

**Testimony Before The United States Sentencing Commission
Concerning Proposed Amendments To the United States Sentencing
Guidelines, Policy Statements and Commentary**

February 16, 2011

by

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Member

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I. INTRODUCTION

Judge Saris, Commissioners —

Thank you for this opportunity to appear today to present comments on the proposed amendments by the United States Sentencing Commission (the “Commission”) to the sentencing guidelines, policy statements and commentary (“Proposed Amendments”)^{2/} resulting from specific directives contained in the Patient Protection and Affordable Care Act, Pub. L. 111-148 (the “Patient Protection Act”), including to provide that the aggregate amount of fraudulent bills submitted to the Government health care program constitutes prima facie evidence of the amount of a defendant’s intended loss.

I am a member of the law firm Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., I serve in our Health Care Section and Health Care Enforcement Defense Group in our Boston and Washington, D.C. offices. The perspective I bring to you is as an attorney who both advises health care providers and manufacturers on the complexities of various Medicare rules and other regulations with which they must comply, and defends clients from allegations of wrongdoing.

^{1/} The views expressed are my personal views and do not represent the formal position of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., any other individual attorneys at the firm, or any of its clients.

^{2/} Notice of Proposed Amendments to Sentencing Guidelines, Policy Statements, and Commentary, 76 Fed. Reg. 3193 (Jan. 19, 2011).

Included in the criminal cases that I have litigated is the Fifth Circuit Court of Appeals decision *United States v. Jones*^{3/} (“*Jones*”) that is relevant to the Proposed Amendments in that the panel, which included Chief Judge Edith Jones, rejected the use of a methodology based on the aggregate amount of Medicare billings as an improper measure in calculating the intended loss in a Medicare related party case. That case illustrates the problems in applying Medicare reimbursement principles in loss calculations.

In my presentation today I will first discuss the complexities of health care regulations, the breadth of the Anti-Kickback Statute, the potential problem for constitutional infirmities in convictions under the Anti-Kickback Statute caused by the lowered *scienter* requirement under that statute, and resulting potential for sentencing disparities. I will then focus my specific comments on Congress’s directive and the proposed special rule in Application Note 3(F) related to the aggregate amount of fraudulent billings. I will discuss my proposal and reasons the Commission should add clarifying language to this provision. In this section, I provide examples of how the loss calculation might operate with various health care fact patterns, and discuss my concern that the Government could seek to turn the standard of aggregate loss of fraudulent billings into a decision rule for courts to use in determining loss when presented with competing evidence.^{4/}

^{3/} 475 F.3d 701 (5th Cir. 2007).

^{4/} The Commission also requested comments on its proposed alternative definition of “Government health care program” in the definitions section to the Application Notes. This term would be defined from either: (1) a specific list of “Government sponsored programs” found in section 1501 of the Patient Protection Act (*codified as* 26 U.S.C. § 5000A(f)(1)(A)); or (2) the definition of “Federal health care program” adopted from section 1128B(f) of the Social Security Act (*codified as* 42 U.S.C. § 1320a–7b(f)). These alternatives get essentially to the same place from different routes: the former utilizes a specific list and the latter incorporates Federal health care programs by reference. In short, the Commission has a policy decision as to which approach is preferable, and for this reason I offer no specific recommendation.

II. COMPLEXITIES OF HEALTH CARE REGULATION AND THE POSSIBILITY OF DISPARATE SENTENCING

The vast majority of health care providers and manufactures are honest and devote significant efforts to comply with the complex body of health care laws and regulations under which they operate. They support and need aggressive enforcement. Health care fraud can drain the public fisc, harm patients, and erode confidence in our health care system and public health care programs. Nothing I say here today should be seen as qualifying the importance of vigorous enforcement of these laws.

However, it must be recognized that health care providers and manufacturers operate in one of the most highly regulated segments of our society. For example, in a recent submission to Congress addressing the regulatory burdens of hospitals, the American Hospital Association cited ten separate bodies of law under which hospitals operate, several of which relate to fraud and abuse enforcement laws, including the Anti-Kickback Statute.^{5/} Medicare and Medicaid regulations span four volumes of Title 42 of the Code of Federal Regulations and the Food Drug and Cosmetics Act spans eight volumes of Title 21.

