that need to be resolved. Clearly, this point is reached when a provider is neglecting its residents by failing to meet the basic care needs (adequate nutrition, hydration, safety) of its residents, thereby violating the heart of the bargain, and more importantly, the trust a long-term care provider has with its residents and their families.[22] This is especially true because the population that is being served is vulnerable to the whims of caregivers, and residents are often afraid to complain about inadequate care for fear of suffering further indignities or harm.

The relationship between an assisted living provider and a resident is very different than in the nursing home setting, even though the medical needs of a resident are becoming strikingly similar. In assisted living, the arrangement may be based on "negotiated risk," that is, recognition that a higher level of care

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20. United States v. NHC Health Care Corp., 163 F. Supp. 2d 1051, 1052-53 (W.D. Mo. 2001).

21. *Id.* at 1055-56 (quoting United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1153 (W.D. Mo. 2000)).

22. *See also* 42 U.S.C. § 1396r(b)(1)(a); U.S. Dep't of Justice, *supra* note 4.

is needed to meet all of the resident's medical needs but a more homelike setting is preferred with less nursing care provided by the facility.[23] So, negotiated risk agreements between residents and the provider, or residents, their families, and the provider, are implemented to clearly delineate how care needs are going to be met.[24] However, there is real concern regarding the negotiating position of the resident and family given the fact that many of these placements occur as a direct result of a hospitalization, and the family experiences enormous pressure to discharge from the hospital.[25]

As government reimbursement for services rendered in assisted living facilities increases, the failure to provide basic care services will expose assisted living providers to potential federal civil and criminal fraud prosecutions.[26] Currently, criminal violations have been brought by state prosecutors based on the neglectful actions of caregivers, such as failing to treat a resident with an impacted bowel for three weeks or making false statements regarding sleeping on the job instead of providing resident oversight.[27] As assisted living environments become more attractive to our aging population, neglect of residents in an assisted living environment will be subject to the same scrutiny as in other institutional settings.[28]

THE WORTHLESS SERVICES THEORY

When deficient care reaches the level that can only be described as being tantamount to no care at all, the Federal

23. *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, ASSISTANT SEC'Y FOR PLANNING AND EVALUATION, OFFICE OF DISABILITY, AGING AND LONG-TERM CARE POLICY, A STUDY OF NEGOTIATED RISK AGREEMENTS IN ASSISTED LIVING: FINAL REPORT 1, 4-7 (Feb. 2006).

24. *Id.*

25. *See id.* at 8-20.

26. U.S. Dep't of Justice, *supra* note 4.

27. Rene Stutzman, *Charged With Neglect, Ex-Director of Assisted-Living Facility Avoids Jail*, ORLANDO SENTINEL, Feb. 20, 2008, at B.2; *Family: Workers Sleeping As Mom Dies In Assisted Living Home*, WSBTV.COM, Feb. 13, 2008, *available at* http://www.wsbtv.com/news/15295424/detail.html.

28. *See id.*

Government's fraud theory under the civil False Claims Act (FCA) has been termed "the worthless services theory."[29] The provision of substandard goods or services or worthless products to the federal government has long served as the basis for an action under the FCA.[30] Any provider that bills the government for a product or service that is of no value, if done with the requisite scienter, violates the FCA.[31] Similarly, billing for services that are performed in such a deficient manner that they have no value, thereby making them worthless, is also actionable under the FCA.[32] It is important to note that under the worthless services theory, the need for any certification by the provider, whether implied or express, is unnecessary.[33]

When evaluating whether grossly inadequate care rises to the level of fraudulent conduct, there are no hard and fast rules, i.e., it requires a case-by-case analysis. While the trigger for this type of investigation typically occurs after unspeakable harm to a resident has occurred, the starting point for this analysis is long before a bill is actually submitted to the government.[34] The analysis starts with a review and evaluation of a facility's policies and procedures.[35] These policies and procedures must ensure that care that meets the individualized needs of residents

29. Mikes v. Straus, 274 F.3d 687, 703 (2d Cir. 2001); *see* 31 U.S.C. § 3729 (2003).

30. 31 U.S.C. § 3729 (2003).

