Voluntary Repayments: The Physician Perspective

Six Specific Implications of the Voluntary Repayment Rules

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The voluntary repayment rules have changed the compliance landscape for anyone submitting claims to Medicare Part A and Part B. The obligation to exercise reasonable diligence based on credible information to determine if overpayments have occurred is far stronger than ever before. The regulations implemented the combined effects of the Fraud Enforcement and Recovery Act of 2009 as well as a section of the Affordable Care Act which established a whole new provision in the Social Security Act pertaining to "reverse kickbacks."[1] Many commentators have addressed what the rules say. But, there is much to be found in the implications of the rules. Although there is less than one page of text in the *Federal Register*, based on only 200 comments received, the regulators spent 25 pages in the *Federal Register* discussing their responses to comments made.[2]

There are real distinctions between the significance of these rules for Part A providers, who generally have their own in-house billing personnel, and physician practices, which often outsource those functions. This article provides a summary of the rules and then addresses six specific implications of the voluntary repayment rules from the physician practice perspective.

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Summary

The power of the voluntary repayment regulations lies in the fact that failure to repay monies that were received from non-compliant transactions puts a practice at risk for from $10,781.40 up to $21,562.80 for each improper claim, plus triple the charges. Those claims not repaid convert to false claims. The regulations define an overpayment as "any funds a person has received or retained under Medicare Part B to which the person is not entitled."[3] The definition is incredibly broad. Overpayments include not only obvious overpayments such as duplicate payments, payments in excess of the allowable amount,

and payments when another payer is primary but also payments for non-covered services including those that did not meet coverage requirements such as "incident to" rules or the teaching physician rules. Still further, the regulators have called out payments received as a result of up-coding, whether intentional or not, as well as claims resulting from the anti-kickback statute or self-referral ("Stark") law violations and payment for non-medically necessary services. Whether a claim does not conform with those rules can be highly nuanced.

When a practice receives "credible evidence" of an overpayment, which the regulators have stated include even a single overpaid claim, there is now an obligation to investigate further and determine whether other claims of the same type have been improperly submitted as well. "Credible evidence" can include everything from a complaint on a compliance hotline to an Explanation of Medicare Benefits to an internal audit or a complaint from a patient. The obligation of "reasonable diligence," explained more fully below, makes it clear that confronting how to find and repay overpayments ought to be part of every practice's compliance plan. With this new obligation, the regulators have essentially said that any practice that is operating without a compliance plan is simply foolhardy.

Once a problem has been identified, there is a timeframe by which the investigation should be completed and the amount at issue quantified. That time is six months. The intent was to make practices address overpayments efficiently and expeditiously. Once quantification is complete, there are 60 days to repay before the claims convert to false claims.

Often it is not possible to identify every single claim at issue, so practices will have to confront when it is appropriate to extrapolate, how to devise the sample upon which to extrapolate, and what is a reasonable way to approach extrapolation. The regulations and regulators specifically walked away from the requirement that the sample be a statistically valid sample, requiring only that it be reliable, random, and accurate. Repayments are to be made to the Medicare administrative contractor (MAC) and no one else. Acknowledging past problems, the regulators have set forth some rules for the MACs as well, in terms of accepting repayments, accepting multiple payments attached to one report, and more. While this brief description of the rules may appear deceptively simple, the pitfalls lurking there demand physician practice attention.

1. Reasonable Diligence

The standard of reasonable diligence turns on what the practice knew or should have known. Ignoring the issue will not work. This is almost a strict liability standard. The 60 days for the group to repay is measured from the date credible evidence did or should have put the practice on notice. When investigation occurs, the regulators would limit the time to six months from the receipt of evidence, although that is not stated in the regulation itself, but in commentary. Further, the regulators have taken the extraordinary position that a single overpaid claim constitutes credible evidence to investigate further and determine if other similar claims have been submitted and paid.[4]

