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# THE OXYMORONIC LANDSCAPE OF VOLUNTARY REPAYMENTS

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**The Oxymoronic Landscape of Voluntary Repayments**

There are many aspects of the fraud and abuse enforcement environment which have become much more difficult over the last few years. Going back at least to the Fraud Enforcement and Recovery Act of 2009[1], additional authorities and bases for action were adopted in the Affordable Care Act[2] a year later. The powers and focus of the enforcers have undeniably increased,. The monetary penalties have doubled, only the second increase since their enactment (from $5500-11,000 up to from $10,781.40 to now-$21,562.80). But, it is the self-initiated voluntary repayment program which may offer some of the biggest challenges for providers, and most particularly for physicians.

This article takes the physician practice perspective to address a range of issues associated with voluntary repayments. From their statutory source, to the responsibilities they impose and how, the role of voluntary repayments in a robust compliance context is addressed. The challenges of identifying and quantifying a repayment are considered, including what the law tells us about extrapolation when the volume of claims at issue is too big to review each one. The relatively few court cases to consider the obligation of repayment are set forth, with more surely to come. How the rules recast the importance of being successful when a practice is audited, and steps to enhance that process are elucidated along with four other practical implications of the rules

1.0 The Legal Foundations

While a review of all of the editions of the Health Law Handbook would reveal that the sheer volume of the fraud and abuse laws has increased over time, most recently, the two statutes at issue here, were enacted barely more than a year apart. The Fraud Enforcement and Recovery Act of 2009 (FERA) was focused well beyond health care to address issues such as securities and mortgage fraud, following the terrible recession of 2008. But it amended the False Claims Act (FCA) in ways that had significance for health care. The Affordable Care Act, in March 2010, focused exclusively on health care related issues. Both offer the principal legal foundations for the voluntary repayment rules and their implications.

FERA claimed to clarify certain aspects of the FCA about which there had been sufficient dispute that Congress enacted language to, in effect, reverse an opinion of the United States Supreme Court in *Allison Engine Co., Inc., et al. v. United States Ex Rel. Sanders et al*[3] There, the Court had said that since the naval subcontractor had not submitted a claim directly to a government payor, it could not be liable for false claims. FERA made it clear that a false claim may be direct or indirect; so, for example, a provider submitting a false claim to an IPA which then submits it to an ACO which then presents it to a

[1] Pub.L. 111–21

[2] Pub L. 111-148

[3] 553 US 662 (2008)

Medicare payor could be held liable. More than that, though, FERA expanded the bases for 'knowingly' presenting or causing to be presented a false claim, to include makes, uses, or causes to be made or uses, a false claim, record or statement material to a false or fraudulent claim, or material to an obligation to pay money to the government.[4]

In a provision frequently referred to as the 'reverse' false claims provision, FERA added to the same section of the law, knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government. The Act added a provision stating explicitly that no specific intent was required. It defined an 'obligation' as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation or from the retention of any overpayment."[5]

The Affordable Care Act took the last phrase far further. Setting forth an entirely new subsection of the Social Security Act, 1128J[6], the language requires a person who has received an overpayment to report and return the overpayment to the Secretary, the state, an intermediary, a carrier or a contractor, as appropriate. The overpaid provider must describe in writing the reason for the repayment. The payment must be reported and made within either (A) sixty days after the date on which the overpayment was identified; or (B) the date any corresponding cost report is due. Making the explicit link with the FERA-expanded reverse false claims provision, the statute specified that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an "obligation" as defined above. This affirmatively opens to whistleblowers, as well as enforcement agencies, false claims charges against overpayments which are not properly identified and returned. Proposed regulations were published in 2012, but the final regulations were not published until February, 2016. They constitute less than a page of text in the Federal Register, but their discussion, based on receipt of only 200 timely comments, takes 26 pages of the Federal Register.[7]

## 2.0 What Triggers The Obligation

### 2.1 *What is an overpayment?*

An "overpayment" is defined in the regulations as "any funds a person has received or retained under Medicare Part B to which the person, after reconciliation, is not entitled."[8]

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[4] Section 4 of the Act, amending 31 USC §3729(a)(1)(G)

[5] 31 USC §3729(b)(3)

[6] 42 USC §1320a-7(k)(d)

[7] 81 Federal Register 7654-7680 (February 12, 2012)

[8] 42 CFR §401.303 The regulations also are applicable to Part A, which will not be discussed here. The statutory language includes all of Titles XVIII and XIX. The regulators anticipate publishing Medicaid regulations separately. Parts C and D have already been addressed in regulations.

Obvious overpayments are cited in the preface to the regulations themselves to include payments in excess of the allowable amount; duplicate payments; payments when another payor is primary; payments for services by an excluded person and improper Medicare as secondary payor payments. Those are relatively easily identified. Also included in the regulators' list of overpayments are problems which are far more subtle and require careful analysis to determine. These include the following: payments as a result of up-coding, intentional or not; payments resulting from anti-kickback statute or physician self-referral law violations and payments for medically unnecessary services.

Very few physicians intentionally up-code. Many physicians under-document, meaning that they do not have adequate documentation to substantiate the service or its medical necessity. Which essential features of a service must be adequately documented to avoid up-coding is not black and white. Disagreements over one level of an evaluation and management code (whether the service was a level 3 or a level 4) can turn on issues of judgment regarding the complexity of the clinical decision-making rendered. The 1995 Evaluation and Management (E&M) Services Documentation Guidelines are 16 pages long and include the following observation about complexity of decision-making:

> "Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option as measured by: the number of possible diagnoses and/or the number of management options that must be considered; the amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed; and the risk of significant complications, morbidity, and/or mortality, as well as co-morbidities associated with the patient's presenting problem(s), the diagnostic procedure(s) and/or the possible management options."[9]

The 1997 Guidelines[10] are 49 pages long because they focus on system-specific, specialty-specific interpretations of the levels of visits. Although there are grids, and lists and bullet points, and a range of things to consider in determining what to include in the documentation of the visits, many of the issues entail judgments, often of a purely clinical nature. Either set of guidelines may be used. For the new codes that pay for coordination of care, including transitional care management and chronic care management, there are no regulations, no Manual provisions and only FAQs, Fact Sheets and MedLearn Matters articles to describe what the services entail.[11] There is almost no way to know which of the highly detailed elements of the services are essential to be eligible to bill the service.

