Health Care Reform Advisory: Solidarity in a Sea of Dissent - Consistencies Between the House and Senate Bills' Provisions Targeting Fraud and Abuse

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By Thomas S. Crane, Brian P. Dunphy, Sarah A. Kaput, Karen S. Lovitch, and Jennifer E. Williams

Despite the many differences between the House-passed health care reform bill[1] and the Senate bill passed on December 24, 2009,[2] the two are remarkably similar with respect to the enhanced fraud and abuse enforcement provisions. This solidarity is not surprising given that many experts estimate that losses resulting from health care fraud could pay for much, or even all, of health care reform.[3] Thus, legislators may see taking a tough stance on health care fraud as a more palatable way to pay for health care reform, as opposed to seeking more reimbursement cuts.

This Advisory discusses the major provisions in the two bills that target fraud and abuse. If health care reform passes, these provisions likely will appear in the final legislation. Where the two bills differ, the Senate bill's provisions likely will trump the House bill's provisions due to the Senate Majority leader's tenuous grasp on the 60 votes needed for passage and the behind-the-scenes discussions with the House leadership about the current differences.

Transparency and Program Integrity

Both bills include provisions designed to enhance transparency and improve program integrity, and such provisions would:

- Require drug, device, biological and medical supply manufacturers to report annually to the Secretary of Health and Human Services (HHS) certain information on payments and other transfers of value to "covered recipients."[4] This provision is known as the "Sunshine Act." The Senate bill would define the term "covered recipients" to include only physicians (other than physician employees of the manufacturer) and teaching hospitals, whereas the House bill defines this term more broadly. In addition, the House bill would apply to distributors as well as manufacturers. Both the House and Senate bills would explicitly preempt duplicative state laws.
- Eliminate the broad exception to the Stark Law for physician-owned hospitals that allows such hospitals to participate in Medicare, unless the physicians held an ownership interest and the hospital had a provider agreement before August 1, 2010[5] (Senate bill) or January 1, 2009[6] (House bill). In other words, while the House bill would ban even some pre-existing physician-owned hospitals, Senator Ben Nelson (D-NE) won a reprieve that would allow new physician-owned hospitals to be formed and certified until August 1, 2010.
- Require pharmacy benefit managers (PBMs) to report certain information to (i) the plans with which they contract, and (ii) the Secretary of HHS (Senate bill) or the Health Choices Commissioner (House bill).[7] The information required to be provided would be confidential, and

could not be disclosed in a manner that identifies the specific PBM, plan, or prices charged for drugs.

Maximum Period for Claim Submissions

Both bills would substantially reduce the maximum period for the submission of Medicare claims from the current three-year period to one calendar year, and allow for the HHS Secretary to provide for exceptions.[8] The Senate bill would impose this reduced period beginning January 1, 2010, whereas the House bill would delay the implementation of the restriction for another year.

Physician Certifications of Need

Both bills would require physicians ordering durable medical equipment (DME) or home health services billable to Medicare to be enrolled in the Medicare program.[9] The HHS Secretary may expand this enrollment requirement beyond DME and home health services if she believes that such expansion will help mitigate fraud. The bills would also permit the Secretary to disenroll, for up to one year, a physician or supplier who fails to maintain and provide requested documentation relating to DME, home health services, or other items or services as determined by the Secretary.[10] Finally, both bills would require physicians (or—in the case of the Senate bill only—certain other health care providers working in collaboration with, or under the supervision of, a physician) to have had a face-to-face patient encounter within the six months prior to a certification relating to payment for home health services or DME.[11] Both bills would allow the Secretary to expand this requirement to other items and services if she believes such expansion will help mitigate fraud.

New Bases for Civil Monetary Penalties

Both bills would bolster the penalty provisions under the Civil Monetary Penalties (CMP) Act by providing for CMPs for:

- failing to provide timely access to the HHS Office of Inspector General (OIG) for audits, investigations, evaluations, or other statutory functions, of up to $15,000 per day
- knowingly making, using, or causing to be made or used a false record or statement material to a false claim for payment for items or services, of up to $50,000 for each false record or statement
- knowingly making a false statement, omission, or misrepresentation on an enrollment application, bid, or contract, of up to $50,000 for each false statement, omission, or misrepresentation
- ordering or prescribing items or services during any period when the person ordering or prescribing has been excluded, of up to $50,000 for each order or prescription.