One of the major challenges for physician practices will lie in the fact that the types of issues that the regulators have identified as subject to repayment include issues that are by no means clear, such as the medical necessity of claims as well as situations such as in transitional care management and chronic care management codes where there are no regulations, nor any manual provisions.[5] The Supreme Court case, *Universal Health Services vs. United States and MA ex rel. Escobar*,[6] took the position that implied certifications of compliance exist in claims when the implication is "material" to whether the claim

Five Takeaways

1. The voluntary repayment rules create vast new territory for whistleblowers.
2. The "should have known" standard makes it imperative for physician practices to have active monitoring programs to identify overpayments.
3. The six-year look-back requires extended review of claims, and if not each claim, close analysis of what samples to use for each year and how to define them.
4. Medicare audits present a new source of danger which must be anticipated and blunted.
5. Employment and shareholder contracts need provisions that recognize that monies will be repaid, and responsibility for those funds might rest on the employee/shareholder.

will be paid. When the implied statement is not true, the claim is false. This is such a grey zone for Stark and anti-kickback violations alone that physician practices will want to lay in a store of fog lamps to work their way through these issues.

The other big problem for reasonable diligence is that if it is not exercised effectively, if repayments are not made within 60 days of identifying the overpayment, the claims convert to false claims that are then available for whistleblowers as well as enforcers to target. Certainly the former and likely the latter will not be daunted by the challenges here. More and more whistleblowers move forward with their lawsuits even when the government declines to join the case. These new rules open vast new territory for them.

2. Compliance Plans

The regulations set forth a standard of reasonable diligence which the regulators have tied directly to compliance efforts. As a result, the need to have a vibrant and robust compliance plan becomes almost an inherent aspect of the ability to exercise reasonable diligence.

Virtually every physician practice that has a compliance plan will have to address who has responsibility for the myriad decisions that have to be made for voluntary repayments to conform with the regulations. Who will have the responsibility to determine when credible evidence has been found? What steps will be taken to monitor enough so that the "should have known" standard will never be an issue? Who will be the "qualified individuals" assigned the task to investigate the claims? Who will determine whether it is too difficult to calculate a specific overpayment, identifying each claim, or whether a statistical sampling should be used to extrapolate? Who will have the authority to determine if outside consultants will be necessary? Who will assure attorney-client and work-product privilege are optimized? How to extrapolate will be fact specific, but choosing a sample, quantifying the results from investigation, and applying it to the universe of claims is an art form — one with big legal consequences. When and how to involve legal counsel will be critical.

3. Six-Year Look Back

A subject of considerable controversy, since the proposed regulations would have required a 10-year look-back, the regulators have settled on a six-year look-back, which is the traditional statute of limitations for false claims liability. However, physician practices tend to be much more dynamic in what could affect the pattern of claim submission than Part A providers. Clinical process redesign in light of the new demands for value would affect the constellation of services submitted for payment. Whether categories of personnel have been added relatively recently (*e.g.*, three years ago)

would militate against looking back six years, if the problem rested with only the mid-level practitioners. The implementation of a new electronic health record or changing to a different billing software program also could affect the way in which claims are submitted.

All of these factors are relevant to the appropriateness of extrapolation as well. Here the regulators have offered some flexibility, asserting that the voluntary reporter should be able to explain the methodology, which need not be statistically valid, but rather reliable, accurate, and random. Who exercises the judgment regarding how far back to look and using what data will be an issue. And all of this has to be completed in six months.

4. Audit Dangers

The regulators have taken the position that audit findings from an outside agency are always credible evidence that should be evaluated further, even if the audit only covers a year or 18 months. If nothing else, there would be an obligation on the practice to look back six years, unless the practice appeals the determination of the auditor. Taking an appeal tolls the six months for investigation and 60 days to repay until the appeals are over. This puts an enormous premium on responding to audit requests in the most effective manner.

The worst failure we see among our physician clients is a failure to provide the totality of the records that the auditor requests. As an example, when the diagnostic testing data is kept in a separate section of the record from the progress notes, it is vital to make sure that everything is included. Even if the auditors ask for information which only implies the full scope of what needs to be submitted, it is always better to err on the side of more information rather than less. If medical necessity is documented in earlier progress notes than those requested, all the relevant notes should be submitted with an explanation.

