AHLA Provision of Legal Background for the Sentencing Commission's Implementation of § 10606 of the Patient Protection and Affordable Care Act

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The American Health Lawyers Association (AHLA) is a not-for-profit 501(c)(3) professional association of over 10,000 members that does not engage in advocacy. In its role as a public resource on health law, however, the Association from time to time seeks clarification from government agencies or provides legal background to government agencies on issues that affect the health law community of providers, health plans, manufacturers and patients. *This letter is intended to provide such legal background. It does not express a specific view or recommendation (i.e. on which definition of "health care program" should be adopted), and should not be construed as an advocacy position of the American Health Lawyers Association or its members.*

In furtherance of its public interest mission, AHLA was pleased to be approached by the staff of the Sentencing Commission seeking background from our membership specifically on what should constitute "a government healthcare program" and "the amount of intended loss" for purposes of amending the Sentencing Guidelines and its policy statements. In response, AHLA appointed a Task Force to discuss these issues, and the Task Force on behalf of the association welcomes the opportunity to respond to the Request for Public Comment published in the Federal Register on January 19, 2011. That Request for Public Comment proposes to implement § 10606 of the Patient Protection and Affordable Care Act ("**PPACA**") by requiring the Federal Sentencing Commission ("**Commission**") to amend the Federal Sentencing Guidelines and policy statements (collectively the "**Guidelines**") applicable to persons convicted of Federal health care offenses involving Government health care programs. The Commission is proposing to implement § 10606 by creating a new Application Note in section 3(F) to the Commentary of Sentencing Guidelines § 2B1.1, which would read:

> (viii) *Federal Health Care Offenses Involving Government Health Care Programs.*—In a case in which the defendant is convicted of a Federal health care offense involving **a Government health care program**, the aggregate dollar amount of fraudulent bills submitted to the Government health care program shall constitute prima facie evidence of the amount of the intended loss, *i.e.,* is evidence sufficient to establish the amount of the intended loss, if not rebutted. ("**Aggregate Dollar Amount approach**") (emphasis added)

I. What Constitutes a Government Health Care Program

The definitional scope of "government or federal health care program" is not subject to uniform or consistent definition in federal health care statutes or regulations or Title 18 of the U.S. Code for criminal statutes. From a health law perspective, in complying with and interpreting federal statutes related to health care fraud and abuse laws, there is a general understanding of this concept that is drawn from different statutes and from government and industry compliance counseling. The following observations and resources may assist any definitional analysis.

A. General Definitional Categories

Foremost, federal statutory provisions appear to fall into two different categories: (1) specific statutes with intentionally restrictive definitions of the term federal health care program. An example of this is the federal anti-kickback statute, which has application to defined federal health care programs and excludes, therefore, other federal health care programs; and, (2) general definitions focused on the general benefit, program or government interest advanced by health care funding or participation privileges. An example of this are the different but similar definitions of federal health care program benefit contained in 18 U.S.C. §24 for several designated criminal health care fraud statutes and in 42 C.F.R. §1001.2, related to the scope of administrative program integrity provisions under the authority of the HHS Office of Inspector General.[1] The specific provisions provide the best illustration of the differing scope of the term.

The anti-kickback statute defines federal health care program as:

> (1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5 [health plans of Government Organization Employees]); or (2) any State health care program, as defined in section 1320a-7 (h) of this title," including (1) a State plan approved under a Grant to States for Medical Assistance Programs; (2) any program receiving funds under a Maternal and Child Health Services

[1] The concept of government interest, program or benefit as a definitional guidepost is illustrated in the recent False Claims Act amendments. The new definitions of claims and obligation introduce the concept of injury to a government interest or program generally. 31 U.S.C. § 3730. The definition of claim includes: any request or demand for money or property...made to a contractor, grantee or other recipient, "if the money or property is to be spent or used on the government's behalf or to advance a government program or interest..." 31 U.S.C. § 3729(b)(2)(A)(ii). The definition of obligation includes: an established duty, whether or not fixed, arising from an express or implied ...relationship...from statute or regulation..." 31 U.S.C. § 3729(b)(3).

> Block Grant or from an allotment to a State under such subchapter; (3) any program receiving funds under Block Grants to States for Social Services or from an allotment to a State under such a program; or (4) a State child health plan approved under State Children's Health Insurance Program. [2]

18 U.S.C. §24 contains a definition of federal health care program benefit that is foundational to several criminal health care fraud statutes, including the general criminal health care fraud statute, 18 U.S.C. §1347.[3]

> As used in this title, the term health care benefit program means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

Many of the federal criminal health care statutes that relate to this definition encompass private plans (commercial health plans) and government programs (Medicare and Medicaid). In the PPACA health reform legislation, 18 U.S.C. 24 was expanded to include violations of the anti-kickback, Food Drug and Cosmetic Act (FDCA) and certain ERISA provisions. It is also referenced in Section 10606 relating to the Sentencing Commission's role establishing sentencing guidelines for federal health care offenses.

