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**David
Hoffman**

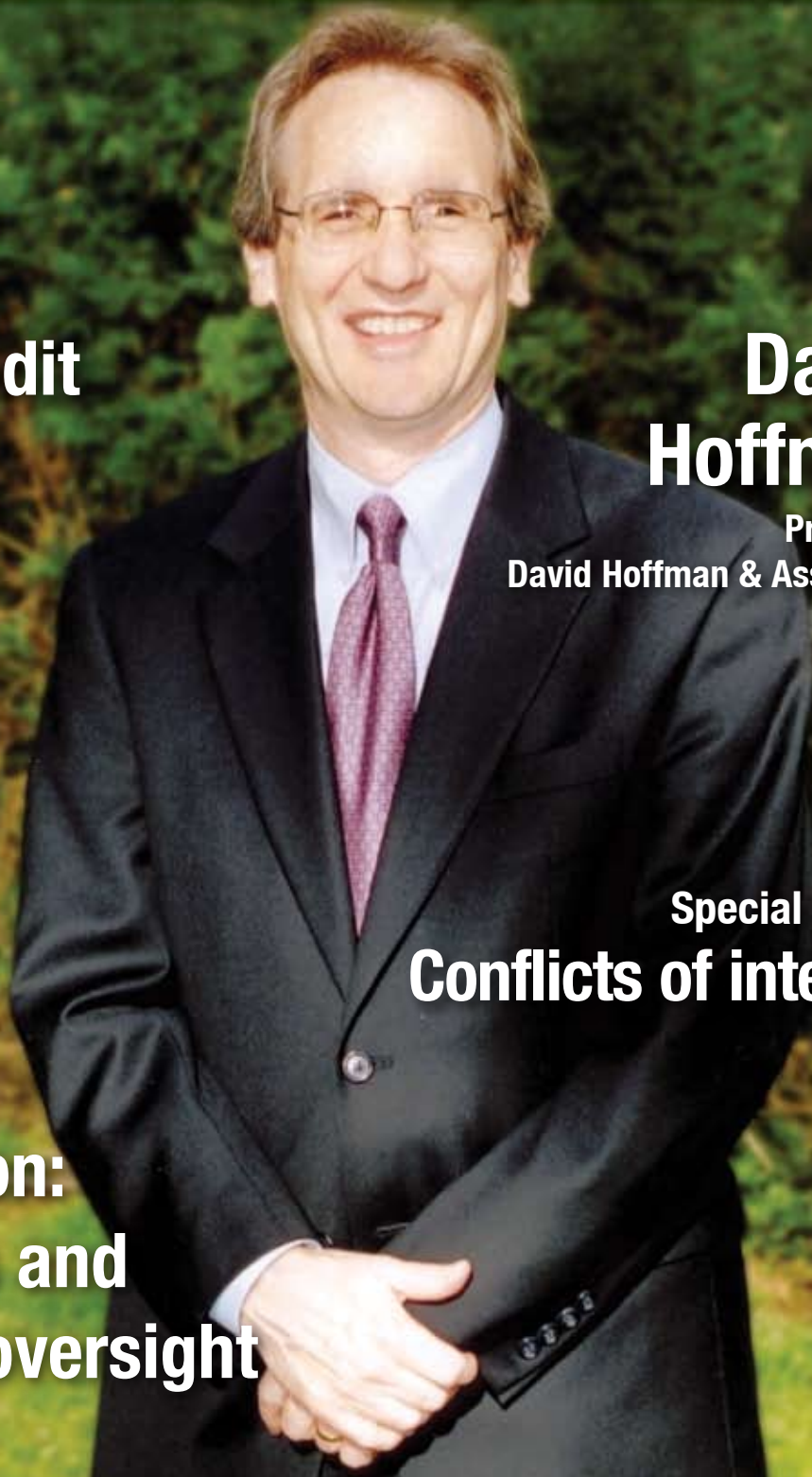
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feature article

Editor's note: This interview with David Hoffman was conducted by Gabriel Imperato, a member of the HCCA Board of Directors, in April 2007. The office of David Hoffman & Associates is located in Philadelphia. He may be reached by telephone at 215/854-6357 or by e-mail at dhoffman@dhoffmanassoc.com

GI: Tell us about yourself and your background and what brought you to your current role with health care compliance matters.

