The HEAT Is On: Prepare Now for Enhanced Government Health Care Enforcement Efforts

Specific Steps Health Care Providers and Suppliers Can Take to Prepare

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The reduction of fraud, waste, and abuse in the federal health care programs (primarily Medicare and Medicaid) has emerged as a significant priority of the Obama Administration. Enforcement efforts have become increasingly coordinated and cooperative between government agencies, including the Department of Health and Human Services (HHS) and the Department of Justice (DOJ) as well as state agencies whose primary focus is the various state Medicaid programs, which are partially funded with federal funds.

These enforcement efforts are not limited to criminal schemes, large corporate entities, or large dollar losses. Rather, the chances that a health care provider or supplier will face enforcement activity are increasing for all providers, including physicians and other professionals. Some owners, operators, and officers of health care entities are facing actions against them as individuals, and some recent corporate integrity agreements require personal certifications from the corporate leadership team that compliance obligations have been met.

All health care providers and suppliers should take action now to prepare for increased enforcement efforts. Some specific steps are suggested at the end of this article.

The estimated loss to fraud, waste, and abuse is significant. One recent study estimated that $700 billion is wasted in the U.S. health care system (not limited to the federal health care programs), broken down as follows (also see Figure 1):

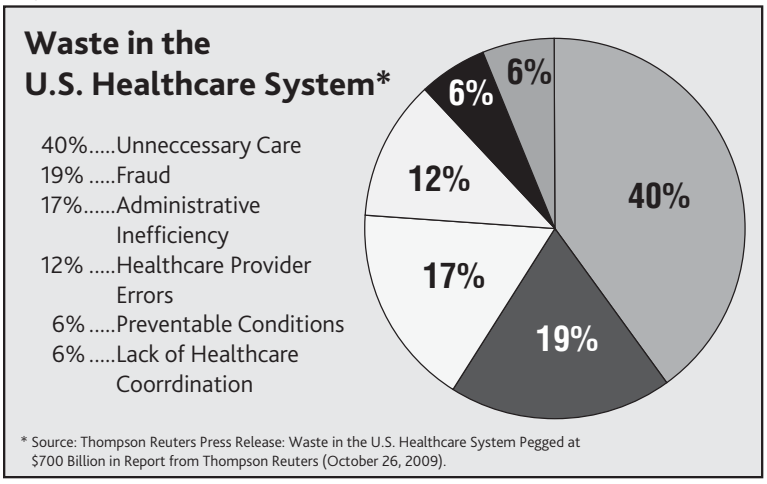
- unnecessary care (40 percent);
- fraud (19 percent);
- administrative inefficiency (17 percent);

- health care provider errors (12 percent);
- preventable conditions (6 percent); and
- lack of health care coordination (6 percent).[1]

The HHS Office of Inspector General (OIG) has stated that it is not possible to measure precisely the extent of fraud in the Medicare and Medicaid programs but has referenced figures calculated by the National Health Care Anti-Fraud Association, which estimates conservatively that at least 3 percent of health care spending is lost to fraud.[2] According to a White House media briefing, of the $98 billion in improper federal government payments identified by the White House Office of Management and Budget for 2009 (improper payments are not limited to fraud), more than $54 billion of that loss was incurred by the federal health care programs. This included almost $24 billion for Medicare fee-for-service, $18 billion for Medicaid health care for the poor and other limited groups, and $12 billion for Medicare Advantage.[3]

One particularly significant reason for the increased enforcement focus is that it may provide the funds to pay for the additional costs associated with health care reform, as identified by President Obama. Both the House and Senate bills for health care reform include additional funds for increased enforcement activity as well as providing additional tools for government efforts such as increased civil money penalties for a variety of conduct.

