

[United States v. Bane](#)

United States Court of Appeals for the Eleventh Circuit

June 28, 2013, Decided

No. 11-14158

Reporter

720 F.3d 818 *; 2013 U.S. App. LEXIS 13318 **; 24 Fla. L. Weekly Fed. C 407; 2013 WL 3242669

[\(11th Cir. Fla., Jan. 24, 2020\)](#)

UNITED STATES OF AMERICA, Plaintiff
- Appellee, versus BEN BANE, Defendant -
Appellant.

Prior History: **[**1]** Appeal from the United States District Court for the Middle District of Florida. D.C. Docket No. 8:09-cr-00352-VMC-MAP-1.

Subsequent History: US Supreme Court certiorari denied by *Bane v. United States*, 571 U.S. 1114, 134 S. Ct. 835, 187 L. Ed. 2d 694, 2013 U.S. LEXIS 9129 (Dec. 16, 2013)

[United States v. Bane, 2010 U.S. Dist. LEXIS 25098 \(M.D. Fla., Mar. 16, 2010\)](#)

Dismissed by [United States v. Bane, 2014 U.S. Dist. LEXIS 112062 \(M.D. Fla., Aug. 8, 2014\)](#)

Disposition: AFFIRMED IN PART, VACATED IN PART, AND REMANDED.

Post-conviction proceeding at, Motion granted by [Bane v. United States, 2014 U.S. Dist. LEXIS 149313 \(M.D. Fla., Oct. 21, 2014\)](#)

Later proceeding at [United States v. Bane, 2018 U.S. Dist. LEXIS 230477 \(M.D. Fla., Jan. 8, 2018\)](#)

Core Terms

Motion granted by [United States v. Bane, 2018 U.S. App. LEXIS 22957 \(11th Cir. Fla., Aug. 16, 2018\)](#)

oxygen, patients, district court, fine, medically necessary, restitution, sentence, testing, calculation, enhancement, guidelines, portable, pulse, oximetry, statutory maximum, supplemental, kickback, amount of loss, sophisticated, labs, restitution amount, sophisticated-means, laboratories, insurers, offset,

Decision reached on appeal by [United States v. Bane, 2020 U.S. App. LEXIS 2272](#)

sentencing guidelines, restitution order, convicted, quotation, purposes

Case Summary

Procedural Posture

Convicted of conspiracy to commit, and committing, health care fraud and making false claims to the government, defendant appealed his sentence, arguing the U.S. District Court for the Middle District of Florida improperly applied [U.S. Sentencing Guidelines Manual § 2B1.1\(b\)\(1\), \(2\)\(C\), \(9\)\(C\)](#), erred in its restitution amount, and imposed a fine that exceeded the statutory maximum in violation of the [Sixth Amendment](#) right to a jury trial.

Overview

Defendant sold oxygen to be reimbursed by Medicare only if an independent laboratory performed a qualifying test. Under [§ 2B1.1](#), cmt., application n. 3(F)(v)(III), the value of the oxygen was not a credit towards the loss amount. Even those who received needed oxygen, as well as those who paid for it, sustained loss. Payment for the goods was actual loss and the payors were victims under [§ 2B1.1](#), cmt., application n. 1. Because there were 270 victims, a 6-level enhancement was proper under [§ 2B1.1\(b\)\(2\)\(C\)](#). The [§ 2B1.1](#), cmt., application n. 8(B), sophisticated-means

enhancement was proper because the offense involved multiple companies, an intricate paper trail, repetitive coordinated conduct, and steps to conceal the offense. Eighty to 90% of the services provided were medically necessary. Because the victims who paid for medically necessary oxygen paid no more than they would have if the tests had been properly performed, the value of the needed oxygen should have been excluded in the restitution calculation. And, because the maximum fine authorized by the facts the jury found was \$2.5M under [18 U.S.C.S. § 3571\(b\)](#), a \$3M fine, without a jury finding, violated the [Sixth Amendment](#).

Outcome

The order of restitution, and the amount of the fine, were vacated, and those matters were remanded for resentencing. The sentence was otherwise affirmed.

LexisNexis® Headnotes

Criminal Law &
 Procedure > Sentencing > Sentencing
 Guidelines > General Overview

[HNI\[↓\]](#) **Sentencing, Sentencing**
Guidelines

Generally, a convicted defendant's sentence is based on the U.S. Sentencing Guidelines Manual in effect on the date the defendant is sentenced.

Criminal Law &
Procedure > Sentencing > Sentencing
Guidelines > General Overview

[HN2\[↓\]](#) **Sentencing, Sentencing Guidelines**

Related offenses committed in a series will be sentenced together under the U.S. Sentencing Guidelines Manual in effect at the end of the series.

Criminal Law &
Procedure > ... > Appeals > Standards of
Review > Clear Error Review

Governments > Legislation > Interpretati
on

Criminal Law &
Procedure > ... > Appeals > Standards of
Review > De Novo Review

[HN3\[↓\]](#) **Standards of Review, Clear Error Review**

An appellate court reviews the district court's interpretation and application of the U.S. Sentencing Guidelines Manual de novo and its findings of fact for clear error.

Criminal Law &
Procedure > Sentencing > Appeals > Pro
portionality & Reasonableness Review

Evidence > Burdens of
Proof > Allocation

[HN4\[↓\]](#) **Appeals, Proportionality & Reasonableness Review**

The party challenging the sentence bears the burden of establishing that the sentence is unreasonable.

Criminal Law &
Procedure > ... > Sentencing
Guidelines > Adjustments &
Enhancements > General Overview

[HN5\[↓\]](#) **Sentencing Guidelines, Adjustments & Enhancements**

[U.S. Sentencing Guidelines Manual § 2B1.1\(b\)\(1\)](#) increases a defendant's offense level by 20 for crimes involving a loss between \$7,000,001 and \$20,000,000.

Criminal Law &
Procedure > ... > Reviewability > Preser
vation for Review > Abandonment

Criminal Law &
Procedure > Appeals > Procedural
Matters > Briefs

[HN6\[↓\]](#) **Preservation for Review, Abandonment**

A party must specifically and clearly identify a claim in its brief, for instance by devoting a discrete section of its argument to that claim; otherwise, it will be deemed abandoned and its merits will not be addressed.

Criminal Law &
 Procedure > ... > Sentencing
 Guidelines > Adjustments &
 Enhancements > General Overview

Criminal Law & Procedure > ... > Fraud
 Against the Government > False
 Claims > Penalties

Criminal Law & Procedure > ... > Fraud
 Against the Government > False
 Statements > Penalties

[HN7](#) [↓] **Sentencing Guidelines,
 Adjustments & Enhancements**

See [U.S. Sentencing Guidelines Manual § 2B1.1](#), cmt., application n. 3(F)(v)(III).