Because of the scope and complexity of the laws in this arena, and the operation of certain health care fraud statutes, there is a very real potential that some convicted health care defendants facing sentencing under the Guidelines for Federal health care offenses may be subject to the same penalties even where their conduct is very different than that of, for example, brazen criminals who present no pretext of having provided legitimate health care services. Let me explain this situation in more detail, specifically with regard to the Anti-Kickback Statute, before turning to the specifics of the Proposed Amendments.

^{5/} Letter from American Hospital Association to Rep. Darrell Issa, Chair of the House Committee on Oversight and Government Reform (Jan. 14, 2011), available at <http://www.aha.org/aha/letter/2011/110114-let-aha-issa.pdf> (last visited Feb. 8, 2011).

Starting in the mid-1980s, providers have been significantly concerned about the uncertain breadth of the Anti-Kickback Statute as a result of the Third Circuit Court of Appeals decision in *United States v. Greber*, in which the court held: “if one purpose of the payment was to induce referrals, the [anti-kickback] statute has been violated.”^{6/} This interpretation has since come to be known as the “one purpose rule.” Although this decision has been widely followed,^{7/} it has not been adopted by the First Circuit Court of Appeals.

One of the many problems with the “one purpose rule” is that it has been interpreted by many quite literally to mean that proof of *scienter* or criminal intent is not an element of an Anti-Kickback Statute violation. For example, the Department of Health and Human Services Office of Inspector General (“OIG”) recently reiterated, consistent with its prior statements,^{8/} that “[t]he statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.”^{9/} A health care provider not steeped in criminal law could easily misinterpret such a statement as meaning that, without any showing of criminal intent, he or she could be convicted and jailed if the provider had any type of hope for or expectation of referrals as part of a financial arrangement with a party that could refer patients or increase business.

^{6/} *Id.* at 69.

^{7/} See, e.g., *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000).

^{8/} See generally, U.S. Department of Health and Human Services, Office of Inspector General, Advisory Opinions, available at <http://www.oig.hhs.gov/fraud/advisoryopinions.asp> (last visited Feb. 8, 2011).

^{9/} OIG Advisory Opinion No. 11-01 at 8, available at <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-01.pdf> (last visited Feb. 8, 2011) (Emphasis in original).

The OIG has recognized that the Anti-Kickback Statute “is extremely broad.”^{10/} So has the Congress, which observed in 1987: “[T]he breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate and which are proscribed.”^{11/} As a result, Congress directed HHS to promulgate safe harbors specifying those payment practices that will not be subject to criminal prosecution under the Anti-Kickback Statute.^{12/} There are now safe harbors covering 24 major categories of financial arrangements, spanning over 26 pages of the Code of Federal Regulations. To assist providers in finding safe harbor regulatory and related commentary, the OIG maintains as part of its website a “Safe Harbor Regulations Archive,”^{13/} which contains 14 separate entries covering the period up to 2002. Importantly, because an arrangement not fitting within one of the narrowly structured safe harbors is not necessarily illegal, a provider must conduct a separate analysis, typically with the assistance of expert fraud and abuse counsel, to determine if the arrangement is lawful.

The breadth of the Anti-Kickback Statute has led to challenges that it is unconstitutionally void for vagueness. In *United States v. Bay State Ambulance and Hosp. Rental Serv., Inc. (“Bay State”)*,^{14/} the First Circuit Court of Appeals rejected such a challenge in which now Judge Nancy Gertner represented the defendants on appeal. In doing so it weighed several factors, citing most importantly the finding that “[t]he unusually high *scienter* requirement mitigates any vagueness. . . .”^{15/}

^{10/} Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35952 (July 29, 1991).

^{11/} S. REP. NO. 100-109, at 27 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 707.

^{12/} Pub. L. No. 100-93, § 14, 101 Stat. 680 (1987).

^{13/} U.S. Department of Health and Human Services, Office of Inspector General, Safe Harbor Regulations Archive, *available at* http://www.oig.hhs.gov/fraud/safeharborregulations_archive.asp (last visited Feb. 8, 2011).

^{14/} 874 F.2d 20 (1st Cir. 1989).

^{15/} *Id.* at 33 (internal quotations omitted).