DH: I am president of a national health care consulting firm, David Hoffman & Associates, which is dedicated to ensuring patient/resident safety. Before creating my firm, I served as an Assistant United States Attorney in Philadelphia for 12 ½ years. I was fortunate enough to prosecute health care fraud both criminally and civilly. I pioneered the use of the federal False Claims Act in quality-of-care cases against nursing homes, personal care operators, and hospitals. Before joining the Department of Justice, I served in the Governor's Office of General Counsel as chief counsel for the Pennsylvania Department of Aging where I was instrumental in developing, among other programs, the protective services system to address elder abuse and neglect. I also served as an Assistant District Attorney in Philadelphia and as a judicial law clerk to the Honorable Anthony J. Scirica. All of these jobs have directly impacted on my ability to assist providers in avoiding situations that could subject them to investigation and prosecution.

GI: How did you originally become involved in these issues and what would you describe as your most developed area of compliance expertise?

Meet David Hoffman, President of David Hoffman & Associates

DH: Compliance means a lot of different things to different people. Historically, compliance meant meeting billing requirements, so a financial fraud did not occur. To me, compliance means not only ensuring that the claim is correct, but it also means delivering care that meets the needs of residents and patients and supports the bills submitted to third-party payers. My belief is that this can only be done by developing a culture of compliance that is integrated into a compliance system well beyond the typical "compliance program." This system is what my firm assists providers in developing and implementing.

GI: Tell us about your practice and the kinds of issues and compliance situations which you typically encounter in the long-term care industry.

DH: My firm has been retained to assist long-term care facilities and assisted living facilities in the defense of alleged failure-of-care cases and regulatory violations investigated by federal and state law enforcement personnel. My firm is the federal monitor for a large nursing home chain pursuant to a Corporate Integrity Agreement entered into by the provider and the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG). I am also consulting with proactive providers in the evaluation of their care delivery systems for legal and clinical compliance with regulatory requirements. I have also been retained by state and



local government agencies to represent them in matters relating to pharmaceutical and regulatory issues. The typical compliance situations involve systems failures in care delivery and the lack of recognition that care delivery failures constitute an overall compliance failure.

GI: Quality of care, medical necessity, and reasonableness of health care services are growing criminal and civil enforcement issues for health care organizations. How did this develop and where do you see it going in the future?

DH: On some level, I can claim ownership for the federal failure-of-care initiative. Back in 1996, I brought the first quality-of-care suit against the largest nursing home provider in the Philadelphia region. The complaint and consent order entered in that

matter inspired my former colleagues in the Justice Department to evaluate the use of the False Claims Act and other statutory tools to address failure of care in long-term care facilities and other institutional settings. Fourteen cases later, I left the government to assist providers in delivering good care, thereby avoiding government investigation and prosecution. The federal failure-of-care initiative remains a top priority of the HHS-OIG, and there are many cases being aggressively investigated and prosecuted on both the state and federal level throughout the country.

GI: Do you believe it is appropriate for the government or *qui tam* relators to utilize criminal enforcement statutes and/or the United States False Claims Act to challenge the quality of care, medical necessity, and reasonableness of health care services? If your answer is “yes,” under what circumstances?

DH: Absolutely. While recognizing that not every individual instance of failing to perform some task associated with care delivery should be prosecuted, when there is a pattern of poor care that is tantamount to no care at all, no meaningful response by the provider, and evidence of some harm associated with this failure of care, then intervention by law enforcement at all levels is not only warranted, it should be mandatory.

GI: Can you explain any differences that you have observed in health care organizational compliance programs today versus when you began involvement in compliance enforcement matters? Better? Worse? Same?

DH: From a compliance perspective, some organizations are now recognizing that care delivery is just as important as the proper billing for claims. I believe that some of this recognition is derived from a careful review of the Corporate Integrity Agreements entered into by providers with the U.S. Health and Human Services Office of Inspector General

and some of my former consent orders and settlement agreements with health care providers. And that is very good news from a patient/resident safety perspective and a compliance perspective.

GI: What do you think are the unique compliance challenges facing the long-term care industry?

DH: I think that staffing is a key challenge in health care today, whether it is in nursing homes, hospitals, or assisted living facilities. When I speak of staffing, it is not only numbers. Staffing entails training, evaluating competencies, and assisting each other in delivering quality care. The use of temporary staff that is unfamiliar with a provider’s policies and procedures oftentimes undermines the care delivery process and compromises care. Also, the lack of meaningful quality assurance/quality improvement programs make sustained compliance virtually impossible. There have been multiple instances where I have seen that the departure of an administrator or director of nursing has thrown a nursing home into complete turmoil with tragic consequences to residents. An effective compliance program goes a long way in reducing risk if administrators depart from the organization.