Criminal Law &
 Procedure > ... > Sentencing
 Guidelines > Adjustments &
 Enhancements > General Overview

Criminal Law & Procedure > ... > Fraud
 Against the Government > False
 Claims > Penalties

Criminal Law & Procedure > ... > Fraud
 Against the Government > False
 Statements > Penalties

[HN8](#) [↓] **Sentencing Guidelines,
 Adjustments & Enhancements**

U.S. Sentencing Guidelines Manual app. C, amend. 617, notes that the purpose of [U.S. Sentencing Guidelines Manual § 2B1.1](#), cmt., application n. 3(F)(v)(III), is to reflect the importance of the regulatory approval

process to public health, safety, and confidence in sentences for regulatory offenses.

Criminal Law &
 Procedure > ... > Sentencing
 Guidelines > Adjustments &
 Enhancements > General Overview

Criminal Law & Procedure > ... > Fraud
 Against the Government > False
 Claims > Penalties

Criminal Law & Procedure > ... > Fraud
 Against the Government > False
 Statements > Penalties

[HN9](#) [↓] **Sentencing Guidelines,
 Adjustments & Enhancements**

[U.S. Sentencing Guidelines Manual § 2B1.1](#), cmt., application n. 3(F)(v)(III), states that, where the approval required is fraudulently obtained, loss shall include the amount paid for the goods with no credit provided for the value of those items or services.

Criminal Law &
 Procedure > ... > Sentencing
 Guidelines > Adjustments &
 Enhancements > General Overview

[HN10](#) [↓] **Sentencing Guidelines,
 Adjustments & Enhancements**

The application notes to the U.S. Sentencing Guidelines Manual define a victim as any person who sustained any part of the actual loss, including individuals, corporations,

companies, associations, firms, partnerships, societies, and joint stock companies. [U.S. Sentencing Guidelines Manual § 2B1.1](#), cmt., application n. 1.

Criminal Law &
Procedure > ... > Sentencing
Guidelines > Adjustments &
Enhancements > General Overview

Governments > Legislation > Interpretation

Criminal Law & Procedure > ... > Fraud
Against the Government > False
Claims > Penalties

Criminal Law & Procedure > ... > Fraud
Against the Government > False
Statements > Penalties

[HN11](#) [↓] **Sentencing Guidelines, Adjustments & Enhancements**

The plain language of [U.S. Sentencing Guidelines Manual § 2B1.1](#), cmt., application n. 3(F)(v), provides that people who pay for goods for which government approval was obtained fraudulently suffer a loss equal to the amount paid for the goods, and are therefore victims. [U.S. Sentencing Guidelines Manual § 2B1.1](#), cmt., application n. 3(F)(v)(III).

Criminal Law &
Procedure > ... > Appeals > Standards of
Review > Clear Error Review

Criminal Law &
Procedure > ... > Sentencing

Guidelines > Adjustments &
Enhancements > Special Skills

[HN12](#) [↓] **Standards of Review, Clear Error Review**

[U.S. Sentencing Guidelines Manual § 2B1.1\(b\)\(9\)\(C\)](#) prescribes a two-level enhancement where the offense involves sophisticated means. The commentary to the Guidelines defines "sophisticated means" as especially complex or especially intricate offense conduct pertaining to the execution or concealment of an offense. [U.S. Sentencing Guidelines Manual § 2B1.1](#), cmt., application n. 8(B). In evaluating whether a defendant qualifies for the enhancement, the proper focus is on the offense conduct as a whole, not on each individual step. Because a district court's conclusion that sophisticated means were involved in an offense is a finding of fact, an appellate court reviews only for clear error.

Criminal Law &
Procedure > ... > Sentencing
Guidelines > Adjustments &
Enhancements > Special Skills

[HN13](#) [↓] **Adjustments & Enhancements, Special Skills**

The [U.S. Sentencing Guidelines Manual § 2B1.1](#) sophisticated-means enhancement is appropriate where the offense involves repetitive and coordinated activities by numerous individuals who used sophisticated technology to perpetrate and attempt to conceal the scheme.

Criminal Law &
 Procedure > ... > Appeals > Standards of
 Review > Clear Error Review

Criminal Law &
 Procedure > ... > Appeals > Standards of
 Review > De Novo Review

Criminal Law &
 Procedure > Sentencing > Restitution

[HN14](#) [↓] **Standards of Review, Clear Error Review**

An appellate court reviews de novo the legality of a restitution order and reviews for clear error factual findings about the specific restitution amount.

Criminal Law & Procedure > Criminal
 Offenses > Fraud > General Overview

Evidence > Burdens of
 Proof > Allocation

Criminal Law &
 Procedure > Sentencing > Restitution

Evidence > Burdens of
 Proof > Preponderance of Evidence

[HN15](#) [↓] **Criminal Offenses, Fraud**

Under [18 U.S.C.S. § 3663A\(c\)](#), a defendant convicted of fraud must pay restitution to victims of the offense. For restitution purposes, a victim is any person or entity directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered. [18 U.S.C.S. §](#)

[3663A\(a\)\(2\)](#). The government bears the burden of proving loss amount by a preponderance of the evidence, and the court must order restitution to each victim in the full amount of each victim's losses. [18 U.S.C.S. § 3664\(f\)\(1\)\(A\)](#).

Criminal Law &
 Procedure > Sentencing > Forfeitures >
 General Overview

Criminal Law &
 Procedure > Sentencing > Restitution

[HN16](#) [↓] **Sentencing, Forfeitures**

Although this might appear to be a double dip, restitution and forfeiture serve different goals.

Criminal Law &
 Procedure > Sentencing > Restitution

[HN17](#) [↓] **Sentencing, Restitution**

Restitution is not intended to provide a windfall for crime victims but rather to ensure that victims, to the greatest extent possible, are made whole for their losses. For this reason, any value of the services or items received by the victim must be offset against the restitution order. And because a defendant's culpability will not always equal the victim's injury, the amount of loss for restitution purposes will not always equal the amount of loss under the U.S. Sentencing Guidelines Manual.

Criminal Law &

Procedure > Sentencing > Restitution

[HN18](#) [↓] **Sentencing, Restitution**

Restitution is intended to put victims in the same position as if the crime had never been committed, not a better one.

Criminal Law &

Procedure > Sentencing > Restitution

[HN19](#) [↓] **Sentencing, Restitution**

Restitution is not intended to punish defendants or to provide a windfall for crime victims, but rather to ensure that victims, to the greatest extent possible, are made whole for their losses.