It is against this background that we see the importance of the change in the intent standard contained in the Patient Protection Act. Section 6402(f)(2) amended the Anti-Kickback Statute by lowering the *scienter* standard required to prove a violation. It states that “a person need not have actual knowledge of [the Anti-kickback Statute] or specific intent to commit a violation of this section.”^{16/} Section 10606(b)(2) of the Patient Protection Act contains an identical amendment of the Health Care Fraud statute.^{17/}

Given the reasoning of the *Bay State* court, this lowered *scienter* standard raises the potential of constitutional infirmity in the Anti-Kickback Statute because health care providers could be convicted without proof of specific intent to violate a law that is steeped in the complexity I described above. When properly understood, this revised *scienter* standard should not undermine the standard of proof for willfulness under *United States v. Bryan* that still requires specific intent, in that the Government must show a defendant knew “the conduct is unlawful.”^{18/} However, a jury instruction that merely quotes the new *scienter* standard could easily lead to conviction without the necessary proof of a guilty state of mind.

The combination of the complex regulatory requirements for health care providers and manufacturers coupled with this loosened *scienter* standard lead inexorably to the conclusion that some providers may be convicted and face similar sentencing outcomes even though they possess fundamentally different characteristics from those of “hardened criminals” who intentionally seek to steal public funds through the Medicare program. The resulting sentencing disparities may be significant, an outcome clearly at odds with some of the basic goals in

^{16/} Codified as 42 U.S.C. § 1320a-7b(h).

^{17/} Codified as 18 U.S.C. § 1347(b).

^{18/} 524 U.S. 184, 196 (1998).

sentencing, to “provide certainty and fairness in sentencing, [and] to avoid unwarranted sentencing disparities.”^{19/} Such disparate treatment may undermine faith in the judiciary.

III. AGGREGATE DOLLAR AMOUNT OF FRAUDULENT BILLS AS PRIMA FACIE EVIDENCE OF LOSS

A. Introduction

Section 10606(a)(2)(B) of Patient Protection Act directs the Commission —

“[To] amend the Federal Sentencing Guidelines and policy statements applicable to persons convicted of Federal health care offenses involving Government health care programs to provide that 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 by the defendant.” (“Aggregate Loss Directive”)

Federal health care offenses include various enumerated crimes such as the Health Care Fraud law and the Anti-Kickback Statute.^{20/} The Commission is proposing to implement this Aggregate Loss Directive by creating a new Application Note section 3(F)(viii) to the Commentary of Sentencing Guideline § 2B1.1, which would read:

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. (Emphasis Added)

^{19/} *Rita v. U.S.*, 551 U.S. 338, 347 (2007) (internal quotations omitted) (*citing* to 28 U.S.C. § 991(b)).

^{20/} 18 U.S.C. § 24(a) states: “As used in this title, the term ‘Federal health care offense’ means a violation of, or a criminal conspiracy to violate--

“(1) section 669, 1035, 1347, or 1518 of this title or section 1128B of the Social Security Act (42 U.S.C. 1320a-7b); or

“(2) section 287, 371, 664, 666, 1001, 1027, 1341, 1343, 1349, or 1954 of this title section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), or section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131), or section 411, 518, or 511 of the Employee Retirement Income Security Act of 1974,[] if the violation or conspiracy relates to a health care benefit program.”

This Aggregate Loss Directive contains two important problems which, if not corrected, could lead to significant miscarriages of justice by causing inappropriately large loss calculations that, in turn, will result in significant increases in incarceration. The first is that, in many health care cases, as a practical matter, it is not always clear what proof the Government needs to present in order to establish the “aggregate dollar amount of fraudulent bills,” and what type of evidence the defendant would then submit in rebuttal. The second, and perhaps more serious problem, is that the Government may seek to turn the Aggregate Loss Directive into a decision rule to decide between competing evidence of actual or intended loss. In other words, I have real concerns that, because of the complexities of health care cases, the standard of “aggregate dollar amount of fraudulent bills” could become the method to decide the amount of intended loss even where defendants have presented substantial rebuttal evidence.

These potential problems are compounded by (a) the possibility, as I discussed earlier, that judges will be asked to sentence individuals who are convicted without proof of a specific intent to violate complicated health care laws; and (b) the related Congressional directive in the Patient Protection Act for significant increases in sentencing loss enhancements based on convictions for Federal health care offenses.^{21/} Under this new loss enhancement rule, the importance of a court’s ultimate determination of loss is magnified.

