

Client Alert

Healthcare Practice Group

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CMS Issues Long-Awaited 60-Day Medicare Parts A and B Overpayment Final Rule

On February 11, 2016, CMS released its much anticipated final overpayment reporting and refunding rule for Medicare Parts A and B (Final Rule). The Final Rule implements Section 6402(a) of the Affordable Care Act (ACA), which addresses the identification, reporting, and refunding of certain overpayments and is now codified at 42 U.S.C. § 1320a-7k(d) (Overpayment Law). Importantly, the Overpayment Law did not require implementing regulations to become effective and thus providers have been subject to the overpayment reporting and refunding requirements since the enactment of the ACA in 2010. The Final Rule comes almost *six years* after the passage of the ACA and *four years* after the Centers for Medicare & Medicaid Services (CMS) issued its proposed rule for reporting and refunding Medicare Parts A and B overpayments (Proposed Rule).

Overall, providers may find the Medicare Parts A and B overpayment Final Rule to be, in some ways, worth the wait. As reflected in the Final Rule, it appears that CMS responded to certain significant concerns voiced by the provider community in its final rulemaking. Since the issuance of the so-called “60-day rule” in the ACA, providers have been grappling with how to interpret the confines of the overpayment reporting and refunding requirements. In the Final Rule, CMS addresses key questions, such as when an overpayment is “identified,” thereby triggering the 60-day clock. As detailed in this Alert, CMS defines “identification” so that an overpayment is not identified until it has been quantified (unless the provider fails to conduct reasonable diligence). However, in the comments to the Final Rule, CMS also provides guidance regarding its expectations for how long an internal review should generally take in order to identify and quantify overpayments. Additionally, in the Final Rule, CMS adopts a six-year lookback period, as opposed to the ten-year period originally proposed by CMS in 2012. The contours of the six-year lookback period are also explored in greater detail in this Alert.

In the Final Rule, while CMS attempts to provide further clarity regarding a provider’s obligation to report and refund Medicare Parts A and B overpayments, many questions remain. Importantly, now that CMS has articulated its expectations for providers with respect to Medicare Parts A

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and B overpayments, providers must ensure that their internal processes and policies are consistent with the Final Rule.

In this Alert we outline several key provisions of the Final Rule, as well as important questions raised by CMS's approach to the Medicare Parts A and B overpayment requirements.

The regulations adopted in the Final Rule will be effective on **March 14, 2016**. With the issuance of this Final Rule, CMS has now issued final regulations for Medicare Parts A, B, C, and D. However, CMS has not proposed or finalized a rule for Medicaid overpayments.

I. BACKGROUND

Since the enactment of the ACA in March 2010, providers and suppliers have been grappling with multiple issues emanating from the Overpayment Law's reporting and refunding requirements, including the issue of when an overpayment is "identified" for purposes of timely satisfying the refunding and reporting requirements. The Overpayment Law requires a person who has received a Medicare or Medicaid overpayment to report and return the overpayment and to notify the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate, in writing of the reason for the overpayment. The Overpayment Law also requires that an overpayment be reported and returned by the later of:

- A. the date which is 60 days after the date on which the overpayment was *identified*; or
- B. the date any corresponding cost report is due, if applicable.

Importantly, identification is not defined in the ACA. Under the Overpayment Law, any overpayment improperly retained by a person after the deadline for reporting and returning an overpayment is an obligation for purposes of False Claims Act (FCA) liability.

CMS issued the Proposed Rule implementing the Overpayment Law in February 2012. The Proposed Rule included many far reaching provisions, including a potentially ambiguous standard for identification as well as an expansive ten-year proposed lookback period. In light of these far reaching provisions, approximately 200 stakeholders submitted timely comments in response to the Proposed Rule. *See* 81 Fed. Reg. 7654, 7655-81 (Feb. 12, 2016). While CMS is typically required to publish final rules within three years of the publication of the proposed regulation, on February 13, 2015, CMS announced a one-year extension to issue its final rulemaking was necessary due to the complexity of the rule and the scope of comments received from the provider community. *See* 80 Fed. Reg. 8247, 8247-48 (Feb. 17, 2015).