Criminal Law &

Procedure > Sentencing > Restitution

[HN20](#) [↓] **Sentencing, Restitution**

Appellate courts decline to consider, in the first instance, a proffered explanation and supporting documentary evidence about the value of offsets to restitution. The duty to hear and determine evidentiary issues most appropriately rests in the district court.

Criminal Law &

Procedure > Sentencing > Restitution

Evidence > Burdens of

Proof > Allocation

[HN21](#) [↓] **Sentencing, Restitution**

As part of its burden to prove a restitution

amount, the government must deduct any value that a defendant's fraudulent scheme imparted to the victims. This simply stands for the proposition that the value of what victims received should be offset in the restitution amount, not that it is the government's burden to prove the amount of those offsets. The defendant bears the burden to prove the value of any goods or services he provided to the victims that he claims should not be included in the restitution amount.

Criminal Law &

Procedure > Sentencing > Fines

[HN22](#) [↓] **Sentencing, Fines**

[18 U.S.C.S. § 3571](#) provides two alternative maximum fine amounts. Under [§ 3571\(b\)](#), a defendant may be fined a maximum of \$250,000 for each felony conviction. Alternatively, under [§ 3571\(d\)](#), if any person derives pecuniary gain from the offense, or if the offense results in pecuniary loss to a person other than the defendant, the defendant may be fined not more than the greater of twice the gross gain or twice the gross loss.

Constitutional Law > ... > Fundamental Rights > Criminal Process > Right to Jury Trial

Criminal Law &

Procedure > Sentencing > Imposition of Sentence > Statutory Maximums

[HN23](#) [↓] **Criminal Process, Right to Jury Trial**

A defendant's [Sixth Amendment](#) jury-trial right requires that, other than the fact of a prior conviction, any fact that increases the penalty for a crime beyond the prescribed statutory maximum must be submitted to a jury, and proved beyond a reasonable doubt. The statutory maximum for Apprendi purposes is the maximum sentence a judge may impose solely on the basis of the facts reflected in the jury verdict or admitted by the defendant.

Criminal Law &
 Procedure > ... > Standards of
 Review > Plain Error > Definition of
 Plain Error

[HN24](#) [↓] **Plain Error, Definition of Plain Error**

To establish plain error, a defendant must show there is (1) error, (2) that is plain, (3) that affects substantial rights, and (4) that seriously affects the fairness, integrity, or public reputation of judicial proceedings. The relevant time period for assessing whether an error is plain is at the time of appellate consideration.

Constitutional Law > ... > Fundamental
 Rights > Criminal Process > Right to
 Jury Trial

Criminal Law &
 Procedure > Sentencing > Fines

Criminal Law &
 Procedure > Sentencing > Imposition of
 Sentence > Statutory Maximums

[HN25](#) [↓] **Criminal Process, Right to Jury Trial**

In June 2012, the United States Supreme Court held that the rule of Apprendi applies to the imposition of criminal fines. In other words, a criminal fine is impermissible where it exceeds the amount authorized by either the facts the jury necessarily found to convict the defendant, his prior convictions, or his admissions.

Criminal Law &
 Procedure > ... > Standards of
 Review > Plain Error > Definition of
 Plain Error

[HN26](#) [↓] **Plain Error, Definition of Plain Error**

An appellate court, under plain error review, may only reverse if the error affects the defendant's substantial rights and seriously affects the fairness, integrity, or public reputation of judicial proceedings. A substantial right is affected if the appealing party can show that there is a reasonable probability that there would have been a different result had there been no error.

Criminal Law &
 Procedure > ... > Standards of
 Review > Plain Error > Definition of
 Plain Error

[HN27](#) [↓] **Plain Error, Definition of Plain Error**

Constitutional claims are normally more important than those having only a statutory

or regulatory base for purposes of a plain error that seriously affects the fairness, integrity, or public reputation of judicial proceedings.

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Judges: Before JORDAN and KRAVITCH, Circuit Judges, and ALBRITTON,* District Judge. JORDAN, Circuit Judge, concurring in part and dissenting in part.

Opinion by: KRAVITCH

Opinion

* Honorable W. Harold Albritton, United States District Judge for the Middle District of Alabama, sitting by designation.

[*822] KRAVITCH, Circuit Judge:

Ben Bane was convicted after a jury trial of one count of conspiracy to commit health care fraud, in violation of [18 U.S.C. §§ 287, 371, 1001](#), and [1347](#); five counts of health care fraud, in violation of [18 U.S.C. §§ 2](#) and [1347](#); and four counts of making false claims against the government, in [**2] violation of [18 U.S.C. §§ 2](#) and [287](#). Bane appeals his sentence, arguing that the district court: (1) improperly calculated his guidelines range; (2) improperly calculated the restitution amount; and (3) imposed a fine that exceeded the statutory maximum. After careful review, and with the benefit of oral argument, we affirm in part, vacate in part, and remand.

I.

This is a Medicare and Medicaid fraud¹ case arising out of Bane's ownership and operation of two companies, Bane Medical Services (BMS) and Oxygen & Respiratory, Inc. (ORT). BMS and ORT provided durable medical equipment, including portable oxygen, to Medicare patients. Medicare reimburses providers of portable oxygen for up to 80 percent of the allowable charge for this equipment, with patients and/or supplemental insurers covering the remaining 20 percent. To qualify for reimbursement, equipment providers must ensure the oxygen is medically necessary by sending patients to an independent laboratory for pulse oximetry testing. In this case, from January 2001 to December 2004,

¹ Because the analysis for all relevant issues is the same for Medicare and Medicaid, we refer to both as Medicare for the sake of simplicity.

instead of referring patients to independent labs, BMS and ORT, at Bane's [*823] direction, conducted the testing themselves and falsely represented to Medicare [**3] that they used independent labs. Bane recruited the help of two companies that were authorized to perform pulse oximetry tests. Bane's employees sent the results of tests BMS and ORT conducted to these labs, and the lab employees stamped the results to make it appear as if they had performed the tests. Bane also falsified test results and doctors' signatures and, when the government began investigating, directed his son to delete hard drives and destroy computers.

