

Long-Term Care Facility Initiatives

David Hoffman & Associates brings decades of experience to address the needs of nursing home providers. The prevention of adverse clinical outcomes before they occur is critical to successful compliance and resident protection. We develop, in conjunction with facility administration, models to evaluate and ensure clinical and regulatory compliance. We also identify distressed facilities through data review and care observation, create intervention policies and procedures coupled with training and education of staff, to reduce the likelihood of clinical and regulatory problems.

We believe that written policies and procedures are a good beginning to ensuring compliance but that appropriate policies and procedures must be implemented by competent staff. To that end, we offer a training and education component that ensures that all individuals involved with the direct care of residents understand the policies and procedures implemented and the role that each employee plays as part of that care delivery. We also offer educational programs for nursing home administration, including administrators, quality assurance personnel, risk managers and compliance officers to ensure that care delivery is elevated to a compliance level.

As part of our nursing home consulting component, we offer an "Emergency Response Team" (ERT) for facilities with serious compliance/sanctions issues. Recognizing that owners and administrators re-deploy precious resources from other facilities when a particular facility is in distress, the ERT will immediately go to the facility and evaluate the care needs of the facility from a systems perspective. The ERT reviews not only the issues identified by state regulators, it will seek to stabilize the facility through immediate changes and then perform a root cause analysis/review. The Team will meet with government regulators to ensure appropriate communication regarding resolution of outstanding issues. Through implementation of these strategies, the ERT will minimize the stress on the organization while stabilizing the distressed facility in a timely fashion.

We also provide action plans in response to federal, state, and local surveys and investigations. We educate nursing home owners, quality assurance staff, risk managers, and compliance officers on how "failure of care" cases are developed and investigated. If an investigation or survey process is on-going, we develop strategies to identify and resolve the issues presented. We monitor care and address systemic problems at a facility during any investigation and/or as part of a negotiated settlement. We also provide expert testimony on behalf of our clients, when warranted.

All projects are evaluated for purposes of testing the interventions offered and the resulting feedback from the client. This evaluation may include analysis of patient outcomes, implementation issues associated with the recommendations offered by us, published papers, and/or client, patient, resident satisfaction analyses.

Clinical Research Initiatives

David Hoffman & Associates assists sponsors of clinical research and academic institutions in ensuring compliance with regulatory requirements governing human participant research. There have been occasions where a lack of oversight/lack of compliance with federal regulations has led to enforcement actions against individual researchers, sponsors and/or academic institutions. We review current practices and advise entities on how to test and revise their systems to ensure regulatory and clinical compliance.

We also facilitate development of policies and standards to ensure a system that mandates training of those engaged in clinical research, that is, all investigators, data collectors and applicable clinical staff (direct care staff). Additionally, it is critical for institutions to be fully informed as to research that is occurring in their facilities whether it is investigator-initiated or sponsor-initiated clinical research. We assist institutions in developing policies and procedures to address this and other important issues associated with clinical research.

We assist researchers and their sponsors in evaluating the informed consent process. We facilitate the development of systems that ensure that research participants are fully apprised of the risks and benefits associated with the research and that the informed consent process is adequately conducted to achieve regulatory and clinical compliance.

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Hospital Initiatives

David Hoffman & Associates assists hospitals with compliance with regulatory requirements and the implementation of innovative geriatric care and patient safety models. Some examples include:

- **Restraint Use** - Despite regulations and professional standards discouraging use of devices and practices that restrain patients, some hospitals continue to struggle with creating and/or maintaining a minimal restraint environment. We assist hospitals in conducting an industry-wide review of policies and procedures that focus on patient safety. We also assist with self-evaluation by conducting on-site review of restraint usage coupled with testing of staff understanding of rules governing restraint usage.
- **Innovative Geriatric-Care Models** - We offer training and education regarding the creation of a geriatric unit or functional equivalent, with specialized equipment and training. Emphasis is placed on proper policies and training in an effort to assist physicians and nurses to ensure patient safety.
- **Medication and Care Errors** - We assist hospitals in implementing an institutional culture in which staff feel comfortable to report medication and care errors. Additionally, we provide consultation on how to conduct system checks and balances to ensure that drugs with similar names not being used improperly.
- **Use of Agency Staff** - We assist hospitals in creating a system for ensuring that agency nurses are qualified and educated on the facilities' policies and procedures to ensure compliance.
- **Development of Quality Assurance Program** - We elevate care to a compliance level that ensures a meaningful quality assurance program. We work with hospital risk managers, compliance officers and quality assurance personnel to test QA programs for regulatory compliance and patient safety.

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