GI: What are the biggest compliance risk areas for nursing homes and other long-term care organizations?

DH: There are many risk areas for nursing homes and other health care providers. Falsification of records is a huge issue. The number of state and federal prosecutions linked to the falsification of records is increasing dramatically. If documented care has not been performed, the entire care delivery system has been compromised. From a clinical compliance perspective, the most obvious issues relate to pressure ulcers, nutrition, hydration, medication issues, falls, and meeting

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the needs of cognitively impaired residents. I believe that the biggest compliance risk area, however, relates to representations/certifications made on plans of correction and how providers implement these promises. A provider who states on a plan of correction that it is going to do something, and never does so, is subjecting itself to criminal and civil prosecution. A provider who does not do a root-cause analysis as to why care was deficient and does not submit a plan that addresses this problem systemically is destined to fail and become a repeat offender. A repeat offender is certainly more likely to surface on an investigator’s radar screen.

GI: We understand that having an “effective” compliance program is critical. How would you define compliance effectiveness for a health care organization?

DH: To me, compliance means that employees who have knowledge of compliance-related matters or concerns are responsible to act to address these issues. It means taking responsibility to intervene and not just saying it is someone else’s job. Compliance *effectiveness* means testing your system to see if this message has been received. I routinely ask providers about their compliance programs and get the traditional speech about the elements of compliance and I am presented with

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a nice large binder of documents. My first question is how many calls have been received by the hotline? I typically hear that there are not too many calls. I then interview staff and quickly discover that there is confusion as to what constitutes a compliance-related issue and the obligation to call the compliance hotline. Had the provider tested its system by interviewing some staff, it would have learned of this disconnect sooner.

GI: Do you have any tips for measuring compliance effectiveness?

DH: Internal auditing is a key to measuring compliance effectiveness. These audits relate to the evaluation of financial and care delivery systems. In other words, review of claims as well as actual care delivery is critical to a successful internal review process. For example, nursing facilities should consider reviewing hospitalizations on a monthly basis to evaluate why residents are being transferred to the hospital. This evaluation may identify problems with falls or infections and then lead to action steps to address these identified issues.

GI: What advice would you give to someone just starting out in compliance and setting up a program in the long-term care industry?

DH: The compliance component of an organization may not be viewed in a favorable light by many within an organization. While this is totally unfair and inappropriate, it is a reality in some organizations. My advice is to bring all of the relevant parties together and advise them of the role and responsibilities of the compliance unit. At the end of the day, there should be no question or suspicion that the compliance unit is all about protecting against adverse outcomes, both financially and clinically. There may be a time when the compliance unit is "investigating" improper conduct but that is one of its important functions.

GI: What do you feel have been major challenges for the health care compliance industry and what do you feel are the biggest challenges yet to come?

DH: Patient/resident safety has finally become a major issue in this country. It is no longer just about medical malpractice claims. The essence of patient safety is that all actors in the health care system must be driven by the notion that patient safety is paramount. This includes those external entities charged with oversight (e.g., regulators and licensing boards, law enforcement including Medicaid Fraud Control Units, HHS-OIG, and state and federal prosecutors), as well as internal compliance programs. We have to do better in protecting frail and vulnerable populations from abuse and neglect. How the compliance industry positions itself in addressing these issues is its biggest challenge yet to come. It is certainly an exciting time to be engaged in health care compliance.

GI: What value do you see in participation with the HCCA and what advantages have you gained from participating in HCCA?

DH: The importance of HCCA cannot be overstated. From my perspective, compliance is an on-going process that is still evolving. It is critical that there is an organization like HCCA in that it offers so many wonderful educational opportunities and affords compliance officers the ability to meet and disseminate best practices. ■



Call for Authors

We need you! The Health Care Compliance Association is seeking authors for **Compliance Today**. We are especially interested in articles covering compliance, regulatory, and enforcement concerns related to:

- Managed Care
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- Home Care
- Hospice
- Ambulatory Surgery Centers
- Assisted Living
- Ambulance/Transportation Services
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- Mental Health Clinics and Hospitals
- Alcohol and Substance Abuse Treatment Facilities
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- Medical Device Manufacturers
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- Physical and Occupational Therapy
- Pharmaceutical Manufacturers

We also need articles for the "Compliance 101" column featured in each issue of **Compliance Today**. This monthly column is meant for the newer compliance officer and compliance staff. All topics are welcome!

Articles generally run between 1,250 and 2,500 words; this is not a limit, just a guide. **Compliance Today** uses *The Chicago Manual of Style*. We require 10 or fewer

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