

# REVIEWS WITH A PURPOSE

HCCA Houston Regional 2020

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## WHAT ARE THE AVAILABLE METHODS TO REPAY OR REPORT AN IMPROPER PAYMENT?

- ▶ Repayment through the MAC/Payer
- ▶ Self Report to CMS
- ▶ Self-Report to HHS-OIG
- ▶ Self Report to DOJ

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## MAC

- ▶ Novitas: <https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00008243>
- ▶ Review questions required to report and pay
- ▶ [https://www.novitas-solutions.com/webcenter/content/conn/UCM\\_Repository/uuid/dDocName:00008285](https://www.novitas-solutions.com/webcenter/content/conn/UCM_Repository/uuid/dDocName:00008285)
- ▶ Review implications of reporting
- ▶ Review limitations

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## NOVITAS FORM B QUESTIONS

- ▶ Multiple Claims
- ▶ Medicare Secondary Payment (MSP) Refunds
- ▶ Statistical Sampling: "If specific Beneficiary/MBI/Claims data is not available, indicate the methodology and formula used to determine the refund amount and explain the reason for the refund"
- ▶ OG Self-Disclosure Refund
- ▶ Certification whether you have a CIA with OIG OR Are participating under the OIG Self-Disclosure Protocol.

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## NOVITAS FORM A QUESTIONS

- ▶ “ STATISTICAL SAMPLING/VOLUNTARY DISCLOSURES”
  - ▶ Why was the voluntary refund made?
  - ▶ How was it identified?
  - ▶ What sampling techniques were employed
  - ▶ What steps were taken to assure the issue leading to the overpayment was corrected?
  - ▶ The dates of the corrective action was implemented?
  - ▶ Then claims and claim information involved in the inappropriate payment?
  - ▶ The methodology used to arrive at the amount of the refund?
  - ▶ Was a full assessment performed to determine the entire time from and the total amount of the refund for the period during which the problem existed that caused the refund?

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## PROVIDER DISCLOSURE ELEMENTS

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
5															
6 Please note the following items:															
7															
8 All fields that start with ** are CMS required fields for adjustment to be completed. The remaining fields are beneficial															
9 for efficiency and accuracy in processing your voluntary refund.															
10															
11 Medicare Secondary Payment (MSP) Refunds should include a copy of the primary insurer's explanation of benefits															
12 (EOB) & indicate the MSP reason.															
13															
**Claim Number	**MBI Number	**Patient Name	From Date of Service	To Date of Service	Billing Provider Number	CIA/DIG Yes or No	Procedure	Modifier	Units Billed	Corrected # of Units	Billed Amount	Paid Amount	Amount Being Refunded	MSP Reason	**Reason For Overpayment

Note adjustment column. Recall anything older than a year has to have a request to reopen and be approved by CMS. It is discretionary.

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## MEDICARE OVERPAYMENTS

- ▶ Overpayments are Medicare funds that you or a beneficiary has received in excess of the amount allowed payable under the Medicare statute and regulations.
- ▶ Once a determination of an overpayment has been made, the amount of the overpayment is a debt owed to the United States Government, via Novitas Solutions, as one of its Medicare contractors.
- ▶ Note: If you have questions related to the overpayment process, please contact our Customer Service Center

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## REASONS FOR OVERPAYMENT

- ▶ A provider is liable for an overpayment received unless they are "without fault". "Without fault" means that you could not have known or been expected to know that this was an overpayment. On the other hand, "with fault" means that you should have known or been expected to know that this was an overpayment.
- ▶ Examples of overpayments where you could be liable include, but are not limited to, the following:
  - ▶ Payment exceeds the reasonable charge for the service
  - ▶ Duplicate payments of the same service(s)
  - ▶ Incorrect provider payee
  - ▶ Incorrect claim assignment resulting in incorrect payee
  - ▶ Payment for non-covered, non-medically necessary services
  - ▶ Services not actually rendered
  - ▶ Payment made by a primary insurance
  - ▶ Change in year of service