The Office of Inspector General program integrity authorities provide another definition of federal health care programs for administrative remedies:

> Federal health care program means any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government (other than the Federal Employees Benefit Program) or any State health care program as defined in this section. [4]

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[2] 42 U.S.C. § 1320a-7b(f). Notably, this definition excludes a major federal health care program, the Federal Employees Health Benefit Program (FEHPB). In 2001, the OIG for OPM confirmed in its Semi-Annual Report to Congress that it did not support including FEHPB in the definition of federal health care program under the anti-kickback statute because, in part, the anti-kickback provisions are tied to Medicare's system of payment limitations and inclusion could "adversely affect the FEHBP's operation as a market-based provider of health coverage." www.opm.gov/oig.

[3] E.g.: 18 U.S.C. § 669 (theft or embezzlement); 18 U.S.C. § 1035 (False Statements); 18 U.S.C. § 1518 (Obstruction); 18 U.S.C. § 1956(a))(Money Laundering). 18 U.S.C. § 1345 (health care fraud injunction).

[4] 42 C.F.R. 1001.2

B. Health Care Compliance Counseling

In health care compliance counseling, the concept of federal health care programs is very broad for purposes of corporate responsibility and risk management and may encompass statutes that provide: (1) a benefit; (2) qualified right of participation; and, (3) any direct or indirect nexus to government funding or data reporting that has a fiscal impact on government program funding.

Illustrations of government health care programs that fall into these categories and may be subject to health care fraud enforcement include:

- Medicare
- Medicaid
- Federal Prison Hospitals
- TRICARE/CHAMPUS/Department of Defense health care programs
- The Veterans' Administration
- Public Health Service
- Children's health insurance under Title XXI of the Social Security Act
- OWCP (Workers comp for Federal Employees)
- Railroad Retirement Board
- The Black Lung Program
- State Legal Immigrant Impact Assistance Grants
- Health benefit plan under section 5(e) of the Peace Corps Act
- Programs funded by Maternal and Child Health Block Grants (Title V of the Social Security Act)
- Programs funded by Social Services Block Grants (Title XX of the Social Security Act)
- Indian Health Service

Appendix 1 includes an illustration of regulatory statutes that fall into these categories and may be the subject of health care fraud enforcement.

C. HHS Office of Inspector General Corporate Integrity Agreements

In connection with its enforcement and oversight responsibilities authorized in the Fraud and Abuse Program under HIPAA, the HHS Office of Inspector General has used the following language in its corporate integrity agreement relevant to the scope of an entity's compliance with health care program requirements: "statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))."

Appendix 2 includes an illustration of important statutes, regulations, and written "directives" regarding Medicare, Medicaid, and all other Federal health care programs.

II. Amount of Intended Loss

Section 10606 of PPACA specifically provides that the amount of the claims at issue should constitute ***prima facie*** evidence of the amount of the intended loss. Implicit in this directive is the concept that a defendant should be permitted to rebut this prima facie showing by introducing evidence that the actual amount of the claim is not a valid measure of the intended loss. Under current government reimbursement systems this will almost always be the case.[5]

Under federal payer rules, the actual charges put on a claim to that program are, as a practical matter, generally irrelevant. For example, Medicare pays health care providers under a variety of payment systems that are unrelated to claimed charges. In the hospital setting, Medicare reimburses for inpatient services using Diagnosis Related Groups ("**DRGs**") by which a set amount is paid based on the patient's admitting diagnosis, generally without regard to the amount of the hospital's charges.[6] Hospital outpatient services are reimbursed by Medicare using Ambulatory Payment Classification groups ("**APCs**") which are also unrelated to charges.[7] In the physician office setting, Medicare reimburses based upon a published fee schedule rather than on a charge basis.[8] Other suppliers of services are similarly reimbursed.

Although Medicare reimbursement is generally set at a fixed amount that the Centers for Medicare & Medicaid Services has pre-determined, health care providers often submit a claim to the Medicare program based upon the provider's usual and customary rates, not based upon the expected reimbursement. Thus, as a general matter, when a provider submits a bill to Medicare, the provider knows that it will not be paid the entire amount of the bill submitted, but rather the Medicare-established rate.

By way of example, a provider could submit a charge to the Medicare Program for $1,000.00, for a service it knew would be reimbursed at $100.00. While the service was, in fact, rendered, the provider used an inaccurate billing code. Had the correct code been used, the provider would have been reimbursed at $60.00. Under the language of the statute, the "aggregate dollar amount of the intended loss" would prima facie be $1000.00, because that was the amount of the claim actually submitted. In fact, however, the provider would have actually known that the excess benefit being sought was the $40 difference between the inflated reimbursement rate being sought and the rate to which the provider was actually entitled.

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[5] The sole exception is when the physician's stated charge on the bill is less than the fee schedule amount. That occurs very infrequently.
[6] 42 U.S.C. §1395ww.
[7] 42 U.S.C. §1395l(t).
[8] 42 U.S.C. §1395w-4.