Before sentencing, a probation officer prepared Bane's Presentence Investigation Report (PSI), which calculated a base offense level of 6 under the sentencing guidelines.² U.S.S.G. §§ 2B1.1(a)(2), 3D1.2(d). The PSI calculated the estimated loss to Medicare, Medicaid, supplemental insurers, and patients was between \$7,000,001 and \$20,000,000 and

accordingly applied a 20-level increase. *Id.* § 2B1.1(b)(1). The PSI also included a 6-level increase because Bane's fraud had 270 victims — Medicare, Medicaid, 109 supplemental insurance companies, and 159 patients. *Id.* § 2B1.1(b)(2)(C). And the [**4] PSI applied a 2-level sophisticated-means enhancement because the offense involved four different corporations and "required that BMS employees create an intricate daily paper trail to mask the fraud." *Id.* § 2B1.1(b)(9)(C). With additional increases for his leadership role, production of an unauthorized access device, and obstruction of justice, Bane's resulting total offense level was 42. With Bane's criminal history category of I, this initially produced a guidelines range of 360 months' to life imprisonment. Because the statutory maximum he could receive was 360 months, however, that became his guidelines sentence. *See id.* § 5G1.1(a) & cmt. (n.1). The PSI also noted that restitution was mandatory under 18 U.S.C. § 3663A and calculated the statutory maximum fine as twice the gross loss under 18 U.S.C. § 3571(d).

Bane filed numerous objections to the PSI. As relevant here, he objected to the PSI's loss and restitution calculations because they included the value of oxygen that was medically necessary and actually provided. He also argued the victim calculation was incorrect for a similar reason — specifically, that patients who received medically necessary oxygen and supplemental insurers that paid co-pays for it were not victims. And he contended that the sophisticated-means enhancement was

²All references in this opinion are to the November 2010 version of the guidelines manual because that was the version in effect on the date Bane was sentenced. *See United States v. Bailey*, 123 F.3d 1381, 1403 (11th Cir. 1997) (HNI[↑]) "Generally, a convicted defendant's sentence is based on the United States Sentencing Commission Guidelines Manual in effect on the date the defendant [**5] is sentenced." (internal quotation marks omitted)). Bane contends that using this version violates the Ex Post Facto Clause because November 2001 and 2003 amendments increased his guidelines level. But because Bane's criminal conduct ended in 2004, after those amendments took effect, this argument is foreclosed by circuit precedent. *See id. at 1404-05* (HN2[↑]) "[R]elated offenses committed in a series will be sentenced together under the Sentencing Guidelines Manual in effect at the end of the series."). Bane does not contend that using the 2004 manual, which was applicable when his conduct ended, instead of the 2010 manual, would change the result. Hence, using the 2010 manual is proper. *See id. at 1403*.

improper **[**6]** because the offense did not involve sophisticated or complex conduct.

At sentencing, the district court overruled Bane's objections to the PSI. The court made minor adjustments to the restitution calculation and maximum fine amount, increasing them to \$7,031,050.68 and \$14,062,101.36, respectively. Despite **[*824]** this, the district court noted that several factors supported a substantial downward variance from the guidelines range. Most significantly, the district court found that a high percentage of the patients actually needed oxygen, estimating that the oxygen BMS and ORT provided was medically necessary for 80 to 90 percent of patients.

Bane asked for a four-year sentence, but the district court opined that would be much too lenient. Instead, the court sentenced Bane to 151 months' imprisonment, a downward variance of 209 months from his guidelines sentence. It also ordered Bane to pay \$7,031,050.68 in restitution and a \$3 million fine. This is Bane's appeal.

II.

Bane first contends that his sentence is procedurally unreasonable because the district court incorrectly calculated his guidelines range. Specifically, he argues the district court erred by: (1) applying a 20-level enhancement **[**7]** for a loss between \$7,000,001 and \$20,000,000 that improperly included the value of medically necessary oxygen that was actually provided; (2) imposing a 6-level increase for an offense involving more than 250 victims because people who received

medically necessary oxygen were not victims; and (3) imposing a 2-level sophisticated-means enhancement because the offense conduct was not sophisticated.

[HN3](#)^[↑] We review the district court's interpretation and application of the sentencing guidelines *de novo* and its findings of fact for clear error. [United States v. Ellisor, 522 F.3d 1255, 1273 n.25 \(11th Cir. 2008\)](#). [HN4](#)^[↑] "The party challenging the sentence bears the burden of establishing that the sentence is unreasonable." [United States v. Willis, 649 F.3d 1248, 1258 \(11th Cir. 2011\)](#). We address Bane's specific challenges in turn.

A.

Bane first challenges his 20-level loss enhancement. [HN5](#)^[↑] [Section 2B1.1\(b\)\(1\)](#) of the guidelines increases a defendant's offense level by 20 for crimes involving a loss between \$7,000,001 and \$20,000,000. The district court included this 20-level increase in its guidelines calculation, finding the loss caused by Bane's offenses exceeded \$7 million. Bane objected that the loss amount **[**8]** should not include the value of oxygen provided that was in fact medically necessary for patients. On appeal, he argues that the district court erred in rejecting his contention and including the 20-level enhancement.³

³ Bane does not meaningfully argue that, if the value of medically necessary services is properly counted as loss, the district court's loss figure is otherwise incorrect. We therefore deem abandoned any other challenge to the district court's loss finding. See [Zhu v. U.S. Att'y Gen., 703 F.3d 1303, 1316 n.3 \(11th Cir. 2013\)](#) ([HN6](#)^[↑] "A party must specifically and clearly identify a claim in its brief, for instance by devoting a discrete section of its argument to that claim; otherwise, it will be deemed abandoned and its merits will not be addressed." (alteration and internal quotation marks omitted)).

We are unpersuaded by this argument. [Application Note 3\(F\)\(v\)](#) provides:

[HN7](#) [↑] In a case involving a scheme in which . . . goods for which regulatory approval by a government agency was required but not obtained, or was obtained by fraud, loss shall include the amount paid for the property, services or goods transferred, rendered, or misrepresented, *with no credit provided for the value [**9] of those items or services.*

[U.S.S.G. § 2B1.1, cmt. \(n.3\(F\)\(v\)\(III\)\)](#) (emphasis added).⁴ Bane sold goods — portable oxygen — for which Medicare [**825] agreed to pay only if an independent laboratory performed a qualifying pulse oximetry test. Bane obtained that approval by fraudulently representing that this prerequisite had been satisfied, when in fact it had not.⁵ The

⁴We do not accept Bane's assertion that this application note is inapplicable. He cites [United States v. Crandall, 525 F.3d 907, 912-13 \(9th Cir. 2008\)](#) for support, but that case merely stands for the proposition that real property is not a "good" within the application note's meaning. Because oxygen is not real property, [Crandall](#) is inapposite.