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## PER CMS

- ▶ **Identifying an Overpayment**
  - ▶ Voluntary Refund (Provider/Beneficiary Reported)
  - ▶ A voluntary/unsolicited refund made to Novitas when a provider has discovered an error, which resulted in an overpayment.
- ▶ **Overpayments can be identified in the following processes:**
  - ▶ Beneficiary or provider may find the payment error
  - ▶ A contractor employee may discover the overpayment during a review process
  - ▶ [Use of Statistical Sampling](#)
  - ▶ [Voluntary Disclosures](#)
- ▶ **The following document will help you to notify us of an overpayment.**
  - ▶ [Notifying Medicare of an Overpayment](#)
- ▶ To facilitate prompt and accurate credit of unsolicited monies or voluntary refunds to Medicare, we developed a **Return of Monies to Medicare form**.
  - ▶ [Return of Monies to Medicare Form](#)
- ▶ Novitas follows the process below when a provider sends us money in error.
- ▶ **Overage checks**
  - ▶ When an overpayment is identified a claim adjustment will occur. This will create a receivable account which will issue a demand letter requesting repayment.

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## NOTIFYING MEDICARE OF AN OVERPAYMENT

- ▶ If you believe that an overpayment has been made, you can notify Medicare by:
- ▶ Medicare Redetermination and Clerical Error Reopening Request Form ([Part A](#)) ([Part B](#)):
- ▶ Do not include a check when sending Redetermination and Clerical Error Reopening Request Form
- ▶ Novitas (Part B only) Billed in Error ([JH](#)) ([JL](#))
- ▶ Unsolicited Return of Monies Form ([Part A](#)) ([Part B](#)):
- ▶ Include a check when sending Unsolicited Return of Money Form
- ▶ If refunding a high volume (100 or more) of claims, please use our [Voluntary Refunds Spreadsheet](#)

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## MEDICARE SECONDARY PAYER OVERPAYMENT

- ▶ Same as slide before plus:
- ▶ If you are returning an Overpayment due to Medicare Secondary Payer (MSP), please provide the following items:
  - ▶ Primary Insurer's explanation of benefits
  - ▶ Type of MSP involved
  - ▶ Other Insurer Information
  - ▶ Employer Information if Applicable
  - ▶ Date of Loss (if available)

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## ELEMENTS FOR SECONDARY PAYER REPORTING

- ▶ Regardless of how you notify Medicare of the overpayment, you must provide the following information:
  - ▶ Provider name and number
  - ▶ Medicare Beneficiary ID Number(s)
  - ▶ Claim number(s)
  - ▶ Reason for overpayment
  - ▶ Amount of overpayment
  - ▶ Method of repayment
  - ▶ Copy of the primary insurance Explanation of Benefits (MSP situations only)
  - ▶ If you do or do not have a Corporate Integrity Agreement with the Office Inspector General (OIG)
  - ▶ If you are or are not participating in an OIG Self-Disclosure Protocol

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## UNSOLICITED / VOLUNTARY REFUND DISCLAIMER

- ▶ According to the Centers for Medicare & Medicaid Services Medicare Program Integrity Manual, Publication 100-08, Chapter 4, §4.16, acceptance of a voluntary refund in no way affects or limits the rights of the Federal Government, or any of its agencies or agents, to pursue any appropriate criminal, civil, or administrative remedies arising from these or any other claims.

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### **4.16 – MAC AND UPIC COORDINATION ON VOLUNTARY REFUNDS** **(REV. 851, ISSUED: 12-14-18, EFFECTIVE: 10-22-18, IMPLEMENTATION: 10-22-18)**

- ▶ Voluntary refund checks payable to the Medicare program shall not be returned to the provider/supplier, regardless of the amount of the refund. The *UPIC* shall communicate with the MAC staff responsible for processing voluntary refunds to obtain information on the checks received. The MAC shall refer to Pub. 100-06, Financial Management Manual, for instructions on processing and reporting unsolicited/voluntary refunds received from providers/physicians/suppliers.
- ▶ The *UPIC* shall perform an investigation on any voluntary refund where there is suspicion of inappropriate payment or if a provider/supplier is under an active investigation.

