

Building a Strong Compliance Program

As part of their commitment to ensuring compliance with laws and regulations applicable to the health provider community, GNYHA's members have developed comprehensive compliance programs designed to establish and enforce high standards of conduct. To support those efforts, GNYHA established its Compliance Workgroup nearly a decade ago to provide members with a forum to discuss effective compliance measures and to confront compliance challenges together. Between meetings, members of the Compliance Workgroup communicate with GNYHA and, more important, with each other, to assess compliance policies and practices and gather timely information. This issue of *Health Care News In-Depth* provides the historical context for today's emphasis on compliance, summarizes GNYHA's compliance-related activities, and looks at compliance issues of particular relevance for 2006 and going forward.

Health Care's Emphasis on Strong Compliance Programs

GNYHA has supported and assisted its members' compliance efforts since the late 1990s—around the same time compliance programs in the health care community were first being formally developed. Although law enforcement agencies tended primarily to target improper Medicare and Medicaid billing, hospitals developed compliance programs that incorporated not just Medicare and Medicaid regulations but also Stark Law and anti-kickback issues as well as antitrust and not-for-profit concerns.

In 1998, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued its *1998 Compliance Program Guidance for Hospitals*, followed in the same year by the *Provider Self-Disclosure Protocol* for reporting health care fraud. The *1998 Guidance* established what have come to be known as the "Seven Elements" required of an effective health care compliance program, which continue to govern hospital compliance today. These seven elements were based explicitly on the seven components of the Federal Sentencing Guidelines.

It was also in 1998 that GNYHA established its Compliance Workgroup. The Workgroup provided—and continues to provide—a forum to help members develop and enhance

their compliance programs. These meetings have been supplemented by several rigorous, two-day seminars on how to create and sustain effective compliance programs and a steady stream of related information and briefings.

Recent Activities: In January 2005, the OIG followed up its 1998 compliance document with the *Supplemental Compliance Program Guidance for Hospitals*, which reinforces the significance of corporate leadership's commitment to compliance and emphasizes the importance of assessing and then improving an

existing compliance program. Since the OIG issued its 2005 document, GNYHA's Compliance Workgroup has focused its energies on how to assess and enhance compliance policies and practices. The workgroup has focused recently on how to develop and implement annual compliance plans, how to ensure that staff members and executives are strongly committed to and provide the necessary leadership for compliance programs, and how to use limited compliance resources effectively. The workgroup has also invited guest speakers

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The "Seven Elements" of OIG's 1998 Compliance Program Guidance for Hospitals

- 1. Written standards of conduct**, as well as written policies and procedures, that promote the hospital's commitment to compliance and that address specific areas of potential fraud.
- 2. A Chief Compliance Officer** and other appropriate bodies, reporting directly to the CEO and governing body, to operate and monitor the compliance program.
- 3. Education and training** programs for all affected employees.
- 4. Reporting mechanisms** to receive complaints, along with procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation.
- 5. A response and enforcement** system to respond to allegations of improper/illegal activities and to enforce appropriate disciplinary action against employees who have violated both internal and Federal compliance policies, statutes, regulations, and program requirements.
- 6. Auditing and monitoring** and/or other evaluation techniques to monitor compliance and help reduce identified problem areas.
- 7. Investigation and remediation** of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

Building a Strong Compliance Program *continued from front*

to discuss how to form effective partnerships with external compliance experts, how to implement the practical guidelines of proposed Internal Revenue Service (IRS) regulations, and how to self-disclose to relevant law enforcement officials.

In light of the current compliance challenges facing health care providers, GNYHA and its members have also taken specific steps in the past year to address concerns raised about both tax-exempt status and Medicaid fraud in particular. With respect to tax exempt status, GNYHA has held a number of briefings and meetings on related governance and excess benefit issues and distributed educational materials to members on both Congressional and IRS priorities. With respect to Medicaid fraud concerns, GNYHA has, on behalf of its members, met with a number of government officials charged with overseeing the Medicaid program in order to promote GNYHA members' very effective compliance programs.