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[9] 1995 Evaluation and Management Documentation Guidelines, https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnedwebguide/downloads/95docguidelines.pdf at p. 11

[10] 1997 Evaluation and Management Documentation Guidelines, https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnedwebguide/downloads/97docguidelines.pdf

[11] For an extensive consideration of these issues see Gosfield, "Beyond Face Time: The Evolution of Medicare Fee For Service in A Value Driven World," HEALTH LAW HANDBOOK, (2016 edition) WestGroup a Thomson company, pp. 1-30

For Stark or anti-kickback violations, simple claims review is entirely inadequate to determine if overpayments have been received. The range of potentially violative transactions is virtually limitless. While the Stark statute's overpayment provision pertains exclusively to the entity submitting the claim, failure to conform to the definition of a "group practice", with its multiple elements, including compensation formulas, is a principal area of vulnerability for physician practices. Relationships with other referral sources where claims for designated health services are submitted by the group can be problematic. Meeting the conditions of 'in office ancillary services" and physician-to-physician referrals offer pitfalls as well.[12] Whenever any of these aspects of a practice's operations are altered, consideration of whether the changes will generate liability under the repayment rules becomes a new obligation.

The anti-kickback statute (AKS) is even broader than the Stark statute, which itself applies only to physician referrals under Medicare and Medicaid, and then, only for designated health services. The anti-kickback statute applies to all federal health programs which are defined as "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5); or (2) any State health care program, as defined in section 1320a–7(h) of this title."[13] The Office of the Inspector General (OIG) has never published a list of what it considers the applicable "federal health care programs", but the voluntary repayment rules explicitly apply only to Parts A and B of Medicare. To determine if an overpayment has been received in violation of the statute, one has to confront the safe harbor regulations[14] to start. But because they only address what is safe and not what violates, the myriad of relationships that can exist up and down the payment chain must be evaluated, including direct claims submission as well as relationships with subcontractors, including referral sources, or the ordering, providing, leasing, furnishing, recommending or arranging for the provision of a service, item or good, payable by a federal health care program. Since most arrangements under Stark and AKS with parties outside the practice are based on written agreements, with a term of at least one year, the voluntary repayment regulations would seem to create a new obligation to review potentially implicated relationships at least annually and when new ones are created.

Determining whether payments were for services which are not medically necessary presents still a different set of challenges. There are, increasingly, external sources for such determinations which may yet rise to a standard of care, including the American Board of Internal Medicine Foundation "Choosing Wisely" campaign.[15] In that program,

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[12] For a consideration of the challenges in interpreting Stark in light of Medicare reimbursement rules, see Gosfield, "Stark and Medicare's Physician Reimbursement Rules: Unraveling The Knots," HEALTH LAW HANDBOOK, (2015 Edition) WestGroup, a Thomson Company, pp. 179-211

[13] 42 USC §1320a-7b(f)

[14] 42 CFR §1001.952 et seq.

[15] http://www.choosingwisely.org/

specialty societies were asked to identify medically unnecessary services which are often performed. As of October, 2106, 73 societies were participating[16], each with a separate list of services that should not be provided. Whether these statements rise to the level of creating overpayments is as yet unknown, since they have not been adopted in any formal way by the federal government. The case for over-utilized services has been made in many quarters and over a substantial period of time.[17] And yet, for all its persistence as a problem in Medicare and beyond, it remains essentially understudied.[18] False Claims Act cases have been brought on the grounds that services were medically unnecessary[19], but the boundaries of medical necessity are hardly clear

The regulatory reference to overpayments arising from non-covered services is also not as straightforward as it might seem. While services excluded from coverage are obviously overpaid if they are paid at all, the implications of coverage conditions can be highly nuanced. Payments for services that do not meet coverage requirements such as the "incident to" or teaching physician rules are at issue. Conditions set forth in National Coverage Determinations or Local Coverage Determinations can render a service as non-covered. Sometimes the coverage only pertains when a series of other services have failed previously.[20] Payments for services not supported by adequate documentation, of something other than levels of visits, raise issues as well.

Under the provisions of FERA, noted above, another potential generator of over-payments lies in quality and other reporting programs, where the reports are inaccurate, or the underlying system generating them, as in e-Prescribing, does not conform to the regulatory standards. Quality fraud in the form of egregiously poor quality, failure to supply enough staff to render proper care, is actionable[21] – but a question arises under the new standards as to whether it qualifies as an 'overpayment', when claims based on those services are submitted and paid.

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[16] http://www.choosingwisely.org/partners/page/5/

[17] See, among many available reports, Nelson, "Waste: Unnecessary Overuse of Medical Care Causes Both Waste and Harm," The Hospitalist 2015: 19(6):1, 23-27, http://www.medscape.com/viewarticle/846299_print

[18] See, Korenstein et al, "Overuse of Health Care Services in the United States: An Understudied Problem," Archives of Internal Medicine (Jan 23, 2012) 172(2):171-178

[19] See Breen and Fundakowski, "Quality of Care, Medical Necessity, and Worthless Services under the False Claims Act: Where Are We Headed Now?" American Health Lawyers Association, Physician Organizations Program, 2013 https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/L_breen_article.pdf.