A number of courts have acknowledged the intricacies of Government health care programs and determined that a defendant's knowledge of reimbursement practices is relevant to loss calculations. For example, in *United States v. Semrau*,[9] the District Court placed emphasis on the defendant's knowledge of what amounts were being reimbursed and the fact that the defendant knew that the bills submitted were not fully reimbursable. The Court stated, "the intended loss for sentencing purposes should be determined by reference to [the defendant's] testimony regarding his intent and knowledge of Medicare billing schedules and reimbursement amounts."[10] Similarly, in *United States v. Singh*,[11] the Second Circuit, in vacating and remanding the District Court's judgment with regard to the calculation of loss, determined that the defendant did not expect or intend to receive reimbursement in the amounts billed. In reaching this conclusion, the Court stated, "[b]ecause of [the defendant's] status as a physician and one familiar with the billings and receipts of his medical practice, an inference surely can be drawn here,…of the loss he intended to cause through his fraudulent scheme."[12] Therefore, by demonstrating knowledge of the reimbursement scheme, and an understanding that the billed amount will not be fully reimbursed by a Federal health care program, the defendant can rebut the presumption of intended loss based solely on billed charges.

Conclusion

AHLA thanks the Sentencing Commission for seeking out our members' expertise and background knowledge on two issues of importance in drafting the proposed new Application Note. AHLA takes seriously its mission to serve as a public resource on selected healthcare legal issues and therefore welcomes this opportunity to serve in such capacity. To reiterate, however, this letter constitutes an effort to provide legal background and should not be construed as an advocacy position of the AHLA.

[9] 2011 U.S. Dist. LEXIS 246 (January 3, 2011)
[10] *Id.*at * 14.
[11] 390 F.3d 168 (May 21, 2004)
[12] *Id.* at 193.

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Appendix 1

- Medicare Conditions of Participation for Hospitals, Long-Term Care and Other Providers and Suppliers;

- Food Drug and Cosmetic Act (FDCA)

- Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8

- Medicare Average Sales Price Methodology, 42 U.S.C. § 1395w-3a

- Limitation on Prices of Drugs Procured by VA and Other Federal Agencies, 38 U.S.C. § 8126

- Federal Supply Schedule and Other Federal Government Contracts
    - Federal Supply Schedule, 48 C.F.R. Subpart 8.4
    - Improper Business Practices and Personal Conflicts of Interest, 48 C.F.R. Part 3 (*e.g.*, Contractor Gratuities to Government Personnel, Other Improper Business Practices, Contractor Code of Business Ethics and Conduct)
    - Debarment, Suspension, and Ineligibility, 48 C.F.R. Subpart 9.4
    - Solicitation Provisions and Contract Clauses, 48 C.F.R. Part 52 (clauses incorporated through FSS contract, wide variety of statutory and regulatory requirements for federal government contracts, e.g., small business and affirmative action obligations)
    - Contractor Business Ethics Compliance Program and Disclosure Requirements, 48 C.F.R. Parts 2, 3, 9, 42, and 52 (impose obligations to detect and report criminal fraud, conflicts of interest, bribery, illegal gratuities, civil false claims, and significant overpayments, and failure to do so may result in debarment or suspension under subpart 9.4)
    - Contract Disputes Act, 41 U.S.C. Chapter 9

- Limitations on Prices of Drugs Purchased by Covered Entities ("340B Program"), 42 U.S.C. § 256b

- Armed Forces Pharmacy Benefits Program, 10 U.S.C. § 1074g

- Medicare Prescription Drug Benefit, 42 U.S.C. § 1395w-102
    - Voluntary Medicare Prescription Drug Benefit, 42 C.F.R. Part 423
    - Medicare Advantage Program, 42 C.F.R. Parts 417 and 422

Appendix 2

- OIG Compliance Guidance for Industry Sectors

- Prohibition Against False Statements, 42 U.S.C. § 1320a-7b(a)
  - Includes: Duty to Affirmatively Disclose Excess Payment, 42 U.S.C. § 1320a-7b(a)(3)

- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
  - Regulations, 42 C.F. R. § 1001.952

- Civil Monetary Penalties, 42 U.S.C. § 1320a-7a
  - Includes: Beneficiary Inducement Statute, 42 U.S.C. § 1320a-7a(a)(5)
  - Regulations, 42 C.F.R. Part 1003
  - Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998), and An Open Letter to Health Care Providers (Mar. 24, 2009) (http://oig.hhs.gov/fraud/selfdisclosure.asp)

- Criminal False Claims Act, 18 U.S.C. § 287

- Civil False Claims Act, 31 U.S.C. §§ 3729-3733

- Physician Self-Referral or "Stark" Law, 42 U.S.C. § 1395nn
  - Regulations, 42 C.F.R. § Part 411, Subpart J
  - CMS Voluntary Self-Referral Disclosure Protocol, OMB Control No. 0938-1106 (https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf)

- Exclusion from Participation in Federal Health Care Programs, 42 U.S.C. § 1320a-7
  - Regulations, 42 C.F.R. Part 1001
  - Regulations, 42 C.F.R. Part 402