⁵The dissent contends that [Application Note 3\(F\)\(v\)\(III\)](#) applies only to cases in which the [**10] good in question cannot be lawfully introduced to the market without prior government approval. We respectfully disagree. Neither the application note's plain language nor any of our sister circuits have interpreted it in this limited way. See, e.g., [United States v. Proserpi, 686 F.3d 32, 43-44 \(1st Cir. 2012\)](#) (applying [Application Note 3\(F\)\(v\)\(III\)](#) where non-specification concrete was used in a government construction project even though concrete requires no regulatory approval to be placed on the market). Crediting Bane for the oxygen he provided after fraudulently certifying that patients qualified for Medicare reimbursements would, in our view, undermine the emphasis on the integrity of the regulatory approval process reflected in the Sentencing Commission's inclusion of this application note. See [HN8](#) [↑] [U.S.S.G. Amend. 617, app. C, Vol. II, at 184](#) (noting that the purpose of [Application Note 3\(F\)\(v\)\(III\)](#) is to reflect "the

application note instructs that, in calculating loss for guidelines purposes, Bane does not receive credit for the value of this oxygen. Hence, even those patients who received medically necessary oxygen, as well as the supplemental insurers who paid for it, sustained loss under the guidelines. Therefore, the district court correctly imposed a 20-level enhancement for loss.⁶ See *id.* [§ 2B1.1\(b\)\(1\)](#).

B.

Bane next challenges his 6-level victims' enhancement. [HN10](#) [↑] The application notes to the sentencing guidelines define a victim as "any person who sustained any part of the actual loss," including

importance of the regulatory approval process to public health, safety, and confidence" in sentences for regulatory offenses); *cf.* [United States v. Canova, 412 F.3d 331, 352 \(2d Cir. 2005\)](#) ("To the extent . . . the tests performed . . . were as clinically sound as [**11] the tests required by Medicare, this fact does not mean that the government sustained no loss from the charged fraud. . . . When a party fraudulently procures payment for goods or services by representing that they were produced or provided according to certain specifications, it is not the task of a sentencing court to second-guess the victim's judgment as to the necessity of those specifications.").

⁶Both Bane and the dissent assert that [United States v. Medina, 485 F.3d 1291 \(11th Cir. 2007\)](#), requires medically necessary services to be excluded from the actual loss amount in Medicare cases. But [Medina](#) is distinguishable. First, [Medina](#) did not even discuss [Application Note 3\(F\)\(v\)\(III\)](#), so we question whether it was properly presented to the panel and, as a result, whether it should inform our decision about the note's application in this case. Moreover, [Medina](#) was a kickback case, in which the fraud involved the disbursement of funds Medicare had already paid. Bane's conduct, by contrast, involved an *ex ante* misrepresentation about compliance with the medical procedures necessary to qualify in the first place for Medicare-provided oxygen. *Id.* at 1295-96. Thus, unlike the defendants [**12] in [Medina](#), Bane's fraud directly affected the approval process, thereby directly implicating [Application Note 3\(F\)\(v\)](#). See [HN9](#) [↑] [U.S.S.G. § 2B1.1, cmt. \(n.3\(F\)\(v\)\(III\)\)](#) (stating that, where the "approval . . . required" is fraudulently obtained, "loss shall include the amount paid for the . . . goods . . . with no credit provided for the value of those items or services" (emphasis added)).

"individuals, corporations, companies, associations, firms, partnerships, societies, and joint stock companies." *Id.* [§ 2B1.1, cmt. \(n.1\)](#). Bane does not dispute that patients who received portable oxygen equipment they did not need were victims. Rather, he claims that patients and supplemental insurance companies that paid for medically [*826] necessary oxygen were not victims.⁷ But this argument fails for the same reasons we previously explained, namely that actual loss includes the amount paid for goods without any credit given for those goods. *See id.* [§ 2B1.1, cmt. \(n.3\(F\)\(v\)\(III\)\)](#). Thus, payment for the goods was actual [**13] loss and the payors were victims under the guidelines. *See id.* [§ 2B1.1 cmt. \(n.1\)](#). Bane does not dispute the district court's factual finding that there were 159 patients and 109 supplemental insurers who paid for oxygen for which he fraudulently obtained approval. Medicare and Medicaid were also indisputably victims. Because there were 270 victims in total, the district court correctly imposed a 6-level enhancement for an offense involving more than 250 victims. *See id.* [§ 2B1.1\(b\)\(2\)\(C\)](#).

C.

Bane also contends that the district court erred [**14] in imposing the sophisticated-

⁷Bane also contends these patients and supplemental insurers were not victims because they did not specifically condition payment on independent labs performing the pulse oximetry tests. Accepting this argument would require us to hold that, to be a victim of fraud, an individual or entity is required to explicitly condition payment on the absence of fraud. And it ignores [HNI1\[↑\]](#) the plain language of [Application Note 3\(F\)\(v\)](#), which provides that people who pay for goods for which government approval was obtained fraudulently suffer a loss equal to "the amount paid for the . . . goods," and are therefore victims. [U.S.S.G. § 2B1.1, cmt. \(nn.1, 3\(F\)\(v\)\(III\)\)](#).

means enhancement in his guidelines calculation. Specifically, Bane contends that his offenses involved only one simple misrepresentation, namely that an independent laboratory had conducted the pulse oximetry testing necessary to qualify patients for Medicare reimbursements for oxygen.

[HNI2\[↑\]](#) [Section 2B1.1\(b\)\(9\)\(C\)](#) of the guidelines prescribes a two-level enhancement where the offense involves sophisticated means. The commentary to the guidelines defines "sophisticated means" as "especially complex or especially intricate offense conduct pertaining to the execution or concealment of an offense." *Id.* [§ 2B1.1, cmt. \(n.8\(B\)\)](#). In evaluating whether a defendant qualifies for the enhancement, the proper focus is on the offense conduct as a whole, not on each individual step. *See United States v. Barrington, 648 F.3d 1178, 1199 (11th Cir. 2011)* ("Each action by a defendant need not be sophisticated in order to support this enhancement."). Because a district court's conclusion that sophisticated means were involved in an offense is a finding of fact, we review only for clear error. *Id.*

The district court determined that the sophisticated-means enhancement was warranted [**15] because the offense involved multiple corporations, required BMS employees to "create an intricate daily paper trail to mask the fraud," involved "repetitive coordinated conduct," and involved steps to conceal the offense. We cannot say this finding is clearly erroneous. Bane recruited two certified pulse oximetry testing labs to participate in the scheme. He

installed pulse oximetry testing software on BMS's computers and used a false name and address to conceal the fact that the software was registered to BMS. His employees then sent test results conducted using that software to the labs. The labs stamped the tests Bane's companies conducted to create the illusion that an independent entity had conducted the testing. Bane also falsified some test results to make it appear as if patients needed oxygen even when they did not, falsified certificates of medical necessity that were submitted to Medicare, forged doctors' signatures on certificates of medical necessity, [*827] created false reports to substantiate the false test results, and, after the government began to investigate, ordered his son to delete hard drives and destroy computers to conceal the crimes. In short, Bane's offenses involved [*16] repetitive, coordinated conduct designed to allow him to execute his fraud and evade detection. On these facts, the district court did not clearly err in imposing the sophisticated-means enhancement. *See id.* (holding that [HN13](#)[↑] the sophisticated-means enhancement is appropriate where the offense "involve[s] repetitive and coordinated activities by numerous individuals who used sophisticated technology to perpetrate and attempt to conceal the scheme"); *cf. United States v. Clarke*, 562 F.3d 1158, 1166 (11th Cir. 2009) ("For purposes of the sophisticated means enhancement, we see no material difference between concealing income and transactions through the use of third-party accounts . . . and using a corporate shell or a fictitious entity to hide assets.").