[20] See, for example, ambulatory blood pressure monitoring, National Coverage Determination (NCD) 50-41 and bariatric surgery for treatment of a co-morbid condition Related to Morbid Obesity, NCD 100.1

[21] See Gosfield, "Quality Fraud: Two Pathways to Trouble," Compliance Today (June 2013) pp 27-30

### 2.2 *How voluntary is the process: "reasonable diligence"?*

The regulations set forth some strikingly clear expectations regarding how overpayments should be identified. Identification of an overpayment triggers a sixty day obligation to report the overpayment. An overpayment is identified "when the person has or should have through the exercise of reasonable diligence determined the person has received the payment and quantified the amount."[22] The reference to when a person "should have" determined an overpayment exists, creates the fundamental obligation to manage this process effectively. Reckless disregard of the truth or falsity of claims or deliberate ignorance of their truth or falsity, has been the standard for false claims liability, since at least 1996.[23] But the language here verges on strict liability, Of course, the standard of how a person would know and therefore should have known but did not, is yet another thicket of practical challenges.

Reasonable diligence has been described by the regulators as fact dependent; but it includes

> "both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayment and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment."[24]

They have offered at least 8 examples of credible evidence that should trigger quantification of the overpayment. (1) Complaints received on a compliance hotline. (2) In reviewing explanations of benefits, over-coding is found. (3) The provider learns a patient death occurred before the date of service. (4) A provider learns services were provided by an unlicensed individual. (5) Internal audit suggests an overpayment. (6) A government agency, presumably including the OIG or a Medicare Administrative Contractor, says there has been a potential overpayment in alerts, newsletters or other notices.[25] (7) Profits from a practice or physician are unusually high in relation to the hours worked or the RVUs associated with the work. (8) An audit by a contractor or federal agency finds overpayments in which case there must be reasonable inquiry to confirm the findings or contest them.[26] Still further, if a contractor determines an overpayment has been made, that is "always" credible information for other potential overpayments.[27] When such a determination is received by a supplier, the regulators

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[22] 42 CFR §401.305(a)

[23] 42 USC §3729(b)(1)

[24] 81 Federal Register 7661, ( Feb 12, 2016)

[25] See, 81 Federal Register 7659, (Feb 12, 2106) See below at 6.3 for a discussion of the implications of audits to avoiding voluntary repayments.

[26] 81 Federal Register 7667, (February 12, 2016)

[27] Id.

assert that the conduct leading to the overpayment may be identical to other conduct in additional time periods, triggering a further obligation to review those time periods. That said, if the provider appeals the determination, it is legitimately premature to calculate additional overpayments until the appeals process is concluded.[28]

As a manifestation of the importance of monitoring contractor judgments and other sources of credible information, the regulators actually take the position that "after finding a *single* overpaid claim, we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim."[29] Their position puts to bed, once and for all, the fantasy of some consultants that examining only pre-submission claims does not trigger an obligation to look at paid claims as well.

They acknowledged that compliance activities under the rule might vary with both the size and type of provider. But in discussing the 'should have known' constructive knowledge standard, they explicitly rejected an actual knowledge only standard.

> "If the requirement to report and return overpayments only applied to situations where providers or suppliers had actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated."[30]

They went further, stating in response to their observation that based on comments on the proposed rule, it was apparent to them that some commenters did not engage in compliance efforts to ensure that the claims they submit are accurate and proper and that payments received are appropriate. Quite simply they said "we advise those providers and suppliers to undertake such efforts to ensure they fulfill their obligations,"[31] making explicit the link between an active and robust compliance program and the obligation of reasonable diligence and repayment. Because of the impact of the failure to fulfill these obligations, they have arguably made not only repayments more required than their "voluntary" appellation would indicate, but they have made having a compliance program an essential requirement to fulfill the repayment obligation.

## 3.0 Identifying The Overpayment

The statute giving rise to the repayment obligation references the sixty day period which is triggered once the overpayment is '"identified". The regulations themselves[32] do not

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[28] 81 Federal Register 7667 (February 12, 2016)

[29] (Emphasis added) 81 Federal Register 7663 (February 12, 2016)

[30] 81 Federal Register 7660 (February 12, 2016)

[31] 81 Federal Register 7661 (February 12, 2016)

[32] 42 CFR §401.305(b)(i)

define what 'identified' means. Nor do they state a specific timeframe within which the determination of the existence and scope of the investigation to identify the claim must be made. But the prefatory language establishes a timeframe for the investigation. They have said that reasonable diligence is established through "timely, good faith investigation of credible information, which is at most 6 months from receipt of the credible information, except in extraordinary circumstances."[33] Stating that they rejected using a standard of 'a reasonable period of time" or "with all deliberate speed", they still did not put the 6 month standard in the regulation itself. Presumably they will interpret the circumstances that present themselves for enforcement under the 6 month rule, but there remains a question as to how rigidly it will be enforced. They stated that they chose 6 months so that providers and suppliers would know that they should prioritize these investigations and recognize that completing them may require devotion of resources and time.

Like reasonableness, for these purposes 'extraordinary' circumstances are deemed to be fact dependent. Unusually complex investigations under the Stark statute which will be reported pursuant to the CMS Voluntary Self–Referral Disclosure Protocol[34] are an example. Natural disasters and a state of emergency are also cited.

### 3.1 *Quantification*

The issue of when an overpayment would become 'identified' was a significant concern before proposed regulations were published and was a topic addressed by the regulators with the final regulations. Commenters had stated that an overpayment cannot be reported and returned if it is not quantified, as well.[35] The regulators responded that the sixty day reporting deadline begins when the reasonable diligence is completed and the overpayment is identified, or on the day the person received credible information of a potential overpayment and failed to investigate. The regulators asserted that reasonable diligence requires "conducting an appropriate audit to determine if an overpayment exists and to quantify it. Providers and suppliers are obligated to conduct audits that accurately quantify the overpayment."[36] From this concept several issues associated with quantification emerge.

First, the regulators acknowledged that in every instance, identifying each individual claim would not be possible, and therefore statistical sampling and extrapolation could be used.[37] This they even documented in the regulation itself.[38] But they explicitly rejected

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[33] 81 Federal Register 7662 (February 12, 2016)

[34] https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html

[35] 81 Federal Register 7663 (February 12, 2016)

[36] Id.