Another factor that can doom a positive audit result is a failure to review all the records before they are submitted. If there are idiosyncrasies or aberrations that need to be addressed, whether in terms of why an otherwise appropriate treatment was not implemented for a specific patient, or that physician uses idiosyncratic abbreviations, this needs to be explained and pointed out so that the reviewer does not miss it. The key to a successful audit and, therefore, less to investigate further is leading the reviewer to exactly what you want him or her to conclude. The most important factor is to make the conclusion blindingly clear. If, however, upon the request for records and their review, real problems are found that will trigger new "credible evidence," that will require its own investigation. Consulting knowledgeable legal counsel early can be key.

5. Billing Company Contracts

Many physician practices outsource to their billing company the functionality of submitting claims to Medicare. If the billing company merely submits claims but does not engage in collection efforts, then the risk of a single denied claim being missed for its implications would not happen, since the company is not collecting the payments. We have long advised our clients to have inserted in the billing company contract the representation that the company has a compliance program and that it will provide a copy to the client, as well as that the client has the right to monitor the billing company for its claim submission accuracy. However, if the client has this right and does not exercise it, and later it turns out that claims were negligently submitted requiring voluntary repayment, the failure of the practice to act in the face of its right could be seen as reckless disregard as to the accuracy of the claims. Revised billing company contracts need to address specific responsibility for communicating with the practice regarding denials and all other forms of communication that would

constitute credible evidence under the voluntary repayment rules.

6. Employment/Shareholder Agreements

Many employment and shareholder agreements in the physician practice require compliance with the compliance plan. We have long advised our clients to include provisions that say if there is an overpayment that is determined by an outside agency that was caused by the individual employee or shareholder's documentation or other behaviors, that individual should be obligated to repay a pro rata portion of the monies they have been paid, especially if they are compensated on a productivity basis. Now that practices will have the proactive obligation to engage in voluntary repayments, disputes are inevitable. These can include the issue as to whether the repayment was required in the first place, how it was calculated, and what is a fair pro rata share. We have written our clauses to be effective including post-termination, although we have never had to have them enforced.

A reasonable medical practice will want to consider what kind of challenge the aggrieved employee or shareholder might be permitted to bring. Consider also the problems associated with going after an employee who no longer is with the practice or a partner who is retired. However, depending on the amount of money at issue, it may be worth the trouble to pursue the issue. At a minimum, providing the physician or mid-level with access to (1) the basis for the determination, (2) the theory behind it, and (3) any consultant review and then allowing the employee or shareholder to engage his or her own consultant at his or her own expense to challenge the determination would be fair.

Determining who would review the "appeal" is another decision to address. Requiring a non-disclosure agreement with injunctive relief to enforce it before releasing the information also can be important. Mediation may be useful in these matters even if the practice does not want to go as far as full arbitration under these circumstances. However, these are cultural judgments that each practice will have to make in light of its risk aversion regarding compliance.

Conclusion

The challenges to physician practices in meeting the obligations of voluntary repayment are considerable and are different from those for Part A providers. Any physician practice, regardless of its location (*e.g.*, freestanding, affiliated with a health system or academic medical center) is foolhardy not to have a compliance plan and program, both of which account for these rules. The risks in today's world are untenable when measured against the challenges of compliance.

Endnotes:

1. 42 USC § 1320a-7(k); §1128J of the Social Security Act.
2. 81 *Federal Register* 7654-7684 (February 12, 2016).
3. 42 CFR §401.303.
4. 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.1-23.
5. For an in-depth discussion of the regulations and their significance, see Gosfield, "The Oxymoronic Landscape of Voluntary Repayments," HEALTH LAW HANDBOOK (2017 Edition) Westgroup, a Thomson Company pp. 1-21.
6. 579 US_ (2016).

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