III.

Bane next challenges the district court's order of restitution. [HN14](#)[↑] We review *de novo* the legality of a restitution order and review for clear error factual findings about the specific restitution amount. *United States v. Foley*, 508 F.3d 627, 632 (11th Cir. 2007). [HN15](#)[↑] Under *18 U.S.C. § 3663A(c)*, a defendant convicted of fraud must pay restitution to victims of the offense. For restitution purposes, a victim is any "person [or entity] directly [*17] and proximately harmed as a result of the commission of an offense for which restitution may be ordered." *Id.* § *3663A(a)(2)*. The government bears the burden of proving loss amount by a preponderance of the evidence, and the court must "order restitution to each victim in the full amount of each victim's losses." *Id.* § *3664(f)(1)(A)*.

Bane argues that the court should not have included the amounts Medicare, patients, and supplemental insurers paid for medically necessary oxygen his companies actually provided in the amount of restitution he was required to pay.⁸ We agree.

[HN17](#)[↑] "Restitution is not intended to provide a windfall for crime victims but rather to ensure that victims, to the greatest

⁸ Bane also argues that the restitution order should have been offset by the amount he agreed to forfeit to the government because otherwise the portion of restitution paid to Medicare and Medicaid would constitute a double-recovery. This argument is foreclosed by circuit precedent. *See United States v. Hoffman-Vaile*, 568 F.3d 1335, 1344 (11th Cir. 2009) ([HN16](#)[↑] "Although this might appear to be a double dip, restitution and forfeiture serve different goals." (alteration and internal quotation marks omitted)).

[**18] extent possible, are made whole for their losses." United States v. Huff, 609 F.3d 1240, 1249 (11th Cir. 2010) (internal quotation marks omitted). For this reason, "any value of the services or items received by the victim . . . must be offset against the restitution order." Id. at 1248. And "because a defendant's culpability will not always equal the victim's injury," the amount of loss for restitution purposes will not always equal the amount of loss under the sentencing guidelines. Id. at 1247 (alteration and internal quotation marks omitted); see also United States v. Germosen, 139 F.3d 120, 130 (2d Cir. 1998) ("Of course, an amount-of-loss calculation for purposes of sentencing does not always equal such a calculation for restitution.").

We have never squarely addressed whether a district court should include the value of medically necessary goods a defendant provided as part of the restitution amount outside of the health-care kickback context. In kickback cases, in which a wrongdoer refers a patient to an authorized [*828] Medicare provider in exchange for a portion of the provider's Medicare reimbursement, we have held that the proper measure of restitution is the amount of the kickbacks [*19] received, not the total amount billed to Medicare. *E.g.*, United States v. Vaghela, 169 F.3d 729, 736 (11th Cir. 1999). In other words, restitution in kickback cases is not based on the full value of the goods or services patients received. *Cf. id.* ("[W]e must assume that the loss suffered by [Medicare] is an amount equivalent to the amount it paid . . . *in excess of the value of services rendered.*" (emphasis added)).

The government argues that kickback cases are distinguishable. We disagree. The only distinguishing factor between this case and a kickback case is the particular misrepresentation made to Medicare (here, that an independent lab performed a test and, in a kickback case, that no kickbacks were paid). We see no reason why that distinction should dictate that the value of medically necessary goods that were actually provided should be offset in the restitution amount for one kind of case but not the other.

Moreover, failing to offset the amounts paid for those goods from the restitution amount would be inconsistent with the purpose of restitution because it would give a windfall to victims who received goods they actually needed in the form of both the goods and what they [*20] paid for them. And Medicare, Medicaid, and supplemental insurers would get back funds they would have expended even absent Bane's fraud. As our case law makes clear, HN18 [↑] restitution is intended to put victims in the same position as if the crime had never been committed, not a better one. Huff, 609 F.3d at 1249; see also United States v. Cutter, 313 F.3d 1, 7 (1st Cir. 2002) ("[R]estitution should not be ordered if the loss would have occurred regardless of the defendant's misconduct underlying the offense of conviction.").

At sentencing, the district court found that 80 to 90 percent of the services Bane provided were medically necessary. The government does not refute this finding nor suggest that the pulse oximetry tests were inaccurate or improperly performed.

Because the victims who paid for medically necessary oxygen paid no more than they would have if the tests had been performed by an independent entity, the only purpose behind restitution of those amounts would be to punish Bane, which is not a proper basis for a restitution award. *United States v. Bowling*, 619 F.3d 1175, 1187 (10th Cir. 2010) (HN19[↑]) "Restitution is not intended to punish defendants or to provide a windfall for crime [**21] victims, but rather to ensure that victims, to the greatest extent possible, are made whole for their losses." (internal quotation marks omitted)).

We therefore hold that the district court erred when it failed to exclude the value of medically necessary goods victims actually received in its restitution calculation. Because the restitution schedule on which the district court relied does not distinguish between medically necessary and unnecessary oxygen, we vacate the district court's order of restitution and remand for recalculation of the restitution amount. On remand, Bane must offer evidence about what goods or services he provided that were medically necessary and the value of them to receive an offset.⁹ [*829] *See, e.g.,*

United States v. Bryant, 655 F.3d 232, 254 (3d Cir. 2011) (emphasizing that the defendant has the burden of establishing offsets to restitution because he is in the best position to know the value of the legitimate goods or services provided to his victims); *United States v. Elson*, 577 F.3d 713, 734 (6th Cir. 2009) (same); *United States v. Sheinbaum*, 136 F.3d 443, 449 (5th Cir. 1998) ("Logically, the burden of proving an offset should lie with the defendant.").¹⁰

IV.