[37] Id.

the requirement that the extrapolation be based only on a statistically "valid" sampling methodology, but rather allowed merely a statistical sampling.[39] Without specifying any methodology, the sampling must be "reliable and accurate", based on "sound and accepted principles" which include that there be random selection of the sample, with extrapolation only within the time period covered by the population from which the sample was drawn.[40] This implies that separate samples likely would have to be constructed for separate years over which the overpayments occurred.

In a different discussion of the rules, they recognized that a common technique to conduct an audit is to use a probe sample and then incorporate that into a larger sample[41]. They admonish that it is inappropriate to return the funds only on a subset of claims in the probe sample and not extrapolate to a larger universe of claims. Moreover, the provider or supplier should not report and return overpayments on specific claims from the probe sample until the full overpayment is identified. And, underscoring their view that a provider or supplier has an obligation to engage in extrapolation, if the reporter chose only to return payments on certain individual claims, the reporter would be seen as failing to exercise reasonable diligence to identify the amounts overpaid.[42] Examining the prefatory language and the regulations themselves, in totality, they have offered scant guidance regarding how to extrapolate, but they claim this is intentional: "we structured the final rule to have certain flexibilities …to account for the various circumstances that may involve an overpayment."[43]

### 3.2 *What do we know about extrapolation?*

The fact that the regulators rejected the requirement for a statistically valid sample for extrapolation is an example of the flexibility they have offered in this context. This is as distinct from the OIG's Voluntary Disclosure Protocol which requires that if the provider extrapolates the repayment it must be on a statistically valid basis.[44] The OIG will only accept as a minimum sample 100 claims, when the issue is false billing. The OIG provides other direction regarding calculation of the sample. Potentially the loosest standard appears in the CMS Self-Referral Disclosure Protocol where the instructions merely require the submitter to "describe the methodology used to set forth the amount

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[38] 42 CFR §401.305(d)

[39] 81 Federal Register 7677 (February 12, 2016)

[40] Id.

[41] 81 Federal Register 7664 (February 12, 2016)

[42] 81 Federal Register 7668 (February 12, 2016)

[43] 81 Federal Register 7677 (February 12, 2016) See 6.2 for discussion of practical challenges in extrapolation.

[44] https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf at p.8

that is actually or potentially due and owing. Indicate whether estimates were used, and, if so, how they were calculated."[45]

The methodology for extrapolation has been addressed in the OIG's Model Compliance Guidances which make reference to RAT-STATS, which has been used by the OIG since the 1970s for audits.[46] The Program Integrity Manual advises the Medicare Administrative Contractors and other auditors on the techniques they must use in extrapolation.[47] Even so, there have been myriad challenges to extrapolated audit findings.[48] Typical bases for challenge have included inadequate sample size, lack of randomness of the sample, lack of stratification of the sample or inappropriate stratification, lack of "representativeness" of the sample, too high or an unreported estimated relative error, or lack of documentation by the auditor of the methodology. More recently, extrapolation was upheld as a basis to determine False Claims Act liability, rather than merely to assess damages.[49] Despite the fact that the voluntary repayment process does not require a statistically 'valid' sample with all of its technical rigidity, issues such as size of the sample and its randomness will be basic matters to address in making a repayment.

### 3.3 *Looking Back*

One of the most commented on aspects of the proposed regulations had been the lookback period that would apply to these repayments. The regulators had proposed ten years as the outermost limits of False Claims Act liability. Commenters proposed using the reopening rules which apply for 1 year for any reason and up to four years for good cause.[50] Others had recommended three years; others five years. But most apparently argued for six years as the more common standard for False Claims Act cases.[51] The

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[45] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf at p. 6

[46] https://oig.hhs.gov/compliance/rat-stats/

[47] Chapter 8, §8.4

[48] For an excellent survey of this area, including technical issues associated with challenging extrapolation, see Perling, "Statistical Sampling: Evolving Legal Issues," American Health Lawyers Association, Medicare and Medicaid Payment Institute (2013) https://www.healthlawyers.org/Events/Programs/Materials/Documents/MM13/bb_perling.pdf

[48] US ex rel Martin v. Life Care Ctrs of Am, Inc., US Dist LEXIS 142660 (ED TN Sept 29, 2014) but the case was settled before it could be heard at the appeals court level,. Topor, "FCA Statistical Sampling Case Settled; Details Pending", BNA Fraud and Abuse Rptr, (Sept 28, 2016) at 620

[50] 42 CFR §405.980, which they amended with the publication of the voluntary repayment rules so they would not be in conflict or present an impediment to the implementation of these rules. The reopening rule at 405.980 is for contractors to reopen claims. They have clarified that if a provider or supplier wants to reopen a claim, they may do so under the voluntary repayment rules.

[51] See discussion at 81 Federal Register 7671 (February 12, 2016)

regulators adopted a six year lookback period, counting from the time the person "identifies the overpayment".[52] That characterization is slightly different from the regulatory language. The regulation itself states

> "An overpayment must be reported and returned in accordance with this section if a person identifies the overpayment, as defined in paragraph (a)(2) of this section, within six years of the date the overpayment was received."[53]

The conundrum in the slight differences turns on whether looking back is part of quantifying and therefore identifying the overpayment, which means it can be conducted within the six months of receipt of credible evidence or, whether the lookback is expected to be a mere calculation to be conducted during the sixty days to report, after identifying the overpayment. The researching of prior periods of time going back six years may be far more difficult for a physician practice than relying on more current data. In addition, if the credible evidence triggering identification is an agency audit[54], for a prior period of time itself (when the payment was received); the lookback could extend farther yet in time beyond six calendar years from receipt of the audit results.