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## 4.16 CONTINUED

- ▶ Through the JOA, the *UPIC* shall establish a mechanism whereby the MAC **notifies the *UPIC* on a regular basis of all voluntary refunds it received.**
- ▶ The *UPIC* or MAC shall send one letter annually (calendar year) to any provider/supplier that submits a voluntary refund during that calendar year, advising the provider/supplier of the following:
  - ▶ **“The acceptance of a voluntary refund in no way affects or limits the rights of the Federal Government or any of its agencies or agents to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims.”**
- ▶ The *UPIC* shall refer to section 4.4.1(G) and (H) of this chapter for law enforcement requests for voluntary refund information.

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## CMS

Self report to CMS-STARK ONLY

- ▶ The SRDP is intended to facilitate the resolution of only matters that, in the disclosing party's reasonable assessment, are actual or potential violations of the physician self-referral law. Thus, a disclosing party should make a submission under the SRDP with the intention of resolving its overpayment liability exposure for the conduct it identified. As provided in the physician self-referral law, no payment may be made for designated health services that are provided in violation of the physician self-referral law. Section 6409(b) of the ACA gives the Secretary of HHS the authority to reduce the amount due and owing for violations of Section 1877 of the Act
- ▶ <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/SelfReferralDisclosureProtocol.html>

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## LOOKBACK PERIOD FOR DISCLOSURES

- ▶ On February 12, 2016, CMS published a final rule for the reporting and returning of overpayments (the “final overpayment rule”). See 81 FR 7653. The effective date for this rule was March 14, 2016. Among other things, the final overpayment rule established a 6-year lookback period for the reporting and returning of overpayments under regulations at 42 CFR 401.305(f).

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## HHS-OIG

- ▶ The Provider Self-Disclosure Protocol (SDP) is intended to facilitate the resolution of only matters that, in the provider’s reasonable assessment, **potentially violate Federal criminal, civil, or administrative laws.**
- ▶ Review implications of reporting:
  - ▶ OIG may confer with the Department of Justice to ensure that it is aware of each disclosure and has an opportunity to offer its opinion before the OIG accepts a provider into the Provider Self-Disclosure Protocol (SDP).
  - ▶ It is important to stress that the OIG’s agreement to resolve an SDP matter is not binding upon the DOJ.
  - ▶ OIG also consults with other affected Government agencies, as needed
- ▶ Review limitations:
  - ▶ Does not release Stark violation.
  - ▶ Providers cannot self-disclose an issue if it is already under investigation.
  - ▶ The SDP should not be used for mere billing errors or overpayments. Billing errors and overpayments should be reported to the contractor responsible for processing claims and issuing payments on behalf of the federal health care program.
  - ▶ <https://oig.hhs.gov/faqs/provider-self-disclosure-protocol-faq.asp>

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## WHO CAN REPORT

- ▶ All health care providers, suppliers, or other individuals or entities who are subject to OIG's CMP authorities found at 42 C.F.R. Part 1003 are eligible to use the SDP.
- ▶ The SDP is not limited to any particular industry, medical specialty, or type of service.
- ▶ For example, a pharmaceutical or medical device manufacturer may use the SDP to disclose potential violations of the Federal anti-kickback statute (AKS), section 1128B(b) of the Act, because such violations trigger CMP liability under section 1128A(a)(7) of the Act, a provision of the CMPL.

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## WHO SHOULD/CAN REPORT

- ▶ The disclosing party should disclose conduct for which it may be liable, **including potential successor liability based on its purchase of another entity**. For example, a disclosing party could have liabilities as the result of a merger or an acquisition.
- ▶ **Disclosing parties already subject to a Government inquiry (including investigations, audits, or other oversight activities) are not automatically precluded from using the SDP.** The disclosure, however, must be made in good faith and must not be an attempt to circumvent any ongoing inquiry. Disclosing parties under Corporate Integrity Agreements (CIA) with OIG may also use the SDP in addition to making any reports required in the CIA.