In addition, both bills would impose intermediate sanctions on Medicare Advantage and Part D plans that

- enroll individuals in a plan without their consent (subject to certain limited exceptions)
- transfer individuals from one plan to another without their consent or solely for the purpose of earning a commission
- fail to comply with applicable marketing restrictions
- employ or contract with any person who engages in conduct prohibited by the intermediate sanctions provisions.[12]

The House bill would also amend the CMP Act to conform to the recent amendments to the False Claims Act[13] (FCA) by including CMPs for violations of the CMP Act committed in furtherance of a conspiracy, and by extending the statute of limitations from six years to 10 years.[14]

Lower Burden of Proof Under the Anti-Kickback Statute

The Senate bill would make it easier for the government to prove a violation of the Anti-Kickback Statute (AKS) by lowering the burden of proof to a civil standard. To prove a violation of the AKS, the government must show that the defendant acted "knowingly and willfully." Courts interpreted the intent requirement narrowly and required specific intent.[15] Because at least one U.S Court of Appeals upheld the constitutionality of the AKS based on its heightened scienter requirement, this provision, if enacted, could re-open the AKS to void-for-vagueness constitutional challenges.

Provider Screening and Other Enrollment Requirements

Although both bills call for enhanced screening procedures for providers and suppliers who wish to participate in Medicare and Medicaid, the Senate bill would mandate that all providers and suppliers be subject to, at a minimum, licensure checks, whereas the House bill would leave the imposition of any enhanced screening procedures to the Secretary's discretion.[16] In addition, both bills would require providers and suppliers who are enrolling or re-enrolling in Medicare or Medicaid to disclose any previous or current affiliation with any provider or supplier who:

- has uncollected debt
- has been or is subject to a payment suspension, or has been excluded, under a federal health care program
- has had its billing privileges denied or revoked.[17]

Mandatory Compliance Programs

For most providers and suppliers, the adoption of a corporate compliance program is currently voluntary.[18] Both bills would require the HHS Secretary to establish "core elements" for a

compliance program for providers and suppliers, and require providers and suppliers to establish compliance programs containing those core elements.[19] The House bill explicitly exempts physicians from this requirement.[20]

Overpayments

Both bills would require the reporting and return of overpayments within 60 days of learning of the overpayment.[21] Any overpayments retained after the 60-day deadline would be considered "obligations" under the FCA,[22] which means that the knowing concealment or retention of such overpayments could implicate the FCA. Beneficiaries are excluded from the definition of "person" under both bills.

"Public Disclosure" and "Original Source" Re-defined

Under the FCA, an individual (called a relator) can bring a claim in the name of the government. But a claim is jurisdictionally barred if it is based on information that has been subject to a "public disclosure" unless the individual is the "original source of the information."[23] The public disclosure bar was intended to prevent so-called "parasitic" relators from bringing cases based on information already in the public domain and has been the subject of extensive litigation, including the U.S. Supreme Court's 2007 helpful clarifications in the *Rockwell* case.[24] Currently before the U.S. Supreme Court is the question whether an audit and investigation performed by a state or its political subdivision may be considered an "administrative report" that qualifies as a "public disclosure".[25] There have been numerous unsuccessful legislative attempts to clarify this provision but, to the dismay of the relator's bar, Congress made no changes to it in this year's amendments to the FCA.[26]

Tucked away in a section of the Senate bill labeled "Special Rules" (which also contains the abortion language compromise), the Senate redefines the requirements for the public disclosure bar.[27] Among the more important changes contained in that section is language that suggests the public disclosure bar would no longer be a jurisdictional bar. The Senate Bill would instead require a court to dismiss a claim brought by an individual relator, "unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" through specified media, unless the relator is the "original source" of the information.