Because of these significant potential problems with the Aggregate Loss Directive, for the reasons discussed more fully below, I urge the Commission to expand Application Note section 3(F)(viii) by clarifying certain open issues created by the ambiguity in the Aggregate Loss Directive. Specifically, I propose the following additional language:

The aggregate dollar amount of bills submitted to Government health care programs in cases of a conviction for a Federal health care offense may not

^{21/} Patient Protection Act, § 10606(a)(2)(C). *See* proposed Guideline § 2B1.1(b)(8).

necessarily be the same as the “aggregate dollar amount of fraudulent bills.” Aggregate dollar amount of fraudulent bills is defined as the total dollar amount of fraudulent entries on claims that the defendant has submitted or caused to be submitted to Government health care programs; it does not include dollar amounts for valid services actually rendered by the defendant at the appropriate reimbursement rate. In cases where the defendant did not provide any of the services for which reimbursement was claimed, the total amount of the bills is the aggregate dollar amount of the fraudulent bills. In cases where the defendant’s claims for reimbursement include both fraudulent and valid services, or some part of the claim is for valid services, the loss is only the amount of the fraudulently billed portion.

In such cases and where the Government has not presented substantial evidence of the aggregate dollar amount of fraudulent bills to Government health care programs, a defendant is not obligated to present rebuttal evidence, and the burden of persuasion of actual or intended loss remains with the Government. Where the Government has met its initial burden of proof of the aggregate dollar amount of fraudulent bills to Government health care programs, but where the defendant has presented rebuttal evidence establishing that the Government’s evidence is unreliable, for example, by demonstrating the dollar amount of allowable services rendered, the burden of persuasion shifts back to the Government to prove the actual or intended loss by a preponderance of the evidence. The measure of “aggregate dollar amount of fraudulent bills” is not intended to be a decision rule to be used by the court in weighing the evidence to determine loss.

B. Background – The Pre-Sentence Investigative Report And Burden and Standard of Proof

The Aggregate Loss Directive must be seen in the context of the traditional way that proof of loss is put into evidence and the burden and standard of proof of loss that is placed on the Government.

After conviction or a guilty plea, evidence of intended loss is first put before the court through the probation department’s Pre-Sentence Reports (“PSR”).^{22/} Under the Federal Rules of Criminal Procedure, the defendant then has an opportunity to object to the report. The court may accept any undisputed portion of the PSR as a finding of fact.^{23/} The evidence of loss must bear a

^{22/} Fed. R. Crim. P. 32(c)(1)(A), (d).

^{23/} Fed. R. Crim. P. 32(f), (i)(3)(A).

reasonable relation to the actual or intended harm of the offense.^{24/} Loss cannot be based on “guesswork or speculation,” and, similarly, the court cannot merely speculate as to the proper amount of loss.^{25/}

If the Government has presented substantial evidence in support of the PSR, the burden shifts to the defendant to come forward with evidence contradicting the Government’s position, but the ultimate burden of persuasion remains with the Government.^{26/} *United States v. Butler* (“*Butler*”) demonstrates the burden-shifting process that takes place when the Government submits evidence that the defendant rebuts.^{27/} There, the Government sought a sentencing enhancement because Butler was a “career offender.” After the Government proved that the defendant had two prior unconsolidated convictions for armed robbery, the “burden then shifted to [defendant] to persuade the court that the two were related because they were part of a single common scheme or plan.”^{28/}

In any event, at the core of the Commission’s consideration of the Aggregate Loss Directive, as part of the loss calculation a court must credit the value of the services a defendant performed.^{29/}

^{24/} *United States v. Randall*, 157 F.3d 328, 330-31 (5th Cir. 1998).

^{25/} See *United States v. Snyder*, 291 F.3d 1291, 1297 (11th Cir. 2002) (Hill, J., concurring); *United States v. Bracciale*, 374 F.3d 998, 1003 (11th Cir. 2004) (internal quotation marks omitted).