The NYS Department of Health (DOH) has shared its compliance concerns and objectives with GNYHA. GNYHA has, in turn, disseminated this information to its members. DOH will also be meeting with GNYHA members on January 18, 2006, to discuss some of its Medicaid enforcement priorities. GNYHA believes that establishing productive partnerships with law enforcement agents and regulators can ultimately reduce the likelihood of violations, unnecessary audits and investigations, and the need for additional State fraud and abuse legislation.

2006 Compliance Watch List

GNYHA is monitoring a number of significant compliance-related areas and will continue to provide briefings and offer members assistance in the following key areas.

First, the **Internal Revenue Service** has shown increasing interest in not-for-profit organizations generally and not-for-profit hospitals specifically. In its *Fiscal Year 2006 Exempt Organizations Implementing Guidelines*, the IRS includes hospital compliance as one of its "New Critical Initiatives," with a focus on executive compensation and community benefit standards. Operationally, such an initiative would include sending "compli-

ance check letters" to hospitals asking them about these and possibly other issues.

The U.S. Senate Finance Committee leadership, working with the *ad hoc* Panel on the Nonprofit Sector, has signaled probable not-for-profit governance legislation for over a year, and Committee Chairman Senator Charles Grassley (R-Iowa) stated recently that he is continuing to examine tax-exempt status, with a focus on improved transparency and board governance, particularly in relation to excessive compensation, self-dealing, and private inurement. In May 2005, the Senator issued letters to 10 not-for-profit hospitals around the country, seeking information on such issues as community benefit standards and charity care policies. The Senator's staff has indicated that follow-up letters and perhaps new inquiry letters to additional hospitals may be issued. In November 2005, the Senate passed initial legislation that would both increase obligations and penalties placed on not-for-profits and promote charitable donations to not-for-profits. Many of the elements of this bill mirror recommendations made to Senator Grassley by the Panel on the Nonprofit Sector. The full Congress is expected to attend to this legislation in early 2006.

The U.S. Department of Health and Human Services Office of Inspector General has published its *Fiscal Year 2006 Workplan*, which covers the OIG's future audits, investigations, and legal actions. It includes a plan to

Tax-Exempt Concerns

In 2006, GNYHA anticipates that Congress and the IRS will continue to focus on not-for-profit hospitals.

The U.S. Senate Finance Committee may probe issues relating to:

- self-dealing;
- private inurement; and
- excessive compensation.

The IRS may look at hospital compliance, focusing on:

- how hospitals determine and pay executive compensation; and
- how hospitals meet community benefit standards for the purposes of 501(c)(3) requirements.

HHS Office of Inspector General: Fiscal Year 2006 Workplan

Each year, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) publishes a comprehensive list of its objectives for the coming fiscal year. This year's Workplan indicates that the OIG will focus on relevant items including:

- Referrals by State Medicaid agencies to State Medicaid Fraud Control Units
- Part D prescription drug benefit
- Pharmaceutical fraud
- Diagnosis-related group coding
- New safe harbors for the Anti-Kickback Law
- Self-disclosure protocols

study the system of referring Medicaid cases to state Medicaid Fraud Control Units, which is particularly timely for New York hospitals. The OIG also expects to focus on Part D drug benefit fraud and pharmaceutical fraud, along with a host of targeted billing issues.

The **New York Attorney General's Office** continues to pursue enhanced investigatory power in relation to health care. Attorney General Eliot Spitzer and his staff have called for the passage of legislation to expand their investigatory tools to match those used previously for the securities industry. Similarly, the **NYS Office of Alcoholism and Substance Abuse Services (OASAS)** has said that it will look at enforcement and compliance activities in the coming year.

Finally, the **Centers for Medicare & Medicaid Services (CMS)** will continue its voluntary, ongoing hospital compliance pilot program, through which it has conducted site visits to 16 hospitals to determine how effective compliance practices are manifested. To date, CMS's Office of Program Integrity has identified some common themes in effective programs, including buy-in from top hospital leaders, a compliance officer who can communicate program details to a broad employee base and has access to the hospital's board of directors, and continuous compliance training that incorporates individual or small group training for doctors. Final findings from this program will be available in spring 2006. ■