In considering the implications of the lookback rule, a range of challenges arise. In considering their position regarding extrapolation accuracy, it is not uncommon for circumstances in a physician practice to change over six years. Physician extenders may have been introduced or eliminated. Different billing systems or billing agents may have been in place. Documentation formats may have changed. A new EHR might have been introduced. New clinical processes or administrative processes may have been initiated, particularly in light of the new emphasis on performance measurement and value based performance. All of these changes have implications for whether it is accurate to extrapolate from current data, across the prior six years., when patterns of delivering care and documenting it, not to mention receiving payment for it, might have changed in significant ways. Since the fee schedule amounts paid per CPT code vary from year to year based on the annually calculated conversion factor for the RVUs, it seems obvious that a separate sample would have to be generated for each year subject to lookback. That said, if the overpayment was generated by failure of documentation by physician extenders who were only introduced into the practice three years ago, there would be no reason to lookback further. How the lookback should be deployed in any set of circumstances will be highly fact-specific.

The regulators did clarify that the regulations were not retroactive; and that failure to comply with them before March 23, 2010, the effective date of the Affordable Care Act, does not give rise to a violation.[55] Providers and suppliers who made a good faith effort

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[52] 42 CFR §401.305(f)

[53] Id.

[54] 81 Federal Register 7672 (February 12, 2016)

[55] 81 Federal Register 7673 (February 12, 2016)

to repay monies prior to February 12, 2016 will not be deemed in violation of the rules. But anyone seeking to voluntarily repay after the publication of the rules, even for periods of time that precede them by years, must follow the new rules. In a carve out from the rules, though, providers and suppliers seeking to use the CMS Voluntary Self-Referral Disclosure Protocol, which has a four year lookback period[56], are not required to repay for the fifth and sixth years, when they use that mechanism. (See 4.2 below)

## 4.0 Reporting The Overpayment

### 4.1 *To whom to report and how*

The statutory language specifically references the ability to report an overpayment to the Secretary, the state, an intermediary, carrier or contractor but the regulators have taken a strict position on this for Medicare Part A and B: "Sending an overpayment report and refund to anyone other than the appropriate Medicare contractor…does not conform to any applicable process as discussed in this final rule."[57] The regulation itself states that "A person must use an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment."[58] This language raises the issue of the various methods by which the repayment itself may occur.

The credit balance reporting process is only available to providers.[59] The claims adjustment process, however, has long been available under Part B. Virtually every Medicare Administrative Contractor has a form by which claims adjustments may be made[60] when the claims are known and the requisite information can be provided for each. If the refund is based on an extrapolation, however, the form does not lend itself to such reporting. Yet, the regulators have supported what we have done in our office for years: a practice can complete the form and attach a description of how the sample was calculated and the universe to which it was applied. The regulation provides that "If the person calculates the overpayment amount using a statistical sampling methodology, the person must describe the statically valid sampling and extrapolation methodology in the report."[61] First, the regulators have explicitly stated that the extrapolation need not be

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[56] CMS Voluntary Self Disclosure Protocol FAQs #2a) at p. 3, March 16, 2016 https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/downloads/faqsphyselfref.pdf

[57] 81 Federal Register 7678 (February 12, 2016)

[58] 42 CFR §401.305(d)(1)

[59] https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms838.pdf

[60] See, as an example, the Novitas approach http://www.novitas-solutions.com/cs/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=00008243&proto=http&domain=www.novitas-solutions.com&space=MedicareJH

[61] 42 CFR §401.305(d)(1)

statistically valid as that term is understood, technically. Second, they have intentionally left open any specific requirements regarding what to say about the overpayment, other than a description of the methodology. They have suggested, in the prefatory discussion, it is advisable to state how the problem was discovered and what corrective action has been taken.[62] They removed the proposed required element list from the final regulations. In addition, they recognized the right of the reporting practice to request a voluntary offset from the contractor.[63] We strongly advise our clients not to take this approach, because the MACs are notoriously bad at being able to follow through effectively. That is not the only problem that rests with the MACs.

The regulators indicated that they will be working with MACs to standardize their processes. They explicitly recognized the right of the overpayment reporter to submit one form with an attached spreadsheet identifying the relevant claims which should include identifying information such as the health insurance claim and Medicare claim control numbers. But commenters pointed out a range of problems with the MACs handling voluntary refunds. Some reported that contractors have returned a refund check or refused to accept it. Others stated that some MACs claimed to be unable to process a refund if the claims were for a time period before that MAC had the contract to do the work. Citing to section 4.16 of the Medicare Program Integrity Manual in Chapter 4, the regulators stated flatly, the Manual "requires contractors to process all voluntary refunds."[64] They say they are considering a processing deadline to be imposed on the contractors for the future.

### 4.2 *Timing: Reporting to voluntary disclosure or OIG*

The report and refund must be made within sixty days of identifying the over-payment. However, if the practice reports to either the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) for a Stark violation or to the OIG Self-Disclosure Protocol (SDP) for an anti-kickback or false claims violation, the sixty day deadline will be tolled.[65] The tolling remains in effect for the duration of the negotiations with the government; but once they are "no longer actively negotiating"[66] the sixty day requirement is reinitiated.

The deadline can also be extended if the person repaying requests an extended repayment schedule as defined in 42 CFR §401.603. The ability to obtain an extended repayment schedule turns on whether repayment would create a "hardship". Hardship exists when the amount to be paid is greater than 10% of the previous year's Medicare payments.[67]

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[62] 81 Federal Register 7676 (February 12, 2016)

[63] 81 Federal Register 7675 (February 12, 2016)

[64] Id.

[65] 42 CFR § 401.305(b)(2)

[66] 81 Federal Register 7678 (February 12, 2016)

[67] 42 CFR §401.607

There are no firm guidelines, but MACs can offer repayment extensions to between 36 and 60 months in cases of 'extreme hardship; but the definition of extreme hardship is circular: "Extreme hardship exists when a provider or supplier qualifies as being in 'hardship" as defined in this paragraph and the provider's or supplier's request for an extended repayment schedule is approved under paragraph (c)(3) of this section."