In the absence of a final rule for Medicare Part A and B overpayments, CMS proceeded to propose and finalize an overpayment rule for Medicare Parts C and D. The final rule for Medicare Parts C and D overpayments, issued in May 2014, differed in several respects from CMS's Medicare Part A and B Proposed Rule, including, for example:

- CMS adjusted the definition of identification to include the concept of "reasonable diligence"; and
- CMS also adopted a six-year lookback period.

Unsurprisingly, with the absence of final rulemaking from CMS, courts also began weighing in on when an overpayment is "identified" in FCA cases. In an eagerly anticipated decision issued on August 3, 2015, the Southern District of New York became the first federal court to interpret and define the extent of a provider's obligations under

the 60-day rule. *See Kane ex rel. New York v. Healthfirst, Inc.*, 11 CIV. 2325 (ER), 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015). The court adopted the government’s position that identification includes situations where “a person is put on notice that a certain claim may have been overpaid.” Thus, based on the Southern District of New York’s interpretation of the meaning of “identification,” the 60-day clock may begin (and indeed may expire) before the provider has had sufficient time to complete a reasonable investigation. Understandably, the aggressive standard for “identification” advanced in *Kane* was troubling to the provider community.

Below we outline the evolving “identification” standards articulated since the passage of the ACA in 2010.

Evolving “Identification” Standard	
CMS Medicare Parts A/B Proposed rule (February 2012)	A person has identified an overpayment “if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.” 77 Fed. Reg. 9179, 9182 (Feb. 16, 2012) (emphasis added).
CMS Medicare Parts C/D Proposed Rule (January 2014)	A person has identified an overpayment if the person had actual knowledge of the existence of the overpayment or acted in reckless disregard or deliberate ignorance of the overpayment. 79 Fed. Reg. 1919, 1997 (Jan. 10, 2014) (emphasis added).
CMS Medicare Parts C/D <u>Final</u> Rule (May 2014)	A Medicare Advantage organization or Part D Sponsor has identified an overpayment when it “has determined, or should have determined through the exercise of reasonable diligence ” that it received an overpayment. 79 Fed. Reg. 29844, 29923-24 (May 23, 2014) (emphasis added).
<i>United States v. Healthfirst, Inc.</i> , No. 11 Civ. 2325 (ER), 2015 WL 4619686 at *11 (S.D.N.Y. Aug. 3, 2015)	A provider “identifies” an overpayment when it is “put on notice that a certain claim may have been overpaid.” (Emphasis added).
CMS Medicare Parts A/B <u>Final</u> Rule (February 2016)	A person has identified an overpayment when the person “has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. ” 81 Fed. Reg. at 7654 (emphasis added).
CMS Medicaid Rule	No proposed or final rule to date.

II. FINAL RULE: MEDICARE PARTS A AND B OVERPAYMENT REPORTING AND RETURNING REQUIREMENTS

Overall, while certain questions remain, providers will likely be relieved to see that CMS appears to have addressed many provider concerns in its final rulemaking. Below we outline several significant concepts contained in the Final Rule and their potential implications for the provider community. We also identify those areas where uncertainty remains.

a. IDENTIFICATION STANDARD

As noted above, since the enactment of the ACA, several differing standards for overpayment “identification” have developed which further complicated the landscape and compliance with the 60-day rule. In the absence of final rulemaking from CMS, providers and the government (and relators’ counsel) have debated the standard for identification and specifically whether an overpayment can be identified *before* it is quantified. Importantly, in the Final Rule, CMS defines identification as when a person “*has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.*” 81 Fed. Reg. at 7654 (emphasis added).

i. Quantification of Overpayments

The Final Rule clarifies that a provider is entitled to the opportunity to conduct the auditing work necessary to quantify the overpayment amount *before* the 60-day clock begins. Said differently, a provider does not have to deplete its 60 days with efforts to quantify Medicare Parts A and B overpayments, which may involve significant effort and multiple layers of analysis. Specifically, CMS stated that “[t]he 60-day time period begins when either the reasonable diligence is completed or on the day the person received credible information of a potential overpayment if the person failed to conduct reasonable diligence and the person in fact received an overpayment.” 81 Fed. Reg. at 7661. CMS explains that the identification standard in the Final Rule “strikes the right balance between creating a flexible yet strong standard that applies to many different circumstances.” 81 Fed. Reg. at 7660.