31. United States v. Bornstein, 423 U.S. 303, 309 (1976).

32. United States *ex rel.* v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001); United States *ex rel.* v. Covenant Health Care, 279 F. Supp. 2d 1212, 1216 (E.D. Cal. 2002); United States v. Cathedral Rock Corp., No. 4:03CV1090 HEA, *6 (E.D. Mo. Nov. 30, 2007); NHC Health Care Corp., 163 F. Supp. 2d at 1056-57; United States *ex rel.* v. Integrated Health Systems, Inc., No. 3:02-3796-24 (D.S.C. Sept. 25, 2003); Order at 18-20, United States v. Health Care Mgmt Partners, No. 04-cv-02340-REB-BNB (Aug. 17, 2006).

33. *Mikes*, 274 F.3d at 702; NHC Health Care Corp., 163 F. Supp. 2d at 1056. This article will not discuss the implied or express certification theories that have been used to address failure of care matters. For a discussion of these theories, *see* David R. Hoffman, *The Federal False Claims Act As a Remedy to Poor Care*, 6 FALSE CLAIMS ACT AND QUI TAM QUARTERLY REVIEW 17, 21-22, (1996) (citing Complaint, *United States v. GMS Mgmt.-Tucker, Inc.*, No. 9601271 (E.D. Pa. 1996)), *available at* http://www.taf.org/publications/PDF/jul96qr.pdf (last visited Sept. 6, 2008); *see generally*, Hoffman, *supra* note 3, at 156.

34. 42 U.S.C. § 1396r.

35. *Id.*

is planned and actually provided.[36] The analysis then includes a review of the roles and responsibilities for all those entrusted with care delivery responsibilities.[37] Next, an evaluation of how these roles and responsibilities were performed and the facility's response to identified inadequate staff performance is reviewed.[38] If there is no detectable evaluation process—no meaningful response to care needs that the facility knew or should have known about—then the FCA may be implicated.[39]

For example, a resident who needs assistance with feeding is identified through a resident assessment and care plan, but through inaction caused by understaffing, the resident does not routinely receive this assistance and as a result, over time, suffers weight loss leading to malnutrition. The facility neglected this resident by failing to provide the services necessary to avoid harm yet submitted a bill to the government for the care allegedly rendered to that resident.[40] The government paid that claim based on a per diem rate that includes room, board, and routine care services. The notion that the services rendered to this resident by the facility did not violate the arrangement and trust between a nursing home and the government is implausible. Cooking food that was never consumed by a resident because of the facility staff's failure to ensure that the resident's needs were met is a worthless service that was paid for by the government, and as such is certainly actionable under the False Claims Act.[41]

The worthless services theory can also be applied in the criminal context.[42] In a recent criminal matter, an owner of a

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*; *see also* 31 U.S.C. § 3729.

41. United States v. McNinch, 356 U.S. 595, 599 (1958); United States *ex rel.* v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) (discussing FCA actions sustained under theories of substandard products or services); United States *ex rel.* v. Lockheed Missiles and Space Co., 722 F. Supp 607, 609 (N.D. Cal. 1989).

42. The Health Care Fraud statute contemplates criminal conduct that has caused harm as part of a sentencing enhancement within the statute. *See* 18 U.S.C. § 1347(11) (2008).

nursing home chain was charged with health care fraud and other related offenses based on the submission of claims to Medicare and Medicaid for worthless services.[43] In denying a motion to dismiss, the judge held that the worthless services theory applied to the matter based on the knowledge of the owner.[44] Specifically, the owner "allegedly oversaw the other organizational defendants, [and] attended meetings where staff shortages and other substandard care issues were discussed."[45]

The lead defendant also allegedly "repeatedly told staff not to report abuse or neglect and to guard what they said to state surveyors."[46] Why the corporate edict controlling the mandatory reporting of abuse and neglect? The answer lies in the simple fact that reporting brings outside government oversight into the facility to determine whether services were truly being rendered to residents.[47] Moreover, facilities are required to have procedures in place to ensure that all cases of alleged resident abuse and neglect are reported and investigated.[48] The court concluded that the defendants' cover-up of potential neglect matters through a deliberate lack of reporting and follow-up investigation evidenced the defendants' intent to maximize profits while neglecting vulnerable residents.[49]

Finally, it is important to note that the institutional defendants had been cited for staffing issues in the past and had promised to address these issues through their plans of correction.[50] Instead, the policies remained unchanged and the staffing shortages continued unabated, thereby making the plans of correction submitted knowingly false.[51]

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43. United States v. Wachter, No. 4:05CR667SNL, 2006 WL 2460790 *1 (E.D. Mo. Aug. 23, 2006).