Figure 1



Other enforcement tools also will contribute to the success of the government's enforcement focus. During 2009, Congress passed revisions to the federal False Claims Act which were especially favorable to government enforcement efforts. Of most significance for health care providers and suppliers is a new provision relating to "reverse false claims," meaning situations in which the claim itself was not false at the time it was made but the recipient subsequently determines that it was not entitled to payment in the amount received (or retained). Under the revised statute, an entity which knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government may face liability for a false claim.[4]

Another increasingly significant tool is data-mining/data analysis of information contained in provider and supplier claims and other submissions, which has become dramatically more sophisticated and is a recurrent theme across several programs. The Centers for Medicare & Medicaid Services (CMS), the component of HHS which administers the Medicare and Medicaid programs, has streamlined provider and supplier audit functions and outsourced many of those audit functions. CMS has also placed a new emphasis on provider enrollment and revalidations, enforced in many instances with relatively new provisions allowing the administrative revocation of Medicare billing privileges. This approach focuses on keeping particularly risky providers from billing the federal health care programs at all (by not enrolling them in the program in the first place, by disenrolling them from the program at the time of revalidation, or by revoking their billing privileges) rather than trying to recover improper payments through a "pay and chase" approach.

There is also an increasing focus on Medicaid enforcement. The federal Medicaid Integrity Program, originally created by Congress in the 2005 Deficit Reduction Act (DRA), has largely finalized its infrastructure and has started performing provider audits. The highly successful efforts of the New York Office of Medicaid Inspector General demonstrate the recoveries that are available to the states, which focus on enforcement in their own Medicaid programs, and several other states now also have installed their own Medicaid Inspectors General.

In short, the government's enforcement efforts recently have aligned several strategies which dramatically increase the risks to health care providers and suppliers. Below we discuss some of the most significant components of this increasingly unified effort.

The enforcement focus on "fraud, waste and abuse" will not be limited to situations involving outright fraud. As recent enforcement efforts have demonstrated, waste and program abuse is often characterized by enforcement entities as fraud, or at least included in the same general category of "improper payments." It is critical that providers not assume that they will face only limited enforcement risk because they are not engaged in activity that generally would be viewed as intentional or even reckless fraud.

1. HEAT: DOJ and HHS Refocus on Fraud-Fighting Efforts

The joint HHS and DOJ effort known as the Healthcare Fraud Prevention and Enforcement Team (HEAT) was announced on May 20, 2009, by Attorney General Eric Holder and HHS Secretary Kathleen Sebelius. Senior level officials from each department will be dedicated to the effort, and the personal involvement of the chiefs of the two departments signifies the importance attached to the effort.

Attorney General Holder has long demonstrated an interest in and commitment to health care fraud enforcement. In 1998, as deputy attorney general, he issued the memorandum entitled *Guidance on the Use of the False Claims Act in Civil Health Care Fraud Matters*, which provided critical direction for the early years of health care enforcement.

An initial action of the HEAT was to expand the strike force approach, already operating since 2007 with great success in Los Angeles and Miami, to Detroit and Houston. In December 2009, additional strike force sites were announced for Tampa, Baton Rouge, and Brooklyn. Each strike force site hosts a federal prosecutor from the respective U.S. attorneys' office, or from the DOJ's Criminal Division's Fraud Section, along with an agent from the Federal Bureau of Investigation (FBI) and from the OIG.

On December 11, 2009, DOJ reported that since the inception of strike force operations in March 2007, it has obtained indictments of more than 331 individuals and organizations that collectively have billed the Medicare program for more than $720 million.[5] The HEAT Web site lists its team successes by month, with links to an expanded discussion about the underlying conduct. The success summary for December 2009, for example, includes indictments, pleas, and sentencings for various health care professionals including physicians; actions against individuals who are owners of health care entities; cases relating to Medicaid (as well as Medicare) fraud; settlement of a voluntary disclosure by a corporation relating to the employment of excluded individuals; and the arrest of an individual for obstruction of a health care investigation.[6]

The high number of criminal cases reported as HEAT successes should not be read as suggesting that "mainstream" providers and suppliers are not at risk. To the contrary, a review of these summaries suggests that more types of health care matters are now being aggressively prosecuted as criminal acts, with an increasing focus on the personal responsibility of individuals and health care practitioners.

Data-mining has been identified as a critical tool for the HEAT's efforts and served as the basis for identifying the areas of geographical focus for expansion of the strike force.