### 4.3 *Recordkeeping and the specter of additional audits*

Commenters on the proposed regulations specifically called out the potential double jeopardy problem that arises in extrapolation: a MAC or other auditor may come along later and seek to audit the universe of claims that was the subject of the extrapolated repayment. Maintaining records of how samples were determined, which samples were used for what time periods, how extrapolation was conducted and explicit documentation of relevant time periods and CPT codes seem to be fundamental, although not explicitly addressed by the regulators.

> "In this situation, providers and suppliers should retain their audit and refund documentation in the event that a Medicare contractor or the OIG audits claims that the provider or supplier believes to have been previously refunded."[68]

If the refunded money results in a redetermined payment amount on specific claims, the standard appeal rights associated with those claims determinations would be available. But,

> "As is the case under the existing voluntary refund process, there are no appeal rights associated with the self-identified overpayments that do not involve identification of individual overpaid claims and individual claim adjustments."[69]

This begs the question as to whether there is any way to challenge a MAC regarding its decision to proceed with an audit of what the voluntary payer asserts are claims that have already been repaid. Presumably if the MAC eventually requests repayments on claims that are part of the universe repaid, the appeal rights on those redetermined claims would be triggered, but that seems unduly burdensome to a good citizen who has followed the entire voluntary repayment process. On the other hand, the regulators do hold out the possibility of reopening claims if the voluntary payer later determines the repayment was made in error, but they expect this to happen rarely.[70]

Since the MAC can only adjust identified claims, including those in the sample that forms the basis for the extrapolation, the regulators have said that they will not exempt from subsequent audits any claims that form the basis for the returned overpayment.

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[68] 81 Federal Register 7667 (February 12, 2016)

[69] 81 Federal Register 7668 (February 12, 2016)

[70] Id.

Claiming that they would not "recover an overpayment twice", the fact of having to respond to an audit request with the assertion the claims have already been accounted for leaves the reporter in limbo. There is no elucidation whatsoever as to what process would be used or what appeal rights might pertain to a MAC's insistence on proceeding. In other words, the voluntary repayment by implication is not a safe harbor. The potential liabilities here are unexplored.

## 5.0 Caselaw

Because the regulations are so new, at this writing, there is not yet caselaw interpreting or applying them. There have been some settlements under the statutory provisions. A Houston hospital settled a whistleblower case alleging it had failed to repay almost $1 million in overpaid claims.[71] Pediatric Health Services of America agreed, in another whistleblower case, to repay $6.88 million dollars for failure to investigate and return overpayments.[72] There are at least two cases, however, where there have been opinions construing aspects of the voluntary repayment statute; and the infamous *Escobar* Supreme Court case has some significance in this arena as well.

### *5.1 Failed motions to dismiss*

In US and Wisc ex rel. Keltner v. Lakeshore Medical Clinic, Ltd.,[73] the relator pitched nine distinct areas of false claims ranging from MRIs, to ultrasounds to hemoccult stool tests, and more. None succeeded, except, significantly, the claims that alleged that the multispecialty group of more than 100 physicians, had for years engaged in annual audits of their physicians' billing patterns for E&M services. They sampled 25 charts from each physician. The relator alleged that the probe audits revealed upcoding among a number of the physicians and the group took no further action. Eventually, after 2011 they had eliminated performing the audits altogether. The court held the claims were pleaded with sufficient particularity to survive the group's motion to dismiss and affirmed the right of a relator to sue under the False Claims Act if a defendant intentionally avoids an obligation to pay the government.

A better known case which eventually settled also addressed the issue of failure to take appropriate action. In US ex rel Kane v. Healthfirst Inc., and State of New York and US v. Continuum Health Partners Inc[74]., a Medicaid contractor, Healthfirst, administered payment to a network of hospitals, Continuum, for the Medicaid program. Under that program, hospital claims would be submitted to Healthfirst and that would be the only

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71 Blesch, "Christus pays nearly $1 million to settle false-claims case" Modern Healthcare (Oct. 6, 2010) http://www.modernhealthcare.com/article/20101006/NEWS/310069971

72 DOJ Press Release, "Pediatric Services Of America And Related Entities To Pay $6.88 Million To Resolve False Claims Act Allegations" (Aug 4, 2015)

73 Case No 11-CV-00892 (ED Wisc, March 28, 2013)

74 11 Civ 3125 (ER), (SDNY, Aug 3, 2015)

payment available to the participants in the network. Healthfirst had a software glitch by which providers submitted additional claims to Medicaid. For a period of two years, the glitch permitted health systems to bill the Medicaid program, which claims the Department of Health paid as secondary claims, when those claims were forbidden under New York State program rules. The New York State Comptroller General came to Continuum asking questions, and Kane, its employee, was assigned the responsibility to determine how many claims might have been improperly submitted. He spent five months gathering data and sent a spreadsheet and report which enumerated about 900 claims, half of which turned out to have been actual overpayments. He was fired shortly after the report was submitted. Continuum dribbled its repayments back to the State over a period of two years. Kane, in his suit, alleged they had sixty days to pay after his report.

The Court had to construe the term "identified" as distinct from "known", as well as what it meant to "avoid" an obligation. The judge also had to determine what a reasonable amount of time to repay might be. Consulting multiple dictionaries, Congressional intent, agency guidance in the form of Medicare Advantage regulations, as well as the proposed Medicare Part A and B regs, he found none of them dispositive of the issues. He ultimately concluded that providers could not evade the obligation to pay by taking no action on reasonable information provided to them. He concluded that the defendants had an obligation to repay, that two years was too long, and that other issues might be decided at trial. If the final regulations analyzed in this article had been available, his job would have been easier. The hospitals settled rather than go to trial. Presenting potentially thornier issues, though, in light of the regulations which have now been published, is the Escobar case.