44. *Id.* at *12.

45. *Id.*

46. *Id.*

47. *See* 42 C.F.R. § 483.13(c)(2-4) (2007).

48. *Id.*

49. *Wachter*, 2006 WL 2460790, at *5.

50. *Id.* at *3.

51. *Id.*

Simply providing bad care is distinguishable from the provision of worthless services. Not all malpractice cases are actionable under the False Claims Act.[52] In the future, "never events" and other preventable hospital-acquired conditions are likely to be analyzed using the worthless services fraud theory.[53] In addressing these issues, it is important not to lose sight of how these cases are investigated and what conduct rises to the level of fraud. For example, food that is not hot enough leading to a resident not eating is clearly distinguishable from routine failure to provide needed assistance with feeding as delineated in a care plan that was developed based on an assessment of resident need. It is the systemic failure to respond to residents' needs that has served as the basis for government enforcement actions through the use of the FCA.[54]

CRIMINAL NEGLECT—STATE PROSECUTIONS

There are state criminal statutes that define neglect by those who are caretakers of care-dependent individuals and who receive payment for this care.[55] To find a caretaker criminally liable, these statutes typically require that a paid caregiver intentionally, knowingly, or recklessly failed to provide care to a care-dependent person.[56] States have pursued criminal neglect in truly egregious cases where individual defendants have acted

52. *See* 31 U.S.C. § 3729 (2003).

53. *See* David R. Hoffman, *Quality of Care and Corporate Compliance-Perfect Together!*, COMPLIANCE TODAY, Dec. 2007, at 35 (stating that The Centers for Medicare & Medicaid Services has determined that, as of October 2008, it will not reimburse hospitals for the following occurrences: pressure ulcers that develop during a hospital stay; two hospital-acquired infections; and three "never events," that is, air embolism, blood incompatibility and an object left behind in a surgical patient). Some states have determined that the Medicaid Program will not pay for these and other medical errors either. The lack of reporting or misrepresentation of these events may lead to fraud prosecutions when health care providers do so with the requisite intent.

54. *See generally* Gabriel Imperato Interview with David Hoffman, President, David Hoffman & Assocs. (July 2007), *in Meet David Hoffman, President of David Hoffman & Assocs.*, COMPLIANCE TODAY, July 2007, at 14-15.

55. 18 PA. CONS. STAT. ANN. § 2713(a), (f) (2007). Of note is the fact that hospitals were not included in the definition of caretaker.

56. *E.g., id.*

with such callous disregard that criminal prosecution was an appropriate remedy.[57]

EFFECTIVE COMPLIANCE AS A DETERRENT TO NEGLECT

The use of federal criminal and civil fraud statutes and state criminal statutes to combat neglect, while appropriate, occur only after unspeakable harm has been inflicted upon a resident or residents.[58] An effective corporate compliance program that integrates clinical concerns may be the best approach to avoiding institutional elder neglect.

Typically, there are seven basic elements associated with corporate compliance programs:[59]

> Standards of conduct and other policies that promote the organization's commitment to compliance;[60]
>
> Designation of a compliance officer or other individual to monitor and implement the program;[61]
>
> An internal reporting system for receiving complaints;[62]
>
> Education and training programs;[63]
>
> Monitoring and auditing systems and techniques to monitor the effectiveness of the compliance program;[64]
>
> Mechanisms for enforcing the program and disciplining

57. *E.g.*, Strine v. Commonwealth, 894 A.2d 733, 735-36 (Pa. 2006) (a nurse's aide placed a nursing home resident who could not speak in a tub of scalding-hot water, then left the resident alone, thereby leading to the resident's death).