> Investigators in the HHS Office of the Inspector General are implementing state-of-the-art, cutting edge technology to identify and analyze potential fraud with unprecedented speed and efficiency. Using this technology, federal law enforcement officials are completing in a matter of days analysis of electronic evidence that previously took months to analyze using traditional investigative tools.[7]

Assistant Attorney General Tony West was even clearer about the reliance on data-mining, when he said, "[w]e are actively analyzing Medicare data in unprecedented coordination between our two agencies [DOJ and HHS], and in as real-time as possible, to identify fraud "hot spots" and expand strike force operations to those areas where there is the most need."[8] Daniel Levinson, HHS's Inspector General, similarly noted that "CMS is building an Integrated Data Repository (IDR) that will, when completed, contain a wealth of data across several programs. Although the system is still under development, the prospect of such a comprehensive data warehouse holds considerable promise for detecting and preventing fraud and abuse."[9]

One identified goal of HEAT is the strengthening of program integrity activities related to Medicare Parts C (Medicare Advantage plans) and D (prescription drug coverage) compliance and enforcement. The potential fraud, waste, and abuse in managed care differs significantly from that with which the government has had success in the traditional fee-for-service programs. For example, the documented medical necessity of specific services may not be a concern for a Medicare Advantage plan, but marketing activities and beneficiary enrollment efforts may present compliance challenges under Parts C and D that are not present in fee-for-service programs.

On January 28, 2010, as part of HEAT, Attorney General Holder and Secretary Sebelius, with others representing private sector leaders, law enforcement, and health care experts, participated in a National Summit on Health Care Fraud. Attorney General Holder provided an update on HEAT's success, indicating that in eight months more than 60 cases had been filed; 200 offenders charged, more than 50 guilty pleas entered; and more than a quarter of a billion dollars in fraudulent billings uncovered. Although the Summit was not open to the general public, a statement released by the Department of Justice indicated that there would be discussions of innovative ways to eliminate fraud and abuse in the U.S. health care system, with specific discussions following many now familiar themes:

- the use of technology to prevent and detect health care fraud and improper payments (data-mining);
- the role of the states in preventing health care fraud;
- the development of prevention policies and methods for insurers, providers, and beneficiaries;
- effective law enforcement strategies; and
- measuring health care fraud, assessing recoveries, and determining resource needs.

Attorney General Holder's remarks at the Summit indicated that HEAT will be expanding to include the private sector, specifically representatives of the insurance industry and the health care provider community.[10]

2. Health Reform

As of this writing, health reform provisions are still under heated debate.[11] Increased enforcement activity is a critical part of the debate because it offers the opportunity to fund (or "budget neutral") the increased costs which may be associated with reform. As President Obama advised Congress, "We've estimated that most of this [health care reform] plan

can be paid for by finding savings within the existing health care system, a system that is currently full of waste and abuse."[12] Both the House and Senate bills include provisions which will assist in enhanced enforcement efforts, including (but not limited to):

- mandatory compliance programs under Medicare and Medicaid;
- increased funding for fraud and abuse activities;
- expansion of the recovery audit contractor (RAC) audits to Medicaid and Medicare Parts C and D (Senate bill only);
- a requirement that overpayments be returned within 60 days (Senate bill allows for delay until corresponding cost report is due);
- "Sunshine Act" reporting provisions for payments to covered recipients (definitions differ) by drug and device manufacturers (and distributors, under House bill); and
- expanded civil money penalties.

Even though it is unclear at this time whether and which of these provisions ultimately will be enacted into law, it is likely that many of them will be part of any health reform package, thus further increasing the enforcement risks for providers and suppliers. Even if these provisions are not enacted this year, they provide a roadmap to the overall approach which the government will pursue in its enforcement efforts going forward. In testimony to Congress provided in connection with the discussions of health care reform, the OIG described its overall strategy to combat health care fraud, waste, and abuse as focused on the following areas:

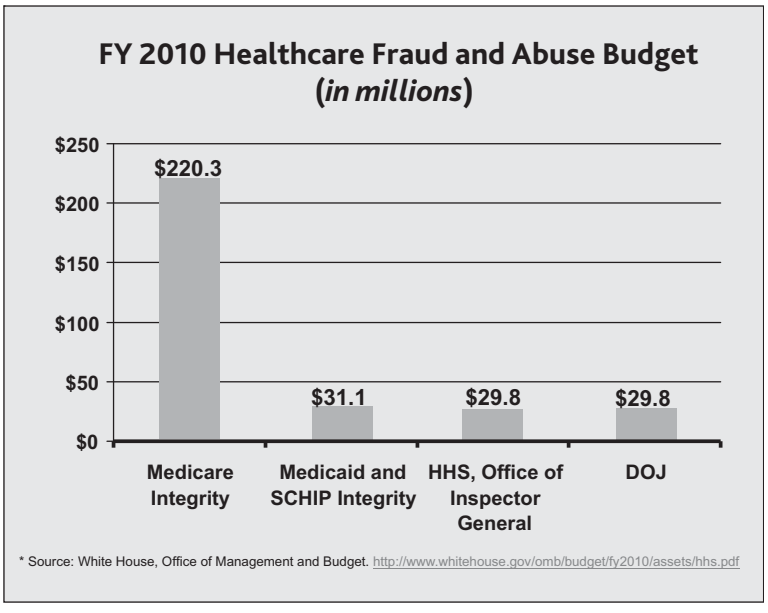
- enrollment — scrutinizing individuals and entities that want to participate as providers and suppliers prior to their enrollment in health care programs;
- payment — establishing payment methodologies that are reasonable and responsive to changes in the marketplace;
- compliance — assisting health care providers and suppliers in adopting practices that promote compliance with program requirements, including quality and safety standards;
- oversight — vigilantly monitoring programs for evidence of fraud, waste, and abuse; and
- response — responding swiftly to detected fraud, and imposing sufficient punishment to deter others, and promptly remedy program vulnerabilities.[13]

These five themes underlie many of the enforcement proposals in the House and Senate bills and will direct future enforcement efforts whether or not the proposals currently under discussion are passed.

3. Ramping Up of the Federal Medicaid Integrity Program and State Initiatives

The DRA created a new federal Medicaid Integrity Program (MIP) and directed CMS to enter into contracts to review Medicaid provider actions, audit claims, identify overpayments, and educate providers and others on Medicaid program integrity issues.[14] As of

Figure 2



the fall of 2009, MIP audits were in progress in at least 25 states. CMS has indicated that "[a]ny Medicaid provider may be audited, including, but not limited to, fee-for-service providers, institutional and non-institutional, as well as managed care entities."[15]

CMS has further indicated that providers generally will be selected for audit on the basis of data analysis by CMS. Unlike the RACs, the MIP auditors are not paid based on their recoveries. In addition to provider audits, the MIP will be working with state programs to identify best practices, and it is contemplated that provider enrollment eventually will be consolidated for Medicare and Medicaid.

Independent of (but cooperating with) the MIP, states are also pursuing their own Medicaid enforcement efforts. In New York, where former federal prosecutor Jim Sheehan serves as the Medicaid Inspector General, for the fiscal year ending September 30, 2008, the Office of the Medicaid Inspector General (OMIG) began 3,281 investigations and completed 2,366. In addition, OMIG far exceeded its financial goals, identifying and recovering (with the aid of other state partners) approximately $551 million for the state coffers.[16]

On its user-friendly Web site, OMIG has provided a detailed work plan, which can be used to assist providers and suppliers in self identification of potentially problematic issues, offers self-disclosure roadmaps, and lists and links state corporate integrity agreements. In addition to New York, there are state Medicaid Inspectors General (or equivalent titles) in Florida, Georgia, Illinois, Kansas, Kentucky, New Jersey, New Mexico, and Texas.

4. CMS Medicare Audits

CMS remains the biggest player in health care enforcement activity, as demonstrated by its share of the fraud and abuse budget. (See Figure 2) Through its Medicare Program Integrity Group, CMS is responsible for the program integrity efforts of its many contractors, identifies and monitors program vulnerabilities, implements requirements for provider/supplier enrollment, and is the primary contact point for Part D fraud, waste, and abuse oversight, along with many other assigned roles critical to the "first line of defense" of the Medicare program.