CMS offers additional commentary in the Final Rule on the potential tension between quantifying overpayments with respect to single claims versus quantifying a more comprehensive overpayment. Often, a provider will conduct a probe sample to better understand the extent of a potential issue and to evaluate whether further efforts, such as extrapolation, may be appropriate. CMS notes “that the provider or supplier should not report and return overpayments on specific claims from the probe sample until the full overpayment is identified.” 81 Fed. Reg. at 7664.

While the quantification concept included in the Final Rule will offer welcome relief to some providers, it is important to recognize that the government or relators’ counsel could pursue more aggressive positions in other contexts (e.g., Medicaid overpayments). As noted above, in *Kane* (which involved Medicaid payments), the Southern District of New York expressly rejected the position that the 60-day clock did not begin until quantification of the overpayment. Given that the Final Rule only applies to Medicare Parts A and B overpayments, providers should continue to monitor the evolving “identification” standards such as the aggressive *Kane* position.

Additionally, the Office of Inspector General (OIG) through its Corporate Integrity Agreements (CIAs) has historically taken the position that overpayments can be identified *prior to* quantification. Specifically, CIAs typically contain a provision stating:

If, at any time, Provider identifies any Overpayment, Provider shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet *quantified, within 60 days after identification*, Provider shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. (Emphasis added).

It is unclear whether OIG may ultimately refine its position for CIA-obligated providers with respect to the timing of overpayment reporting requirements based on CMS's position in the Final Rule. This may be an issue that CIA-obligated providers wish to address with their OIG Monitors.

ii. Reasonable Diligence

Unsurprisingly, like the Proposed Rule, the Final Rule's definition of identification guards against the so-called "ostrich defense." Providers cannot avoid liability by ignoring indications of potential Medicare Parts A and B overpayments. The Final Rule indicates that a person has identified an overpayment "***if the person fails to exercise reasonable diligence and the person in fact received an overpayment.***" 81 Fed. Reg. at 7683 (emphasis added). "Reasonable Diligence" is a subjective term and even CMS acknowledges that "reasonableness" is "fact-dependent." 81 Fed. Reg. at 7662. However, CMS indicates that reasonable diligence "includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment." 81 Fed. Reg. at 7661. Thus, the Final Rule uses the term "reasonable diligence" to "cover both proactive compliance activities" and "reactive investigative activities." 81 Fed. Reg. at 7661. CMS further states in the Final Rule that "undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or supplier to liability under the identification standard articulated in [the Final Rule] based on failure to exercise reasonable diligence if the provider or supplier received an overpayment." 81 Fed. Reg. at 7661.

The February 2012 Proposed Rule indicated that providers must conduct reasonable inquiries into potential overpayments with "all deliberate speed." However, in the Final Rule, CMS discards the concept of "all deliberate speed." Rather, CMS establishes a six-month benchmark for reasonably diligent investigations. CMS states that absent "extraordinary circumstances," a timely, good faith investigation of credible information will last ***at most*** six months from the receipt of the credible information. 81 Fed. Reg. at 7662. Thus, generally, a provider will have no more than eight months total to report and return Medicare Parts A and B overpayments (six months for investigation and two months for the reporting and returning efforts). However, Medicare Parts A and B overpayments should be reported more quickly (i.e., in less than eight months), if feasible, in light of the factual circumstances of the overpayment analysis. "Extraordinary circumstances" will be a fact-specific inquiry but CMS indicated that "extraordinary circumstances" may include unusually complex investigations, such as physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol. CMS advises providers to "maintain records that accurately document their reasonable diligence efforts to be able to demonstrate their compliance with the [Final Rule]." 81 Fed. Reg. at 7662.