### 5.2 *Implications of Escobar*

The long-awaited and ultimately unanimous (!) Supreme Court opinion in Universal Health Services Inc., v, United States and Massachusetts, ex rel Julio Escobar and Carmen Correa[75] considered the implied certification theory of false claims liability. Coming out of the First Circuit, the Court reviewed the hair-splitting differences among the Circuits on the issue of whether a claim might be false only if it violated a specific condition of payment or, instead, when a claim is submitted, it stands for the proposition that the underlying services comply with all of the statutory and regulatory requirements imposed on the service delivered. It is a remarkable opinion in that both sides claimed victory; and one Assistant United States Attorney has described it as "the gift that keeps on giving."[76] The opinion reported that the Seventh Circuit said only express or affirmative falsehoods can trigger False Claims Act liability. Other courts had accepted the theory but limited its application to cases where defendants failed to disclose violation of expressly designated conditions of payment. Still others holding that

[75] 136 S. Ct. 1989 (2016)

[76] Comments of Margaret L. Hutchinson, Chief of the Civil Division, Office of the US Attorney, Eastern District of Pennsylvania, at "A Day of Health Law", Pennsylvania Bar Institute, Philadelphia,. PA, October 5, 2016

conditions of payment need not be expressly designated as such to be a basis for False Claims Act liability.

Because Congress did not define what makes a claim "false" or "fraudulent", the Court looked to the common law on fraud, which has long-standing acceptance and goes beyond express falsehoods. The Court held that the implied certification theory could be a basis for liability when two conditions are satisfied:

> "[F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory or contractual requirements makes those representations misleading half-truths."[77]

The opinion went further to say "Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry."[78]

Applying the opinion to the obligation to voluntarily repay, the question becomes "what part of the services and their documentation are 'material' in the host of circumstances where a physician practice can run afoul of the rules?" From the judgments associated with levels of visit codes, to the new coordination of care codes for which there are neither Manual provisions, nor regulations[79], to the grey zones in the Stark and anti-kickback statutes, if a failed voluntary repayment becomes subject to the False Claims Act standards, presumably *Escobar* provides the basis upon which such claims will be brought. What if the services were of poor quality? (See § 2.1) Is that material if the services were, in fact, provided by appropriately qualified personnel? Are all technical failures to comply with Stark (e.g. compensation formulas in group practices, lack of fair market value in lease payments) material to the claim for services? The boundaries of materiality are not at all clear; and the wrongful acts to be challenged neither plainly black nor white. In many instances, whistleblowers will likely not be daunted, nonetheless. The risks at hand pose a number of practical challenges to physician practices.

## 6.0 Practical Implications

### *6.1 Revised compliance plans*

Virtually every compliance plan will have to be revised to assign responsibility for the much extended monitoring responsibilities which 'reasonable diligence' now requires. If a single claim can trigger the obligation to investigate, who will be reviewing those claims and making judgments as to what further action needs to be taken? Who will have

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[77] Id at 11.

[78] Id at 12

[79] See, Gosfield "Beyond Face Time: The Evolution of Medicare Fee For Service In A Value-Droiven World,", HEALTH LAW HANDBOOK (2016 ed.) pp. 1-30

the authority to determine whether to identify every claim at issue or to use a sample upon which to extrapolate? Who will serve as the 'qualified individuals' to conduct further investigations and look back six years or determine a shorter time is permissible? When will legal counsel be consulted? All of these, and many more, are matters best determined before problems arise. At a minimum, assigning responsibility for these judgments in the compliance plan is a start, even if all the details are not set forth, because they will be fact-specific.

### *6.2 When, how and how much to extrapolate*

The regulators have provided relatively few restrictions on extrapolation. They haven't even provided guidance as to when extrapolation should not be used. Generally, if it is possible to identify all of the problematic claims, it is better to do that so as to avoid the potential double jeopardy problem noted above. The only real limits on the extrapolation are that it must be accurate and random. Choosing a proper sample size will be fact specific; and whether different sample sizes are necessary for different repayment years will turn on billing patterns and how consistent they are. In its Model Compliance Guidance, the OIG has said that a probe sample is typically 10 claims,[80] but that hardly seems a legitimate basis for extrapolation. All of these decisions turn on the precision in the definition of the problem generating the overpayment to be paid. That, in turn, drives the universe to which the sample would be applied.

We had a client who had one physician who appeared to be billing too many visits at too high a level. They chose to look at the worst cases they could identify and then sought to extrapolate that. We advised them that the sample wasn't random and now having looked, they had an obligation to repay any improper amounts in the sample they reviewed, but they also had to construct a new random sample and still quantify which visits should not have been billed, or should have been billed at a lower rate.

How far to look back is also fact specific. Is it a problem with one physician or all physicians? Were all the physicians in the practice six years ago? Was the problem generated by non-physician practitioners who were not hired until three years ago? Had there been an educational program for all practitioners? Was there an audit to determine if the program had been effective? The fact patterns that will drive voluntary repayments will be many and require explicitly constructed decisions associated with them.

Sometimes outside consultants can help define both how the sample should be derived as well as how it should be applied to the universe. Sometimes, the investigation of the problem will be so time-consuming that drawing on outside help might alleviate resource limits in the practice. If outside consultants are used, deploying the attorney-client privilege should always be considered. While there is relatively little caselaw regarding

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[80] OIG Compliance Program for Individual and Small Group Physician Practices , 65 Federal Register 59434 et seq (October 5, 2000) at 59437 recommending that 5-10 records per physician be analyzed annually in followup to a baseline audit.

the boundaries of the privilege in fraud and abuse cases,[81] it is certainly worth trying to derive protection from its application.

### *6.3 Heightened danger from audits*

Because the results of an audit mandate either an appeal or further investigation even outside the temporal limits of the audit, getting the best possible result out of an audit becomes an imperative. There are a myriad of agencies with audit rights under Medicare. While the MACs are the principal actors, Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (PSCs), not to mention Recovery Audit Contractors (RACs) are also in the auditing business. In our experience, MAC audits tend to be more physician-friendly. We have rarely seen ZPIC or PSP audits that we thought were fair or validly reasoned. Our clients routinely appeal those determinations.