Bane next argues that the \$3 million fine the district court imposed violated the Supreme Court's decision in *Apprendi v. New Jersey*, 530 U.S. 466, 120 S. Ct. 2348, 147 L. Ed. 2d 435 (2000), because it exceeded the statutory maximum without a jury finding regarding the amount of the loss. Bane was sentenced under HN22[↑] 18 U.S.C. § 3571, which provides two alternative maximum fine amounts. Under § 3571(b), a defendant may be fined a maximum of \$250,000 for each felony conviction. Alternatively, under § 3571(d), "[i]f any person derives pecuniary gain from the offense, or if the offense results in

⁹The [**22] government argues that the evidence Bane offered at sentencing is insufficient to establish medical necessity and that the district court's restitution order is therefore not erroneous. But the district court ruled that medical necessity was not a basis for reducing the amount of restitution. It did not find one way or the other whether the evidence Bane offered established medical necessity. Remand is therefore necessary so the district court can consider this evidence in the first instance, along with any other evidence Bane or the government may present at resentencing, to determine the value of medically necessary goods or services provided. *See United States v. Ruff*, 420 F.3d 772, 776 (8th Cir. 2005) (HN20[↑]) "We decline to consider, in the first instance, the proffered explanation and supporting documentary evidence [about the value of offsets to restitution]. The duty to hear and determine

evidentiary issues most appropriately rests in the district court.").

¹⁰Bane contends that our decision in *Huff* establishes that the government bears the burden of proving offsets to restitution. But *Huff* merely states in dicta: HN21[↑] "As part of its burden to prove a restitution amount, the government must [**23] deduct any value that a defendant's fraudulent scheme imparted to the victims." 609 F.3d at 1247 (alteration and internal quotation marks omitted). This simply stands for the proposition that the value of what victims received should be offset in the restitution amount, as we explain above, not that it is the government's burden to prove the amount of those offsets. The defendant bears the burden to prove the value of any medically necessary goods or services he provided that he claims should not be included in the restitution amount.

pecuniary loss to a person other than the defendant, the defendant may be fined not more than the **[**24]** greater of twice the gross gain or twice the gross loss"

Bane does not dispute that the court could have ordered him to pay a \$2.5 million fine under [§ 3571\(b\)](#), \$250,000 for each of his ten felony convictions. The district court, however, calculated the statutory maximum fine under [§ 3571\(d\)](#) as \$14,062,101.36, reasoning that this figure was equivalent to twice the \$7,031,050.68 gross loss the court found resulted from the offense. The district court then imposed a \$3 million fine. But the jury did not find the \$7,031,050.68 loss amount on which the court's statutory maximum calculation was based.

Apprendi held that [HN23](#)^[↑] a defendant's [Sixth Amendment](#) jury-trial right requires that, "[o]ther than the fact of a prior conviction, any fact that increases the penalty for a crime beyond the prescribed statutory maximum must be submitted to a jury, and proved beyond a reasonable doubt." [530 U.S. at 490](#). "[T]he statutory maximum for *Apprendi* purposes is the maximum sentence a judge may impose solely on the basis of the facts reflected in the jury verdict or admitted by the defendant." [Blakely v. Washington, 542 U.S. 296, 303, 124 S. Ct. 2531, 159 L. Ed. 2d 403 \(2004\)](#) (internal quotation marks omitted).

[*830] Because Bane did not raise **[**25]** his *Apprendi* argument before the district court, we review only for plain error. [United States v. Underwood, 446 F.3d 1340, 1344 \(11th Cir. 2006\)](#). [HN24](#)^[↑] To

establish plain error, Bane must show there is (1) error, (2) that is plain, (3) that affects substantial rights, and (4) that seriously affects the fairness, integrity, or public reputation of judicial proceedings. [Johnson v. United States, 520 U.S. 461, 466-67, 117 S. Ct. 1544, 137 L. Ed. 2d 718 \(1997\)](#). The relevant time period for assessing whether an error is plain is "at the time of appellate consideration." [Henderson v. United States, 133 S. Ct. 1121, 1130, 185 L. Ed. 2d 85 \(2013\)](#).

When Bane was sentenced, our sister circuits were split about whether *Apprendi* applied to criminal fines, and we had not decided the issue. But [HN25](#)^[↑] in June 2012, after Bane's sentencing, the Supreme Court held that "the rule of *Apprendi* applies to the imposition of criminal fines." [Southern Union Co. v. United States, 132 S. Ct. 2344, 2357, 183 L. Ed. 2d 318 \(2012\)](#). In other words, a criminal fine is impermissible where it exceeds the amount authorized by either the facts the jury necessarily found to convict the defendant, his prior convictions, or his admissions. *See id.*

Because the jury convicted Bane of ten felonies, the maximum **[**26]** fine amount authorized by the facts the jury found was \$2,500,000. *See* [18 U.S.C. § 3571\(b\)](#). The imposition of a \$3 million fine, without a jury finding, was therefore error because, under *Apprendi*, it violated Bane's [Sixth Amendment](#) jury-trial guarantee. *See* [Southern Union, 132 S. Ct. at 2357; Apprendi, 530 U.S. at 490](#). And because the error was made plain during the pendency of the appeal, we may notice it, provided it

meets the additional requirements for plain error review. See Henderson, 133 S. Ct. at 1130-31.

Specifically, HN26 [↑] we may only reverse if the error affects Bane's substantial rights and seriously affects the fairness, integrity, or public reputation of judicial proceedings. See Johnson, 520 U.S. at 467. "A substantial right is affected if the appealing party can show that there is a reasonable probability that there would have been a different result had there been no error." United States v. Bennett, 472 F.3d 825, 831-32 (11th Cir. 2006). Here, because the fine the district court imposed exceeded the maximum amount constitutionally permissible under *Apprendi* and *Southern Union*, Bane has demonstrated a reasonable probability of a different result. Had the district court applied **27 *Apprendi*'s rule to criminal fines, the court would have been required to either impose a fine no greater than \$2.5 million or instruct the jury to find a loss amount. The error therefore affected Bane's substantial rights. See *id.*

And we have little trouble concluding that the error seriously affects the fairness, integrity, or public reputation of judicial proceedings. We have previously held that a district court's improper characterization of a prior conviction as a serious drug offense, so that the statutory maximum penalty for the defendant's offense increased, satisfies this requirement. See United States v. Sanchez, 586 F.3d 918, 930 (11th Cir. 2009). Here, the district court's error seriously affects the fairness, integrity, or public reputation of judicial proceedings at least as much. In *Sanchez*, the error was a

statutory one. Id. at 929-30. By contrast, the error in this case affected Bane's constitutional right to a jury trial, an interest we guard more closely. See Stinson v. Hornsby, 821 F.2d 1537, 1540 (11th Cir. 1987) (HN27 [↑] "Constitutional claims [are] normally more important than *831 those having only a statutory or regulatory base" (internal quotation marks omitted)). **28 We therefore vacate the district court's imposition of a \$3 million fine and remand for resentencing with respect to the fine amount.¹¹

V.