^{26/} See, e.g., *United States v. Blanco*, 888 F.2d 907, 908-09 (1st Cir. 1989); *United States v. Acosta*, 303 F.3d 78, 82 (1st Cir. 2002); see also Roger W. Haines, Jr., Frank O. Bowman, III, & Jennifer C. Woll, *Federal Sentencing Guidelines Handbook: Text And Analysis* 1678-1680 (2010-2011 ed.) (collecting cases).

^{27/} 970 F.2d 1017, 1022 (2d Cir. 1992).

^{28/} *Id.* at 1026-27; see also *United States v. Westbrook*, 986 F.2d 180 (7th Cir. 1993) (defendant had the burden of production to come forward with evidence showing that the PSR allegations were unreliable, and if met, the prosecution bears the final burden of persuasion); *United States v. Levy* 992 F.2d, 1081, 1083 (10th Cir. 1993) (stating that after the Government presented substantial evidence in the presentence report, the defendant must “directly and substantially contradict the Government’s evidence”).

^{29/} U.S. Sentencing Guidelines Manual, § 2B1.1, cmt. n. 3(E)(i); *Jones*, 475 F.3d at 706; *United States v. Sublett*, 124 F.3d 693, 694 (5th Cir.1997).

These principles are not controversial. I repeat them here because they provide important context to help understand the Aggregate Loss Directive. Indeed, seen with these principles in mind, it becomes clear that, while Congress's use of the term "prima facie evidence" is a new concept in the Guidelines, Congress did not intend to change Government's initial or ultimate burden of proof or the standards of evidence. Rather, Congress made a simple statement that, as an initial matter, the Government need only present substantial evidence of the aggregate dollar amount of fraudulent bills submitted to Government health care programs, and once such evidence is presented, a defendant may present rebuttal evidence. The Commission and courts should not read more into this provision.

Nevertheless, even with these limitations understood, significant problems remain with practical application of the Aggregate Loss Directive.

- C. The Aggregate Dollar Amount Of Bills Submitted To Government Health Care Programs In Cases Of A Conviction For A Federal Health Care Offense May Not Necessarily Be The Same As The "Aggregate Dollar Amount Of Fraudulent Bills."

When applied to common fact patterns that arise in actual health care fraud cases, the Aggregate Loss Directive raises two questions: (1) what, specifically, are the "fraudulent billings," and (2) what evidence must a defendant submit to the sentencing court to disprove that the intended loss equals the aggregate dollar amount of the "fraudulent billings." These questions are important because the easiest source of data for the Government to submit in the PSR is the aggregate dollar amounts billed to Government health care programs. But this is not the measure Congress directed to be used, and in health care fraud cases this measure is not necessarily the same as the aggregate dollar amount of fraudulent billings.

The Medicare reimbursement system inherently drives the determination of the loss calculation. The majority of Medicare payments go to hospitals for inpatient and outpatient services and to physicians for services and supplies. Medicare pays hospitals for inpatient services under the Inpatient Prospective Payment System by classifying the service under Diagnostic Related Groups (“DRGs”) and for outpatient services under the Outpatient Prospective Payment System by classifications known as Ambulatory Payment Classification (“APCs”) groups. Physicians are paid under the Physician Fee Schedule using Current Procedural Terminology (“CPT”) codes. When there are fraudulent billings paid under DRGs, APCs and CPT codes, the following general scenarios are possible, which are explained in examples below. First, the entire claim is fraudulent; second, there is one claim that includes valid, payable services, but some part is fraudulent; third, the fraud triggers a different, higher paying DRG, APC or CPT code; fourth, there is separate reimbursement and the fraud can be isolated to that service or procedure, typically a separate CPT code; and fifth, the fraudulent item or service is an input cost to the hospital and Medicare’s payment is unaffected by the fraud.

To better understand these general reimbursement principles and how the loss calculation might work in health care cases, I offer several common scenarios. In each fact pattern below, I assume there has been a conviction for a Federal health care offense. My point in raising these examples is not to have the Commission decide these issues, but to point out that the loss calculation in many health care cases can be difficult, and that the Guidelines should make clear that courts need to avoid shortcuts and weigh the parties’ evidence carefully.

1. *Services not rendered.*

This is the simplest fact pattern. Here the defendant provided no services, and, as a matter of logic, all of the claims to Government health care programs are fraudulent. When

services are not rendered at all, the Government should be able to meet its burden with little difficulty. It is doubtful that Congress created the Aggregate Loss Directive with this fact pattern in mind.