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## CONDUCT ELIGIBLE FOR THE SDP

- ▶ The SDP is available to facilitate the resolution of matters that, in the disclosing party's reasonable assessment, potentially violate Federal criminal, civil, or administrative laws for which CMPs are authorized. In making a disclosure, a disclosing party must acknowledge that the conduct is a potential violation. Disclosing parties must explicitly identify the laws that were potentially violated and should not refer broadly to, for example, "Federal laws, rules, and regulations" or "the Social Security Act."

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## CONDUCT INELIGIBLE FOR THE SDP

- ▶ ...the SDP is **not available for disclosure of an arrangement that involves only liability under the physician self-referral law**, section 1877 of the Act (the Stark Law), without accompanying potential liability under the AKS for the same arrangement. Disclosing parties must analyze each arrangement involving a physician to determine whether it raises potential liability under the AKS, the Stark Law, or both laws. Stark-only conduct should be disclosed to CMS through its Self-Referral Disclosure Protocol (SRDP), which can be found at: <http://www.cms.gov/PhysicianSelfReferral/>. OIG reserves the right to determine whether an arrangement is appropriate for resolution in the SDP.

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## TIME LIMITS AND TOLLING

- ▶ To preserve the rights of the parties while the matter is being resolved through the SDP, OIG expects disclosing parties to disclose with a good faith willingness to resolve all liability within the **CMPL's six year statute of limitations** as described in section 1128A(c)(1) of the Act. Accordingly, the disclosing party agrees, as a condition precedent to the OIG's acceptance into the SDP, to waive and not to plead statute of limitations, laches, or any similar defenses to any administrative action filed by OIG relating to the disclosed conduct

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## FALL OUT

- ▶ Prior to disclosure, the disclosing party should ensure that the conduct has ended or, at least, in the case of an improper kickback arrangement, that corrective action will be taken and the improper arrangement will be terminated within 90 days of submission to the SDP. Additionally, all other necessary corrective action should be complete and effective at the time of disclosure.

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## INVESTIGATION REQUIREMENT-TIMING

- ▶ The disclosing party is expected to conduct an internal investigation and report its findings to OIG in its submission.
- ▶ If the disclosing party is unable to complete its internal investigation before sending its submission, the **disclosing party must certify in its submission that it will complete the internal investigation within 90 days of the date of its initial submission.**

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## SOME ELEMENTS OF INTEREST

- ▶ If the disclosing party is an entity that is owned or controlled by or is otherwise part of a system or network, an organizational chart, a description or diagram describing the pertinent relationships; the names and addresses of any related entities; and any affected corporate divisions, departments, or branches.

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## FULL DISCLOSURE

- ▶ A concise statement of all details relevant to the conduct disclosed, including, at minimum, the types of claims, transactions, or other conduct giving rise to the matter; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the matter.
- ▶ A statement of the Federal criminal, civil, or administrative laws that are potentially violated by the disclosed conduct.

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## ESTIMATE VS ACTUAL DAMAGES

- ▶ An estimate of the damages, as described in the applicable section below, to each Federal health care program relevant to the disclosed conduct, or a certification that the estimate will be completed and submitted to OIG within 90 days of the date of submission. When a disclosing party can determine the amount of actual damages to Federal health care programs, the actual damages amount must be provided instead of an estimate.

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## REQUIREMENTS FOR CONDUCT INVOLVING FALSE BILLING

- ▶ OIG will verify a disclosing party's calculation of damages.
- ▶ The disclosing party's estimation of damages **must** consist of a review of either: (1) **all** the claims affected by the disclosed matter **or** (2) a **statistically valid random sample** of the claims that can be projected to the population of claims affected by the matter.
- ▶ A disclosing party may not extend the time to resubmit claims to Federal health care programs through the SDP; therefore, the damages estimation must not include a reduction, or "netting" for any underpayments discovered in the review.