From the first request for records, managing an audit requires attention to details and optimal presentation of information. The records are what they are, and, of course, cannot be altered; but explanations of what is in them are completely acceptable and often essential to guide the reviewers to a positive result. First, the client should read the records with as jaundiced an eye as possible. If specific dates of service were requested, but the documentation of the medical necessity of the service happened at a prior moment in time, that additional documentation should be included. Each date of service and records for it should have a cover note explaining what is included.

The worst and yet common failure we have seen among our clients who contact us after they have turned over the records, is the failure to include absolutely everything the auditor requests. If diagnostic services are recorded in a separate part of the record, bring everything together. If there is anything idiosyncratic about the documentation style, it should be explained in the cover note.

The goal in submitting the records is to facilitate the auditor's clear understanding of what is there and why it supports the way the claims were submitted. The goal is to afford the reviewer no wiggle-room. The conclusion should be obvious. Of course there are certainly instances where the audited records are sub-optimal. Sometimes it is best to repay those claims and remove them from the audit. In the past, that would have been the end of that. Today, the repayment regulations would mandate a further review with a six year look-back for similar claims. The choice becomes whose extrapolation is preferred--the auditor's or the practice's. Knowledgeable lawyers can be useful in characterizing the information for a better review, in any case. The need to appeal any negative determination from an audit is even more important, since it tolls the repayment obligations while the appeal is pending. If the client does not appeal, then the six year lookback is triggered.

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[81] See, Bttinger, "Wave Interference: A Case Study of the Halifax Hospital Judgment on In-House Health Attorney's Practices", HEALTH LAW HANDBOOK (2016 Ed). Pp. 336-374 and Horton, "When Two Worlds Collide: Legal Ethics, OIG Policy and The General-Counsel Compliance Officer Relationship, HEALTH LAW HANDBOOK (2016 Ed.) pp. 298-335

### *6.4 Billing agent contract issues*

Physician practices will have to amend their contracts with billing agencies that do collection, to accommodate the obligation to notify the practice of any denied claims. Cooperation with the clients' direction regarding voluntary repayments and facilitating the process of investigation and quantification should be new obligations in the billing company contract. Whether these are now, with the regulations, such fundamental obligations that they should be included in the company's basic fees is an issue for negotiation as well. Still further, given the implications of the voluntary repayment obligation, the client will also want the right to audit the billing company on the issue of providing adequate contemporaneous information about denied claims, as well as basic billing accuracy in the first place. But if the client has the right to monitor and doesn't exercise it, and problems later arise, there is the potential for an assertion, by a whistleblower or the government, of the practice's reckless disregard.

### *6.5 Employee/Shareholder Contracts*

We have, for many years, routinely written into employment agreements provisions that make an employed physician who has generated the claims which produce an overpayment, as determined on an outside audit by a government agency or commercial payors, responsible to repay pro rata amounts he received which are recouped from the audit, even post-termination. We have never had to have one of our clauses enforced post-termination. These provisions have not been entirely contentious, however, because if poor documentation or other billing aberrancies are caused by a physician or practitioner who was otherwise not entitled to the money, most parties believe it is fair to ask for contribution by the primary perpetrator. This is especially true where the compensation model is based on productivity, which can incentivize over-utilization. That is why, even as Medicare payment moves from pure work RVU based payment to incentives and penalties based on quality,[82] tempering productivity incentives with quality and value performance will be increasingly important.

Now, with the practice's obligation to engage in voluntary overpayments, there will undoubtedly be disputes over whether a repayment needs to be made, who caused the overpayment, the amount of the overpayment, how much is an appropriate pro rata share, and, likely, more as well. That raises the question as to what type of challenge should be permitted to an employee, or even a partner or shareholder, disputing the repayment and the assessment. Whether to allow this to go to formal dispute resolution mechanisms, like arbitration or even court, is a question practices will have to answer for themselves.

Given the range of issues that can generate overpayments, amounts to be assessed might be quite small or very large. Some materiality standard (if the amount in dispute is more than $5,000) may be appropriate for getting to review by a formal process. Otherwise, to write into the agreement, whether for employee or shareholder, a mechanism that allows

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[82] See, Shay, "To Quality and Beyond! The Present and Future of Medicare's Physician Quality Reporting Programs," HEALTH LAW HANDBOOK (2016 Ed), pp. 31-66

the aggrieved physician to engage a consultant at his/her expense to review the analysis, within a defined timeframe, and ask for a reconsideration may be useful. Above the materiality threshold, even if mediation is not generally provided for in the agreement, mediation can precede arbitration, in the hopes of getting the matter resolved quickly. Employment and shareholder agreements should explicitly acknowledge (1) both the group's right, in good faith, to make these assessments, and (2) what process applies to their review.

The group will have exposure itself because the Medicare reassignment rules require that the reassigning physician and the entity getting the reassignment are jointly and severally liable for overpayments,[83] but, in addition, under the voluntary repayment rules, the regulators have stated that "an entity to which a provider or supplier has reassigned Medicare payments has a duty to determine whether it has received overpayments associated with that provider or supplier."[84]

## 7.0 Conclusion

The brevity of the regulatory language establishing the obligation to voluntarily repay monies inappropriately received belies the complexity of the undertakings demanded. How often to look for overpayments, how to monitor for deviations, what to audit internally, how to use outside consultants and attorneys, as we have seen, are only the beginning of the issue. Because of the utter loss of control when whistleblowers weigh in, all physician practices ought to reevaluate the viability and robustness of their compliance program. These regulations make it abundantly clear, that getting it right with the initial claim submission, and complying with Stark, the anti-kickback statute and the myriad coverage and reporting rules, are, together, the most fundamental bulwark against problems under these rules.

[83] 42 CFR §424.80(d)(1)

[84] 81 Federal Register 7665 (February 12, 2016), although that specification does not appear in the regulatory language, the implications of who a 'person' receiving an overpayment is, encompasses reassignees.