iii. Credible Source of Overpayments

Importantly for providers, CMS stated that it believes that "contractor overpayment determinations are ***always a credible source*** of information for other potential overpayments" and that "in certain cases, the conduct that serves as the basis for the contractor identified overpayment may be nearly identical to conduct in some additional time period not covered by the contractor audit." 81 Fed. Reg. at 7667 (emphasis added). In light of the expansive CMS contractor program and the exponential increase in contractor reviews, this position being advanced by CMS is concerning for multiple reasons. For example, CMS specifically limits the lookback period for Quality Improvement Organization (QIO) and Recovery Auditor (RAC) reviews of patient status determinations under the Two Midnight Rule. However, based on the Final Rule, the government could argue that, if a QIO or RAC identifies patient status issues within their limited lookback period, a provider's investigative responsibilities could extend beyond the contractor's lookback period.

iv. Overpayments Associated With Items Included on the Medicare Cost Report

Pursuant to the Overpayment Law, CMS held that overpayments that would typically be settled on a provider's annual cost report need not be returned within 60 days of identification but instead must be returned when the cost report is filed, which is five months after the cost reporting period ends. In other words, CMS has determined that for virtually all cost report overpayments, "applicable reconciliation" . . . occur[s] when the cost report is filed" (two limited exceptions to this rule are discussed below). 81 Fed. Reg. at 7668. CMS reasoned that "[w]hen a provider files its cost report, it is attesting to the accuracy of the provider's reconciliation of the interim payments and costs." 81 Fed. Reg. at 7669. Therefore, "the 'applicable reconciliation' is the provider's year-end reconciliation of payments and costs to create the cost report." It follows, then, that any "overpayment should be returned at the time the cost report is filed." 81 Fed. Reg. at 7669.

As mentioned above, CMS established two exceptions to this rule for (1) overpayments associated with changes in the Supplemental Security Income (SSI) ratio used in calculating a hospital's disproportionate share payment (DSH) and (2) overpayments attributable to outlier payment reconciliation. In those limited cases, there is no "refund obligation until such time as the final settlement of the hospital's cost report occurs." 81 Fed. Reg. at 7669.

The obvious practical ramification of CMS's policy is that providers will be forced to include payment-in-full with any cost report that indicates they have been overpaid or risk liability under the Overpayment Law. (Previously, if a provider filed a cost report that indicated the provider was overpaid by Medicare and the provider did not accompany the filed cost report with the overpayment amount, interest would begin to accrue on that amount as of the date of filing.)

Some commenters asked what should be done if an overpayment is identified *after* the cost report is filed but *before* a Notice of Program Reimbursement (NPR) has been issued. CMS's response, although a bit opaque, suggests that providers must return any overpayment identified after the cost report has been filed within 60 days of identification and may not wait for the NPR: "If the provider self-identifies an overpayment after *the submission and applicable reconciliation* of the Medicare cost report, it is their responsibility to follow the procedures in [the Final Rule], and report and return the overpayment within 60 days of identification." 81 Fed. Reg. at 7670 (emphasis added). Since CMS previously explained that "submission" of a cost report constitutes "applicable reconciliation," it is odd that CMS's answer suggests that these are two separate events. The remainder of CMS's answer, however, suggests that providers may not wait for the NPR to make repayments under these circumstances since CMS explained that when overpayments are identified after the original cost report has been filed, providers should "submit an amended cost report[] along with the overpayment refund." 81 Fed. Reg. at 7670. Amended cost reports are usually submitted prior to the issuance of an NPR (providers would generally request a "reopening" after the issuance of an NPR). In addition, if "after reconciliation of the Medicare cost report" meant the issuance of the NPR, CMS's reference to repayment within 60 days would be unnecessary since the NPR itself would state the repayment deadline. This repayment policy may prove to be a substantial burden on providers. As commenters pointed out, the policy potentially "force[s] providers to send in numerous overpayments for minor errors while the cost report is open." 81 Fed. Reg. at 7670. This is especially true since there are no *de minimis* exceptions.