2. *Upcoding.*

In this scenario a health care provider has provided medically necessary services, but has inflated the value of the services by billing at a higher code than is justified. That is, the provider submits a DRG, APC or CPT code that yields a payment rate higher than is due for the actual services rendered. (Below, I discuss a potentially important variation of this offense where the upcoding may involve the submission of a proper billing code along with separate inflated codes.) In this basic type of upcoding case the Government might put on proof asserting that the aggregate amount of the billings submitted to the Government, for example \$1 million, is entirely fraudulent. Under the Aggregate Loss Directive, it is understandable that a court might accept the evidence of the aggregate \$1 million as representing fraudulent billings to the Government, and determine that the Government has met its initial burden.

Or the court could require that the Government prove that some part of the services were valid. In the alternative, it would be up to the defendant to provide rebuttal evidence, for example by submitting evidence that \$900,000 of billing was in fact the value of the services legitimately provided. Such evidence might be presented through expert testimony or otherwise. In essence, in this example, it is the defendant's theory that it/he/she should be credited for the \$900,000 as the value of reasonable services rendered, so that the intended loss is only \$100,000.

3. *Related party rule.*

The Medicare related party rule can operate in a similar manner. This rule applies in situations in which a contractor provides services to a health care provider through a related party. As the *Jones* case stated, the rule is intended “(1) to avoid the payment of a profit factor to the provider through the related organization (whether related by common ownership or control), [and] (2) to avoid payment of artificially inflated costs which may be generated from less than arm’s length bargaining.”^{30/}

In the *Jones* case, Jones and other defendants pled guilty, and the PSR listed the full amount of Medicare’s reimbursement to the hospital for services rendered through the related parties.^{31/} Despite expert evidence at the sentencing hearing showing the value of the services actually rendered by the defendants, the District Court accepted the PSR as evidence regarding the loss, with few adjustments and without crediting the defendants for the value of the services performed. As a result it sentenced the defendants to significant terms of imprisonment. The defendants appealed on the grounds that they should not be held liable for the full amount paid based on their billings.^{32/} The Fifth Circuit reversed, finding, *inter alia*, that the Government failed to meet its burden to demonstrate that defendants performed no services or to determine the amount of profit defendants billed to the hospital that was passed on to the Medicare program.^{33/}

In short, this was a case that took a carefully considered decision by the Fifth Circuit Court of Appeals to clarify that the loss in a Medicare related party case is not the aggregate

^{30/} *Jones*, 475 F.3d at 703.

^{31/} *Id.* at 704.

^{32/} *Id.* at 704-705.

^{33/} *Id.* at 706-707.

billings to Medicare. This case not only helps in our understanding of the proper calculation of the loss enhancement where there are violations of the related party rule, but perhaps as importantly shows the intricacies of Medicare rules.

4. *Medical Devices*

Medical devices are used in every health care setting. In two of their most common uses, they are implanted or used as part of a diagnostic test or procedure. As discussed above, the nature of the Medicare reimbursement methodology – DRGs, APCs or CPT codes – will affect the loss calculation. Unlike reimbursement for drugs which uses National Drug Codes, a provider’s claim for an item or service that involves the use of a medical device does not identify the particular device or brand. Although physicians may implant devices in their offices, a common situation involves a provider billing under a DRG, APC or CPT code for example where the implant is part of a larger inpatient stay, outpatient treatment or office service. The billing process may follow one of three possible scenarios. The hospital may bill a DRG or APC code, which represents a bundle of services provided to a patient, with the implantation included in the “bundle.” Where the services involve the implantation of a medical device, a higher DRG or APC is used. In the second scenario there is discrete reimbursement for the implantation itself, that is, the device is billed separately, typically as a CPT code, from other services provided to the patient. In the third scenario, the medical device is merely an input cost, either as part of a DRG or APC code, or because the device is used to provide a diagnostic test and Medicare is paying for that test, not the device. The first scenario is similar to the upcoding example discussed above. In the second, there are legitimate billings separate from the fraudulent billing, and such legitimate billings, for example for the hospital stay, should not be

part of the loss calculation. In the third example Medicare payment is unaffected by the use of the medical device, and there is no loss.