58. *Id.*

59. Publication of the Office of Inspector General Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000).

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.*

> employees for violation of the code of conduct and conditions of the program;[65]
>
> Implementation of program modifications to prevent future problems.[66]

The federal sentencing guidelines state that in order to have an effective compliance and ethics program, an organization must:

> (1) exercise due diligence to prevent and detect criminal conduct; and
>
> (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.[67]
>
> Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct.[68]

These elements describe the process for implementing a compliance program whereby alleged illegal activity can be identified and responded to in a timely fashion.[69] Due diligence in this regard includes a number of different factors that ensure the governing body is actively engaged in the business of compliance and exercises reasonable oversight.[70]

The focus of compliance programs has traditionally been on financial fraud, e.g., billing for services never rendered and "upcoding" for an enhanced payment.[71] Fraudulent conduct has now been defined to include the provision of grossly

65. *Id.*
66. *Id.*
67. U.S. SENTENCING GUIDELINES MANUAL § 8B2.1(a)(1)-(2) (2008).
68. *Id.* § 8B2.1(a)(2).
69. *Id.* § 8B2.1(b)-(c).
70. *Id.* § 8B2.1(b).
71. Imperato, *supra* note 54, at 14.

substandard care and therefore, compliance programs are not just about billing, but must also address integrating care delivery in order to ensure that care is rendered in such a fashion as to support claims submitted to the government for payment.[72]

The basic compliance elements delineate what needs to be done internally in order to develop an effective compliance system.[73] Improper care delivery rising to the level of neglect, however, does not occur in a vacuum, and the need to implement additional components to any compliance program in order to address this concern is critical. Neglect is systemic in nature, and it is critical that those charged with compliance functions be knowledgeable about care issues and compelled to respond in a timely fashion.[74] When cited for deficiencies, for example, a skilled nursing facility must, as part of its plan of correction, demonstrate to the Centers for Medicare and Medicaid Services (CMS) that it has put systems in place to prevent similar occurrences.[75]

Compliance starts at the top of an organization and works its way down to all levels. The governing body and all staff must be educated on the structural components of the company's compliance program as well as the mission to provide quality care.[76] It is imperative that the message of compliance be such that it is everyone's responsibility to act proactively before compliance-related issues are implicated.[77] Simply stated, a provider must ensure, from the moment an employee starts his or her employment, that compliance with all laws and regulations are paramount and that every employee has the obligation to come forward if he or she suspects illegal or

72. Devin S. Schindler, *Quality of Care Initiatives: Malpractice and Pay for Performance*, COMPLIANCE TODAY, Nov. 2007, at 5.

73. U.S. SENTENCING GUIDELINES MANUAL § 8B2.1(b)-(c).

74. *See generally* Andrea Billups, *Deadly Neglect: The Shocking Truth About What's Going on in America's Nursing Homes*, READER'S DIGEST, Dec. 2006, at 97-98.

75. Hoffman, *supra* note 53, at 32-33.

76. *See* U.S. SENTENCING GUIDELINES MANUAL § 8B2.1(b).

77. *See id.* § 8B2.1(b)(5)(C).

improper activity.[78]

When integrating care delivery into traditional compliance programs, several key components and functions need to be implemented:

BACKGROUND SCREENING

It is critical that the screening of potential employees include not only accurate criminal background checks, but also truthful references from prior employers.[79] All too often, the only answer offered by a past employer is that it would "not rehire" the employee, as if those words would ensure the prospective employer will not hire that individual.[80] This is not always the result, however.

The need for truthful disclosure was never more evident than in the case of Charles Cullen, a serial killer in Pennsylvania and New Jersey who was able to go from a nursing home to multiple hospitals without full disclosure of his prior employment record and performance.[81] His heinous acts compelled the Pennsylvania and New Jersey legislatures to enact legislation protecting employers from suit when they truthfully report a former employee's conduct to a potential future employer.[82] If there are gaps in employment, further review and investigation by the prospective employer are warranted. If a former employer has information that pertains to a former employee's conduct, the former employer should readily disclose the information to any potential employer.

It is also critical that this screening process apply to temporary workers. Potential employers must familiarize

78. *See* Hoffman, *supra* note 53, at 33, 35.

79. *See* Jon Socolof & Julie Jordan, *Best Practices for Health Care Background Screening*, 8 J. HEALTH CARE COMPLIANCE 5, 9 (Sept.-Oct. 2006).

80. *See, e.g., id.* at 5.

81. Richard Perez-Pena, David Kocieniewski & Jason George, *Through Gaps in System, Nurse Left Trail of Grief*, N.Y. TIMES, Feb. 29, 2004 at N1.