For the foregoing reasons, we vacate the district court's order of restitution, as well as its imposition of a \$3 million fine, and remand for resentencing in a manner consistent with this opinion. In all other respects, we affirm Bane's sentence.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED.

Concur by: JORDAN (In Part)

Dissent by: JORDAN (In Part)

Dissent

JORDAN, Circuit Judge, concurring in part

¹¹ Because we hold that it was error for the court to base its statutory maximum fine under § 3571(d) on a judicial factfinding of the loss caused by Bane's crime, we do not consider Bane's alternative argument that the district court erred in including medically necessary oxygen Bane actually provided as part of the loss.

and dissenting in part.

Except as to the discussion and conclusion about the calculation of loss under the Sentencing Guidelines, I join the majority opinion. With respect to loss, the issue is a close one, but on balance I conclude that the special rule set forth in [Application Note 3\(F\)\(v\)\(III\) to U.S.S.G. § 2B1.1](#) does not apply under the facts presented.

In order to ensure **[**29]** that they have a medical need for portable oxygen, Medicare requires that patients undergo pulse oximetry testing at independent laboratories. Pulse oximetry, "a routine and non-invasive means of testing oxygen levels in the blood," [Doctors Nursing & Rehab. Ctr. v. Sebelius](#), 613 F.3d 672, 675 (7th Cir. 2010), consists of a monitor receiving and interpreting a signal from a sensor attached to a finger or ear on the patient's body.¹ As the majority explains, the health care fraud in this case consisted of having the pulse oximetry tests done by Mr. Bane's own companies — not by independent laboratories — and then representing to Medicare that the testing had been performed by independent entities.

Insofar as Mr. Bane billed Medicare \$69,814.14 for the pulse oximetry tests themselves, that entire sum was properly counted as loss under the Sentencing Guidelines. After all, Medicare paid for the tests believing that they had been conducted by independent laboratories. **[**30]** See

[United States v. Curran](#), 525 F.3d 74, 82 (1st Cir. 2008) ("Thus, even supposing such services as the 'full body assessment' provided some naturopathic benefit, or at least were believed by some clients to have done so, no credit is available under the Guidelines for them where Curran was falsely posing to be a licensed medical doctor at the time.").

But Mr. Bane was also held responsible under [§ 2B1.1](#) for the over \$7 million billed to Medicare for the portable oxygen provided to the patients who underwent the pulse oximetry testing, and it is here that I part company with the majority. The district court found at sentencing that for 80-90% of the Medicare patients portable oxygen was medically necessary, see Sentencing Transcript at 211, and in my view the amounts billed for the portable oxygen provided to these patients must be offset (i.e., deducted) when determining loss.

[*832] [Application Note 3\(E\)\(i\)](#), entitled "Credits Against Loss," provides that "[l]oss shall be reduced by . . . the fair market value of the property returned and the services rendered, by the defendant . . . to the victim before the offense was detected." Given that 80-90% of the patients had an undeniable medical **[**31]** need for portable oxygen — notwithstanding the fact that the pulse oximetry testing was not done by independent laboratories — it seems to me that language of [Application Note 3\(E\)\(i\)](#) applies. "Value may be rendered even amid fraudulent conduct," [United States v. Blitz](#), 151 F.3d 1002, 1012 (9th Cir. 1998) (internal quotation marks and citation omitted), and a "straightforward application

¹ See generally [Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP](#), 592 F.3d 991, 994 (9th Cir. 2010); Merriam-Webster Online Medical Dictionary, www.merriam-webster.com/medical/pulse+oximetry (last visited June 18, 2013).

of the [G]uidelines [i.e., [Application Note 3\(E\)\(i\)](#)] requires discounting the actual loss by the value of the [portable oxygen] dispensed" to those patients who needed it. [United States v. Klein, 543 F.3d 206, 214 \(5th Cir. 2008\)](#) (holding that, even though doctor improperly billed for administration of injections that were self-administered by patients, the loss amount under the Guidelines had to be reduced by the value of the drugs themselves). *See also United States v. Medina*, 485 F.3d 1291, 1304 (11th Cir. 2007) (concluding, in health care fraud case involving the payment of kickbacks, that loss under the Guidelines could not include amounts paid for items or services that were medically necessary).²

I do not think [Application Note 3\(F\)\(v\)\(III\)](#), which constitutes a "Special Rule," controls with respect to the portable oxygen which the district court found was medically necessary. The portable oxygen provided to the patients did not constitute "goods for

which regulatory approval by a government agency was required but not obtained." Simply put, Medicare did not require any regulatory approval by any government agency before claims could be submitted for portable oxygen. [Application Note 3\(F\)\(v\)\(III\)](#) is best seen as governing special cases in which items or goods or services (e.g., drugs or medical devices) are sold or provided or placed on the market without obtaining the required prior approval of a government agency (e.g., the Food and Drug Administration). *See, e.g., United States v. Goldberg, 538 F.3d 280, 290 (3rd Cir. 2008)* ("F.D.A. approval was required for these drugs to be sold. . . There was no such approval because the drugs were misbranded. This means Goldberg was selling goods for which regulatory approval was required but not obtained.").

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²Unlike the majority, I do not read our decision in *Medina* as merely resting on the district court's **[**32]** failure to make specific findings as to loss. Although we did ultimately remand for such specific findings, we first ruled that amounts paid for items or services that were medically necessary could not be considered in determining the loss suffered by Medicare: "As to Guerra, the total amount billed to Medicare on the health care fraud claims that we affirm is only \$11,820. We find these claims fraudulent not because they were based on illegitimate prescriptions, but because the patients or doctors received kickbacks after Guerra certified to Medicare that she would not pay such remunerations. *There was no evidence presented that these claims were not medically necessary. Even though Tanya Moore testified that Medicare would not play a claim if [it] knew that parties were receiving kickbacks, this is not sufficient to establish a loss to Medicare.*" [485 F.3d at 1304](#) (emphasis added). Indeed, when the case came back up on appeal after remand, we cited *Medina* for the proposition that Ms. Guerra "did not merit any additional levels from the [§ 2B1.1](#) loss table because *she was not responsible for any loss to Medicare. See Medina, 485 F.3d at 1304-05[.]*" [United States v. Guerra, 307 F. App'x 283, 287 \(11th Cir. 2009\)](#) **[**33]** (emphasis added).