As key new enforcement initiatives ramp up, CMS continues its more "routine" program integrity audits administered primarily through a variety of contractors. In late 2008, CMS announced that it was consolidating its program integrity efforts with new program integrity contractors, which would focus on scrutiny of billing trends and patterns across Medicare to focus on providers and suppliers whose billings for Medicare services are higher than the majority of providers and suppliers in the community.[17]

Medicare's program safeguard contractors (PSCs) and the Medicare drug integrity contractors (MEDICs) were consolidated with new zone program integrity contractors (ZPICs). RAC audits are now permanent, with all contractors in place and audits ongoing with audit issues as approved by CMS. In late 2009, CMS announced that it had implemented measures which better reflected (*i.e.*, increased) the actual payment error rates (and made for higher provider and supplier errors in claims audits).[18]

5. Key Steps to Take Now to Prepare for Increased Enforcement

Assess Your Compliance Plan

A compliance plan is the first line of defense against increased enforcement. Given the government initiatives discussed above, it is imperative that every provider and supplier assess its compliance plan to be sure it is ready for these additional challenges. For example, many compliance plans historically have focused primarily on Medicare compliance, with the assistance of readily available CMS program manuals and OIG compliance guidances.

In sharp contrast, many states do not provide sophisticated compliance re-

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sources relating to their state Medicaid programs. Compliance officers must consider how they will determine applicable state Medicaid requirements and assure compliance with them. Health care entities also should consider whether they wish to revisit refund policies and procedures in light of the 2009 changes to the False Claims Act.

Do Your Own Data-mining

As discussed above, one key theme which crosses several of the government's enforcement strategies is increased reliance on data-mining to determine patterns of outliers which may suggest fraud, waste, or abuse. With an increasing emphasis by CMS on pay-for-performance and quality reporting, more and more data is being reported to the government. Some of this information also will be available to the public and to competitors. Providers and suppliers should (1) catalogue what information they are providing; (2) be sure that it is provided completely, timely, and accurately; and (3) consider what their data footprint will say about their operations.

Integrate Quality of Care into Compliance Efforts

The government has repeatedly indicated that it will treat inadequate care as grounds for enforcement activity, up to and including treating a failure of care as grounds for a case under the False Claims Act or in some cases even criminal charges. As more and more quality data is reported, there undoubtedly will be increased enforcement scrutiny of the quality of care provided.

Providers and suppliers also must be sensitive to the often multiple avenues for quality enforcement, including surveys which can result from complaints about care provided. The quality of care provided to federal health care program beneficiaries in nursing homes has been a special focus for DOJ, where the Civil Division houses the Elder Justice and Nursing Home Initiative to coordinate and support law enforcement efforts to combat elder abuse, neglect, and financial exploitation of this population.

As noted in recent congressional testimony, "[e]ach year Medicare and Medicaid spend over $120 billion on long-term care services, including nursing homes. At the same time, research shows that 11 percent of our seniors report experiencing at least one form of abuse, neglect, or exploitation."[19]

Recent examples of quality of care enforcement activity reflect civil fines, a criminal deferred prosecution agreement for the owner of a health care entity, and a permanent exclusion of an individual. Some corporate integrity agreements are including prospective quality obligations, over and above those already required by the conditions for coverage or conditions of participation. Areas of emerging risk for quality enforcement include unnecessary care, adverse event reporting, medical errors, and "never events."

Assess and Address Whistleblower Risks

Total federal False Claims Act settlements and judgments from 1986 to 2008 totaled $21.6 billion, of which the whistleblower recovery was $2.2 billion. Of that amount, $14.3 billion represented health care cases, with a whistleblower share of $1.6 billion.[20] Clearly, there is significant and documented risk to health care entities as a result of whistleblower actions.

DRA, the 2005 statute that created the Medicare Integrity Program, also required certain entities (those receiving at least $5 million in Medicaid funds) to implement policies and procedures which advised employees of applicable state and federal false claims acts and whistleblower protections. It seems likely that increased employee knowledge of whistleblower opportunities and protections will lead to increased whistleblower actions.