82. *See* 42 PA.CON. STAT. ANN. § 8340.1(a) (West 2007). Even with this legal protection, many employers still use the words "do not rehire" and do not get into specifics regarding why an individual's employment was terminated.

themselves with how employees are screened by temporary employment agencies to ensure that the screening process meets appropriate standards.[83] A thorough review of the temporary agency's policies and evidence that the temporary employee meets all of the employer's requirements is critical to the background screening process.[84]

ORIENTATION AND TRAINING

While traditional compliance programs advocate training regarding the prohibition of illegal activity and reporting of same, clinical training on neglect is also critical.[85] Several outcomes associated with neglect include malnutrition, dehydration, skin breakdown, and development of pressure ulcers.[86] It is imperative that all employees recognize that these outcomes may be evidence of neglect, albeit not in all cases and that immediate steps must be taken to address these issues. All too often, a provider will offer one in-service training on nutrition as a means to address malnutrition and six months later, all of the employees who attended the in-service have left.[87] Objectively, there has been no meaningful intervention to prevent this event from reoccurring. An effective compliance program must evaluate all training programs and ensure that training on critical issues occurs on a routine basis.[88]

Orienting new employees is a critical part of the training process. All too often, new employees are thrown into the fire without the necessary tools to provide proper care. Continued

83. Michele Cordova & Regina Martinez, *Temporary Employees or Temporary Headaches? You Decide...*, July 19, 2006, http://www.diversifiedriskmanagement.com/articles/temp-employees.html.

84. Compliance Program Guidance for Nursing Facilities, Compliance Program Elements, 65 Fed. Reg. at 14296-97.

85. *See id.* at 14300.

86. Billups, *supra* note 74, at 98.

87. *See generally* Terasa Astarita, Gayle Materna & Cynthia Blevins, COMPETENCY IN HOME CARE, at 116 (Aspen Publishers 1998).

88. *See* DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., COMPLIANCE PROGRAM GUIDANCE FOR MEDICARE FEE-FOR-SERVICE CONTRACTORS 8-9 (March 2005).

evaluation of the competency of all employees is mandatory in order to ensure compliance with the organization's policies and procedures as well as the delivery of care according to accepted standards of practice.[89]

From a harm-avoidance and compliance perspective, it is critical for an organization to be in sync with caregivers at all levels.[90] To that end, administrators must be cognizant of employees' signs of stress and frustration and how employees interact with residents. Caregivers who avoid difficult-to-manage residents soon cease to meet residents' needs, thereby placing those residents at risk for neglect.

Finally, there must be competent trainers educating staff to ensure that evidence-based care is provided to all residents. A thorough review of the trainer's qualifications, training materials, and presentation style is warranted and should be confirmed through the compliance system.[91] On the care delivery side, the notion that having a wound care specialist treat all residents with pressure ulcers is proper treatment but ignores prevention, which is critical to ensuring compliance with federal law and regulations.[92]

EXTERNAL REPORTING

As noted earlier, external reporting leads to increased scrutiny by government regulators.[93] Effective internal reporting of compliance-related issues is critical to ensure timely identification and investigation of compliance-related issues. Equally important for compliance purposes is ensuring that all mandatory external reporting to regulators and law enforcement personnel occurs. As noted in the *Wachter* case, self-reporting to

89. Compliance Program Guidance for Nursing Facilities, *supra* note 84, at 14300.

90. Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 20696 (Apr. 16, 2008).

91. *See generally* Astarita et al., *supra* note 87, at 40.

92. Amanda Schaffer, *Fighting Bedsores With a Team Approach*, N.Y. TIMES, Feb. 19, 2008, *available at* http://www.nytimes.com/2008/02/19/health/19sore.html.