Currently, an "original source" must have "direct and independent knowledge of the information on which the allegations are based."[28] But under the Senate bill, an "original source" must either (i) prior to a public disclosure, have voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, *or* (ii) have knowledge that is independent of, and that materially adds to, the publicly disclosed allegations or transactions, and have voluntarily provided the information to the Government before filing an action. The first clause is entirely new and provides an easy alternative to qualify for original source protection. With respect to the second clause, the relator need not meet the rigorous standard of having "direct and

independent knowledge," but instead must only have "knowledge" of the information that is "independent of" and that "materially adds to" the previously disclosed information about the allegations or transactions. Taken together, this new definition of original source would dramatically tip the scales in favor of relators bringing cases and away from providers defending them.

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Lest anyone think that the final legislation's provisions will be "all bark and no bite," both bills would increase funding to the Health Care Fraud and Abuse Control (HCFAC) program beginning in 2011, albeit by significantly different amounts. The Senate bill would provide for an additional $10 million in funding for fiscal years 2011 through 2020, and permanently applies the CPI-U adjustment to HCFAC funding.[29] The House bill would allocate a whopping $100 million per year to the HCFAC program beginning in fiscal year 2011, with no pre-determined end date.[30]

These increases come on top of the $48 million allocated to the HHS OIG by the American Recovery and Reinvestment Act of 2009, and are consistent with the overall trend towards increased government enforcement seen during the Obama Administration, discussed in previous Mintz Levin articles, Alerts, and Advisories.

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Endnotes

[1] H.R. 3962.

[2] H.R. 3590.

[3] One report estimates a loss range of $68 to $226 billion. Federal Bureau of Investigation, Financial Crimes Report to the Public, Fiscal Year 2007.

[4] H.R. 3590, Sec. 6002; H.R. 3962, Sec. 1451.

[5] H.R. 3590, Secs. 6001, 10601.

[6] H.R. 3962, Sec. 1451.

[7] H.R. 3590, Sec. 6005; H.R. 3962, Sec. 233.

[8] H.R. 3590, Sec. 6404; H.R. 3962, Sec. 1636.

[9] H.R. 3590, Sec. 6405; H.R. 3962, Sec. 1637.

[10] H.R. 3590, Sec. 6406; H.R. 3962, Sec. 1638.

[11] H.R. 3590, Secs. 6407, 10605; H.R. 3962, Sec. 1639.

[12] H.R. 3590, Secs. 6402 and 6408; H.R. 3962, Secs. 1611, 1612, 1613, 1615, and 1617. The intermediate sanctions provisions may be found at Section 1857(g)(1)(A)-(K) of the Social Security Act.

[13] The False Claims Act was amended on May 20, 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA") (Pub. L. 111-21).

[14] H.R. 3962 Sec. 1645.

[15] Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995).

[16] H.R. 3590, Sec. 6401; H.R. 3962, Sec. 1631.

[17] H.R. 3590, Sec. 6401; H.R. 3962, Sec. 1632.

[18] Providers subject to the Medicaid compliance policy requirements imposed under Section 6032 of the Deficit Reduction Act of 2005 and certain state laws, such as New York, are required to adopt compliance programs.

[19] H.R. 3590, Sec 6401; H.R. 3962, Secs. 1635, 1753.

[20] H.R. 3962, Secs. 1635, 1753.

[21] H.R. 3590, Sec. 6402; H.R. 3962 Sec. 1641.

[22] Both bills cite to the definition of "obligation" added by FERA at 31 U.S.C. § 3729(b)(3).

[23] 31 U.S.C. § 3730(e)(4).

[24] *Rockwell International et al. v. United States*, 549 U.S. 457 (2007)

[25] *Graham County Soil & Water Conservation District v. United States ex rel. Wilson,* No. 08-304.

[26] The False Claims Act was amended on May 20, 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA") (Pub. L. 111-21).

[27] H.R. 3590, Sec. 10104(c), amending Section 1303(j)(2) (Special Rules).

[28] 31 U.S.C. § 3730.

[29] H.R. 3590, Sec. 6402.

[30] H.R. 3962, Sec. 1601.