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Health Reform Update: It's 2010 and Voluntary Compliance Is No Longer an Option

CLIENT ADVISORY

Health care administrators hold fast to an ancient lament – “Failing to plan is planning to fail.” But in the new era of health reform, it isn’t just a saying; it’s a tidy restatement of a cumbersome law. And failure to act now could put you out of business.

With the passage of the Patient Protection and Affordable Care Act (“PPACA”, the “Act”), the Federal government focused its continued attack on corporate fraud, waste, and abuse on the private healthcare industry. The Act transformed the fraud-combating compliance programs for providers enrolled in Medicare and Medicaid (formerly voluntary initiatives with comforting bonus benefits), into required regimes. (See PPACA, Section 6102 and Section 6401).

Many providers remain undaunted by the requirement of a compliance program; after all, the PPACA does not yet specify the content of such a program, nor does it even set forth a timeline (except for skilled nursing facilities¹). But experience has taught us that those who start planning their programs now, with the maximum amount of lead time for trial, error, and tracked success, will have the greatest chance of satisfying authorities when they make their yet-

unannounced evaluations. Moreover, they will hold the most favorable odds of satisfying a highly attuned, corporate-wary public, which will be eager in the meantime to see which providers comply first, and comply best.

What Is a Compliance Program?

Until the PPACA, a compliance program was a system of guidelines, policies, and procedures, implemented (with a few exceptions) on a voluntary basis only by providers enrolled in Medicare and Medicaid. The Department of Health And Human Service’s Officer of Inspector General (“OIG”), founded the concept of a voluntary compliance program more than a decade ago, when it developed The Provider Self-Disclosure Protocol (the “Protocol”). Designed for providers who wished to self-report fraudulent conduct to the Federal government, the Protocol purported to offer providers “the opportunity to minimize the cost and disruption of a full scale audit and investigation, to negotiate a fair monetary settlement, and to prevent an OIG permissive exclusion preventing the entity from doing business with the Federal health care programs.” (See OIG News Release, dated 10/21/1998, available at:

¹ Pursuant to Section 6102, skilled nursing facilities (“SNFs”) are required to implement compliance and ethics programs within 36 months after development of the PPACA. SNFs must also implement a Quality Assurance and Performance Improvement Program (“QAPI”).



Hancock, Daniel, Johnson & Nagle, PC (HDJN) provides assistance and guidance to health care providers in virtually all legal matters affecting healthcare. Generally, these include corporate, employment, administrative, and transactional matters; litigation; and governmental affairs.

<http://oig.hhs.gov/fraud/docs/complianceguidance/dispress.pdf>).

Many providers liked what OIG was offering, and sought more industry-specific guidance on how their programs could achieve maximum benefit. OIG obliged, and over the next decade issued specific guidance for the development of compliance programs for more than a dozen types of health care providers, including hospitals, nursing facilities, hospices, and clinical laboratories. (A complete list of the compliance program guidance issued by OIG can be found here: <http://oig.hhs.gov/fraud/complianceguidance.asp>.) The breadth of OIG's issued guidance should prove particularly useful with respect to the PPACA, which broadly mandates compliance programs for all Medicare and Medicaid enrolled "providers." No provider or supplier type – not even small-business DME suppliers or individual physicians – has been exempted.

What's In a Compliance Program?

With the exception of nursing facilities (the first targets of scrutiny under the PPACA, which sets forth specific content and timing requirements for compliance programs in these facilities, only), health care providers looking to develop plans that will expressly comply with the Act will have to wait for the promulgation of regulations. But they need not table their preparations in the meantime. Legal and regulatory experts agree that the compliance plan requirements will closely track the aforementioned industry-specific guidance promulgated by the OIG, while further building upon the foundation of that guidance – the Federal Sentencing Guidelines (the "Guidelines").

The seven criteria underlying the Guidelines remain the only elements continually cited by the OIG as required for provider compliance.

They are:

- Development and distribution of written standards of conduct, policies and procedures that promote provider compliance;
- Designation of a chief compliance officer and other appropriate bodies;
- Development and implementation of regular, effective training programs for all affected employees;
- Maintenance of a process, such as a hotline, to receive complaints and protect the anonymity of complainants;
- Development of a system to respond to allegations of improper/ illegal activities and the enforcement of appropriate disciplinary action against offending employees;
- Use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem area; and
- Investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

"We already do that. Why revisit our current plan? And why the urgency?"

Most large scale providers and institutions already have compliance plans. *But do they work?* Again, the climate of corporate accountability has forced the Federal government to evaluate maximum effectiveness along with minimum compliance. The compliance plan regulations issued under PPACA will most certainly evaluate benchmark achievement levels in addition to baseline obedience. Having a plan in place will count, but having a *working* plan



HDJN is one of the largest Virginia law firms primarily focusing its practice on the needs of the healthcare industry.

in place will count much more. The benefit of starting a plan now, or assessing the effectiveness of a current compliance plan, means more time to gauge effectiveness, and more time to document a track record of improvement by the time the authorities show up to look at it. And the upsides of early planning don't stop there:

- A record of continued reassessment of a provider's compliance plan is evidence, in and of itself, that a provider and the government are on the same page; and that the hospital is taking reasonable, good faith steps to reduce waste, fraud, and abuse.
- Compliance plans make good business sense. They maximize organizational efficiency, minimize loss, and reiterate a provider's interest in responsible conduct to the community.
- Waiting until the last minute for a generic plan solution can yield

disaster. Large-scale providers are all familiar with the generic "model" policies, procedures, and guidelines, available for purchase from various consultants in an instant. But by its continued refusal to offer model plan language, OIG has made clear its reluctance to accept "one size fits all" provider compliance plans. Plans must be specific. Specificity takes time, and close evaluation by persons with an intimate knowledge of legal and compliance issues affecting health care providers.

HDJN is pleased to assist health care providers of all sizes, and at all stages of compliance program development and assessment. If your organization needs to develop a plan, or if it's time for an objective, external assessment of your current program, please do not hesitate to contact Mary Malone (mmalone@hdjn.com) at (804)-967-9604.

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