Health care entities should ensure that they have policies and procedures which

will effectively address employee and contractor concerns and thereby reduce the risk that whistleblower actions will be filed. Providers and suppliers also should assure that they are and will be fully compliant with all laws prohibiting retaliation against whistleblowers.

Conclusion

As the new decade begins, enforcement activity for health care entities is likely to increase in an exponential curve. Providers and suppliers must and can proactively prepare for this increased focus to reduce their enforcement risks.

Endnotes:

1. Thompson Reuters Press Release: Waste in the U.S. Healthcare System Pegged at $700 Billion in Report from Thompson Reuters (Oct. 26, 2009).
2. Testimony of HHS Inspector General Daniel Levinson before the House Committee on Energy and Commerce, Subcommittee on Health (June 25, 2009).
3. Tom Cohen, CNN.com, White House reports billions in improper payments in 2009, www.cnn.com/2009/POLITICS/11/18/government.improper.payments/index.html (Nov. 18, 2009).
4. 32 U.S.C. § 3720(a)(1)(G).
5. HHS News Release, December 15, 2009, "Medicare Fraud Strike Force Expands Operations into Brooklyn, N.Y.; Tampa, Fla.; and Baton Rouge, La; Continuing Strike Force Operations Lead to Indictment of 30 Individuals Charged in Miami, Detroit and Brooklyn with more than $61 Million in Fraudulent Billing to Medicare," available at www.dhhs.gov/news/press/2009pres/12/20091215a; www.justice.gov/opa/pr/2009/December/09-crm-1332.html.
6. www.Stopmedicarefraud.gov/heatsuccess/index.
7. Home page, www.stopmedicarefraud.gov.
8. Statement of Assistant Attorney General Tony West before the Senate Judiciary Committee Entitled "Effective Strategies for Preventing Health Care Fraud" (Wednesday, Oct. 28, 2009).
9. Testimony of HHS Inspector General Daniel Levinson before the House Committee on Energy and Commerce, Subcommittee on Health (June 25, 2009).
10. "Attorney General Eric Holder Speaks at the National Summit on Health Care Fraud," U.S. Department of Justice, Justice News (Jan. 29, 2010), available at www.justice.gov/ag/speeches/2010/ag-speech-100128; "Attorney General Holder, Secretary Sebelius Convene National Summit on Health Care Fraud, Unveil Historic Commitment to Fighting Fraud in President's FY 2011 Budget," U.S. Department of Justice, Office of Public Affairs Release (Jan. 28, 2010), available at www.justice.gov.
11. While the recent election in Massachusetts is likely to impact the progression of the Senate bill, and probably will delay any reform legislation, it seems clear that fraud, waste, and abuse enforcement provisions will continue to be pursued even separately from a larger health care reform package. On January 28, 2010, Sen, Chuck Grassley (R-Iowa) introduced H.R. 3590, which includes several provisions from the Senate bill.
12. Remarks by President Obama to a Joint Session of Congress, Sept. 9, 2009 (available at www.whitehouse.gov).
13. Testimony of HHS Inspector General Dan Levinson before the House Committee on Energy and Commerce, Subcommittee on Health (June 25, 2009).
14. Social Security Act, Section 1936, 42 U.S.C.A. § 1396u-6.
15. CMS Fact Sheet, "MIP: Medicaid Integrity Program" (Nov. 2009).
16. 2008 Annual Report, available at www.omig.state.ny.us.
17. CMS Press Release: CMS Enhances Program Integrity Efforts to Fight Fraud, Waste and Abuse in Medicare (Oct. 6, 2008).
18. CMS Press Release: HHS Employs New Tougher Standards In Calculation of Improper Medicare Payment Rates For 2009, Part of Administration-wide Strategy to Eliminate Errors and Prevent Waste and Fraud (Nov. 18, 2009).
19. Statement of Assistant Attorney General Tony West Before the Senate Judiciary Committee, entitled "Effective Strategies for Preventing Health Care Fraud" (Wednesday, Oct. 28, 2009), available at www.justice.gov/dag/testimony/2009/dag-testimony-091028.
20. Fraud Statistics – Overview, Oct. 1, 1986 to Sept. 30, 2008, Civil Division, U.S. Department of Justice.

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