93. *See* 42 C.F.R. § 483.13(c)(2-4) (2007).

external sources is grounded in the belief that facilities will attempt to address their issues in an honest fashion while recognizing that an effective response from regulators will be forthcoming.[94]

MONITORING AND OVERSIGHT/PEER REVIEW

When integrating clinical oversight into a compliance function, the expectation is not that the compliance unit or compliance officer will be directly evaluating all clinical care issues, because in many instances, those types of issues require clinical expertise.[95] Instead, the compliance officer's function is to ensure that clinical evaluation by competent individuals is actually occurring.[96] To this end, the use of data is critical in evaluating and monitoring performance improvement. The data includes, among other items, the quality indicator reports, incident reports, information related to staffing issues, and reportable events.[97]

In addition, meaningful peer review is also critically important. While challenging, the peer review process must ensure that those who provide direct care, i.e., medical directors, attending physicians, nursing staff, and aides, are periodically evaluated for competency. The peer review process will help address individual concerns and will often identify systemic issues as well.[98] There is an important role for peer review in the compliance process. For a provider to ignore this responsibility and knowingly place residents at unnecessary risk for neglect is simply unconscionable.

94. *See generally Wachter*, 2006 WL 2460790 at *1-*14.

95. *See* Hoffman, *supra* note 53, at 33, 35.

96. *See id.*

97. *See generally* Patricia Shaw et al., QUALITY AND PERFORMANCE IMPROVEMENT IN HEALTHCARE 4-7 (Am. Health Info. Mgmt. 3d ed. 2007).

98. *See* Richard Grol, *Quality Improvement by Peer Review in Primary Care: A Practical Guide*, 3 QUALITY IN HEALTH CARE 147, 147-52 (1994).

INVESTIGATION

The role of compliance in the investigation of institutional elder neglect needs to be clearly defined. All investigations into elder neglect should be conducted by an individual trained in these types of investigations who does not have a conflict of interest. For example, all too often, victims of nursing home neglect are hospitalized, yet once back in the nursing home, no evaluation of the resident's previous hospital laboratory studies is performed by the nursing home.[99] These lab values are critical in evaluating how the resident appeared at the hospital because that information reflects the medical condition of the resident resulting from the nursing home's care.[100] An effective compliance program will ensure that investigations into possible institutional elder neglect are effective and result in changed practices and improved care delivery.

REMEDIES

Once institutional neglect has been identified, investigated, and substantiated, the organization's response for that facility, and across the entire organization, must be evaluated.[101] This analysis includes the identification of the factors that caused or contributed to the organization's failures that led to the lack of care delivery.[102] A root-cause analysis must be performed to evaluate what occurred and how to prevent reoccurrence.[103] Outside expertise may be necessary during the evaluation process and in implementing new strategies to avoid neglectful conduct.[104]

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99. *See* Kevin M. Terrel & Douglas K. Miller, *Critical Review of Transitional Care Between Nursing Homes and Emergency Departments*, 15 ANNALS LONG-TERM CARE 33, 35-36 (Feb. 2007).

100. *See id.*

101. *See* Compliance Program Guidance for Nursing Facilities, *supra* note 84, at 14303.

102. *Id.*

103. Hoffman, *supra* note 53, at 33.

104. *See* OFFICE OF INSPECTOR GEN. OF THE U.S. DEP'T. OF HEALTH AND HUMAN

OWNER/MANAGEMENT OVERSIGHT

The Health and Human Services-Office of Inspector General and the Health Care Compliance Association convened a government-industry roundtable to discuss board of director oversight of quality of care matters in the long-term care industry.[105] This roundtable led to the publication of helpful recommendations related to quality care oversight responsibilities.[106]

CONCLUSION

The worthless services theory is a viable and effective criminal and civil theory that the government will continue to use to prosecute health care provider care delivery failures associated with neglectful conduct.[107] The term neglect should be clearly defined from an operational perspective in order to ensure that regulators, health care providers, and consumers understand what conduct constitutes institutional neglect. The best way to avoid institutional neglect and the needless suffering associated with poor care is to integrate compliance activity with care delivery.[108] A robust compliance program will ensure that a culture of compliance is pervasive throughout a health care organization and that employees have an avenue for reporting care deficiencies. Moreover, an effective compliance program ensures a timely response to care delivery deficiencies before they become systemic and result in unnecessary and preventable harm to frail and vulnerable people.

SERVICES & HEALTH CARE COMPLIANCE ASS'N, DRIVING FOR QUALITY IN LONG-TERM CARE: A BOARD OF DIRECTORS DASHBOARD 3-5 (2008), http://www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf (last visited Oct. 23, 2008).

105. *See id.* at 1-8.

106. *See id.*

107. *See* Imperato, *supra* note 54, at 15.

108. *See* Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg., at 20696.

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