Another troubling aspect of CMS's Final Rule is CMS's policy that "[i]f the [Medicare Administrative Contractor] MAC notifies a provider of an improper cost report payment, the provider has received credible information of a potential overpayment and *must conduct reasonable diligence on other cost reports within the lookback period* to determine if it has received an overpayment." 81 Fed. Reg. at 7670 (emphasis added). Providers, in other words, no longer can wait to see if a MAC that discovered an alleged overpayment in a current year will reopen earlier years but arguably must now affirmatively seek such a reopening. CMS's reference to the "lookback period" is also concerning because it could be read as superseding the usual three-year cost report reopening window and requiring repayment

for payments received up to six years earlier. CMS specifically disavowed making any changes to the three-year cost report reopening limitation, however, and did not explain how to reconcile a six-year lookback period included in the Final Rule with a three-year limitation on cost report reopenings.

One of the few bright spots in the Final Rule policies regarding cost report repayments is CMS's policy that only cost report errors that result in actual overpayments need be disclosed: "If a provider identifies an error or omission that does *not* result in an overpayment, then the requirements of the [Overpayment Law] or [the Final Rule] do not apply." 81 Fed. Reg. at 7669 (emphasis added). Since most providers are now paid under the Prospective Payment System, and are not paid based on their reasonable costs, not all items on the cost report will affect actual reimbursement. The interplay between cost report items and reimbursement can be complex, however, so providers would be well advised to seek expert advice before determining that a cost report error is "harmless."

b. DEFINITION OF OVERPAYMENT

The Overpayment Law defines overpayment as meaning "any funds that a person receives or retains [under the Medicare or Medicaid programs] to which the person, after applicable reconciliation, is not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B). CMS uses this same definition in the Final Rule but acknowledges the concern expressed by the provider community regarding the "breadth" of the overpayment definition. 81 Fed. Reg. at 7656. CMS explained that it has addressed these concerns by "expanding the ways in which overpayments may be reported and returned to include the claims adjustments or reversal and credit balance reporting process." 81 Fed. Reg. at 7656. In the Final Rule, CMS explains that it is "unable to make blanket statements or address every factual permutation in this rulemaking, and thus it is not feasible for [the agency] to enumerate all specific examples of overpayments." 81 Fed. Reg. at 7657. CMS instructs providers and suppliers to "analyze the facts and circumstances relevant to their situation to determine whether an overpayment exists. Commenters also stated that the concept of "overpayments" is less than clear when dealing with issues such as alleged "insufficient documentation" or "lack of medical necessity." In response, CMS states that sufficient documentation and medical necessity are "longstanding and fundamental prerequisites to Medicare coverage and payment." 81 Fed. Reg. at 7658.

In response to the Proposed Rule, many providers adopted policies regarding who within the organization is authorized to "identify" overpayments. One purpose of such policies is to ensure that the appropriate leadership team is made aware when overpayments are "identified" within the organization so that appropriate remediation can be pursued (including refunding efforts). In the Final Rule, CMS rejected the commenters' recommendations that senior leadership must confirm the existence of an overpayment before "knowledge" could be attributed to the organization. Specifically, CMS stated that "organizations are responsible for the activities of their employees and agents at all levels." 81 Fed. Reg. at 7665.

c. LOOKBACK PERIOD

Providers have long struggled with respect to what lookback period should be relied upon when conducting internal reviews. In the absence of clear guidance from CMS, many providers have relied upon the four-year reopening period for Medicare contractors contained in 42 C.F.R. § 405.980. Pursuant to the Final Rule, Medicare Parts A and B overpayments must be reported and returned "only if a person identifies the overpayment within *six years* of the date the overpayment was received." 81 Fed. Reg. at 7654 (emphasis added). As noted above, CMS had originally proposed a ten-year lookback period for Medicare Parts A and B overpayments in its Proposed Rule, but had finalized a six-year lookback period for Medicare Parts C and D in May 2014.