5. *Kickbacks*

Many health care convictions involve kickbacks, which involve knowing and willful payments to induce referrals. An example of this category of fraud might include a hospital paying illegal fees to a physician in return for referrals of patients for which the hospital bills Medicare and Medicaid. Kickbacks are an unusual economic crime, and in applying the Aggregate Loss Directive, courts will be presented with very difficult questions that are akin to fitting a square peg into a round hole.

The essential problem is that kickbacks are not directly aimed at raiding the Government's fisc, where the amount of loss is central to the crime. Instead, the point of paying a kickback is to give preferential treatment to a person to induce the referral of business. But the service likely would have been provided anyway by someone else or a different device implanted as part of an otherwise medically necessary procedure. It is not an element of the offense that unnecessary services were provided or that there were damages to Federal health care programs, and typically there is no such proof offered by the Government in its case in chief. Therefore, in such circumstances the question is what is the loss to Federal health care programs that is to be proved at sentencing.

To put this question into context, the amount typically paid to the physician, for example for a consulting agreement, is disproportionately small compared to the amounts the hospital may bill for services referred by that physician. It would not be uncommon, for example in the case of a high-referring cardiologist, for a hospital to bill Medicare \$7 million or more over the life of an agreement that is subject to a prosecution.

Congress's incorporation of the Anti-Kickback Statute into the category of Federal health care offenses^{34/} clearly shows that it knew this section of the Guidelines would apply. If Congress had intended that the Government's initial burden of proof could be met simply by submitting the aggregate amount billed to Federal health care programs for the referrals by the physician who is subject to the illegal kickback arrangement – in my example \$7 million - it would have said so clearly without mandating that the Government must show the aggregate amount of “fraudulent bills.”

In the example of kickbacks, the stakes can be enormous. Based on my example of \$7 million in Medicare billings irrespective of the relatively small amount of illegal remuneration paid to the physician, if a court were simply to accept this aggregate amount billed as the intended loss, then, under the increased loss enhancements mandated by the Patient Protection Act, the loss enhancement would be a level 3 increase,^{35/} resulting in a very significant period of incarceration.

I submit that in cases involving illegal kickbacks, Congress did not intend that the Aggregate Loss Directive be used to permit the Government to meet its initial burden of proof of loss simply by submitting evidence of the aggregate amount of Medicare claims submitted by a hospital for patients referred by a physician who was paid illegal kickbacks.

D. The Aggregate Loss Directive Should Not Be Turned Into A Decision Rule

We use the law in society to assist in deciding hard questions. Especially now that, under *United States v. Booker*, the Guidelines are advisory and only one factor for a sentencing court's

^{34/} Patient Protection Act, § 10606(c) (*codified as amended at* 18 U.S.C. § 24(a)).

^{35/} Patient Protection Act, § 10606(a)(2)(C). *See* proposed Guideline § 2B1.1(b)(8).

consideration in imposing a sentence,^{36/} it is essential that the Aggregate Loss Directive not be misunderstood as something more than was intended. This is particularly the case given the intricacies of Medicare and health care law generally, where the Government and defendants may be asking a court to wade through highly technical billing rules to determine the intended loss. In that context, it would not be surprising if the Government were to invite a court to gloss over the part of the Aggregate Loss Directive that says that it is merely a standard for establishing the basis for the Government's prima facie evidence of loss, and ask the court to use this standard as a rule of decision in weighing competing evidence of loss.

It is important to emphasize, therefore, that, once the Government has met its burden, the purpose of the Aggregate Loss Directive ends. At that point, the defendant may present evidence showing the Government's evidence is unreliable or its own theory of loss, and it is then up to the court to use well-established evidentiary rules to determine intended loss.

To ease the burden of courts and provide clarity in the proper application of the Aggregate Loss Directive, I urge the Commission to give more guidance by adopting the language I have suggested above, to be added to the new Application Note section 3(F)(viii) to the Commentary of Sentencing Guideline § 2B1.1.

* * * * *

^{36/} 543 U.S. 220, 245-46 (2005).

Again, thank you for this opportunity to present my views about this important subject. I reserve my right to supplement these statements prior to the close of the comment period on March 21, 2011.

Respectfully submitted,

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