While the reduced lookback period from ten years to six years is a positive development for providers, there may be numerous challenges when utilizing a six-year lookback period. For example, the relevant Medicare guidance may

have evolved over the six-year period which may significantly increase the difficulty of the internal review if different standards must be applied. Moreover, it is possible that a provider may have experienced a system conversion during the six-year period which may increase the difficulty of obtaining the relevant medical records. There are also recordkeeping considerations which may further complicate the utilization of a six-year lookback period.

We also note that this lookback period is a *maximum* threshold. Accordingly, we do not believe providers should be foreclosed from using a more limited lookback period if justified by the relevant circumstances. For example, if an audit focuses on overpayments resulting from a specific coverage change or an electronic health record system conversion, a provider should be able to justify a lookback period of less than six years. If a reduced lookback period is utilized, providers may want to consider disclosing the reasons supporting the reduced lookback period in their overpayment refund submission.

d. PROCESS FOR REPORTING AND RETURNING OVERPAYMENTS

Under the Final Rule, to report and return Medicare Parts A and B overpayments, providers are instructed to use existing processes. Specifically, the Final Rule states that providers and suppliers must use an applicable claims adjustment, credit balance, self-reported refund, or another appropriate process to satisfy the obligation to report and return Medicare Parts A and B overpayments.

In the Proposed Rule, CMS proposed an extensive list of data elements required for overpayment reporting. *See* 77 Fed. Reg. at 9181. However, in the Final Rule, CMS abandoned that proposal and instead will rely on the information required for the applicable reporting and returning overpayment process, with one exception; CMS indicated it continues to believe that additional detail is needed where an overpayment amount is extrapolated based on a statistical method. Accordingly, pursuant to 42 C.F.R. § 401.305, providers will be required to describe the statistically valid sampling and extrapolation methodology in any Medicare Parts A and B overpayment report involving extrapolations based on a statistical method. Additionally, providers using the OIG Self-Disclosure Protocol or CMS's Self-Referral Disclosure Protocol must comply with the requirements of these respective protocols.

Historically, MAC voluntary refund processes have varied by contractor. MACs may issue updated refund guidance in light of the Final Rule and, accordingly, providers should consider monitoring their MAC's website for such issuances.

e. ADDITIONAL CONSIDERATIONS

As noted above, the Final Rule only applies to Medicare Parts A and B and thus does not address Medicaid overpayments. However, the Overpayment Law is not so limited. In the Final Rule, CMS stresses that providers who identify overpayments received from the Medicaid program should report and return those overpayments to the appropriate payor as required by the Overpayment Law.

As noted in the Final Rule, many commenters stated that providers and suppliers who submit claims to Medicare Parts A and B also submit claims to Medicare Parts C and D and Medicaid. Thus, commenters requested that CMS issue a rule which is applicable to *all* Medicare and Medicaid overpayments. CMS declined such request from the provider community and instead responded that there are distinctions between Medicare Parts A and B and Medicare Parts C and D and Medicaid. Thus, CMS concluded that "separate rulemaking processes are appropriate to address those differences." 81 Fed. Reg. at 7655.

Additionally, CMS has emphasized that the Overpayment Law did not require implementing regulations to become effective. Accordingly, even prior to the issuance of the Final Rule providers were subject the Overpayment Law and could face potential FCA and Civil Money Penalties (CMP) liability for failing to properly report and return Medicare Parts A and B overpayments. However, CMS does clarify that the Final Rule is *not* retroactive. Thus, providers that reported and/or returned Medicare Parts A and B overpayments prior to the effective date of the Final Rule (March 14, 2016) are not expected to have complied with each provision of the Final Rule. 81 Fed. Reg. at 7673. For the time period between the enactment of the ACA in 2010 and the effective date of the Final Rule on March 14, 2016, CMS notes that providers and suppliers may rely on their good faith and reasonable interpretation of the Overpayment Law. 81 Fed. Reg. at 7674.

III. CONCLUSION

In light of this significant Final Rule, providers should consider whether any policies and procedures may need to be refined given the important developments and considerations outlined in this Alert. The Final Rule will continue to shape compliance and enforcement efforts regarding the improper retention of overpayments.

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