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## SAMPLE MINIMUMS

- ▶ When using a sample to estimate damages, the disclosing party must use a sample of at least 100 items and use the mean point estimate to calculate damages. If a probe sample was used, those claims may be included in the 100-item sample if statistically appropriate.

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## SUBMISSION CONTENT

The disclosing party's report **must** include, at a minimum, the following information:

1. **Review Objective:** A statement clearly articulating the objective of the review.
2. **Population:** A description of the group of claims about which information is needed, an explanation of the methodology used to develop the population, and the basis for this determination.
3. **Sources of Data:** A full description of the source of the data reviewed and the information upon which the review was based, including the sources of payment data, and the documents that were relied upon.

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## CONTINUED

4. **Personnel Qualifications:** The names and titles of the individuals who conducted the review. The review should be conducted by qualified individuals, e.g., statisticians, accountants, auditors, consultants, and medical reviewers, and the review report should describe their qualifications.

5. **Characteristics Measured:** The review report should identify the characteristics used for testing each item. For example, in a review designed to estimate the value of overpayments due to duplicate payments, the characteristics used are those that must exist for an item to be a duplicate. The amount of the duplicate payment is the measurement of the overpayment. **The report must also explain the method for determining whether an item entirely or partially meets the criterion for having the characteristics measured.**

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**IF THE FINANCIAL REVIEW WAS BASED UPON  
A SAMPLE, THE REVIEW REPORT MUST ALSO  
INCLUDE THE SAMPLING PLAN THAT WAS  
FOLLOWED.**

1. **Sampling Unit:** Any of the designated elements that constitute the population of interest.
2. **Sampling Frame:** The totality of the sampling units from which the sample was selected and the way in which the audit population differs from the sampling frame (and the effect this difference has on conclusions reached as a result of the audit).
3. **Sample Size:** The size of the sample reviewed to reach the estimate of the damages. The sample size must be at least 100 claims.
4. **Source of Random Numbers:** The sample must be selected through random numbers. The source of the random numbers used must be shown in the report. We strongly recommend the use of OIG's Statistical Sampling Software, also known as "RAT-STATS," which is currently available free of charge at <https://oig.hhs.gov/compliance/rat-stats/index.asp>.
5. **Method of Selecting Sampling Units:** The method for selecting the sample units.
6. **Sample Design:** Unless the disclosing party demonstrates the need to use a different sample design, the review should use simple random sampling. If necessary, the disclosing party may use stratified or multistage sampling. Details about the strata, stages, and clusters should be included in the review report.
7. **Missing Sample Items and Other Evidence:** If the review was based on a sample, missing sample items should be treated as errors, pursuant to Federal health care program rules requiring the retention of supporting information for submitted claims. Missing sample items should be noted in the report. The report must also describe any evidence, other than the sample results, that was considered in arriving at the review results.
8. **Estimation Methodology:** If the review was based on a sample, because the general purpose of the review is to estimate the monetary losses to the Federal health care programs, the methodology to be used must be variables sampling (treating each individual item in the population as a sampling unit) using the difference estimator (estimates of the total errors in the population are made from the sample differences by multiplying the average audited difference by the number of units in the population).

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## **ANTI-KICKBACK**

- ▶ Any disclosure must clearly acknowledge that in the disclosing party's reasonable assessment of the information available at the time of the disclosure, the subject arrangement(s) constitute potential violations of the AKS and, if applicable, the Stark Law.
- ▶ As with other self-disclosed conduct, OIG needs to understand the precise nature of the disclosed conduct that creates potential AKS liability or both AKS and Stark Law liability. Therefore, the disclosing party must include in its narrative submission (not by reference to attachments or other documents) a concise statement of all details directly relevant to the disclosed conduct and a specific analysis of why each disclosed arrangement potentially violates the AKS and Stark Laws.

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## AK DAMAGES

- ▶ Thus, a disclosing party must submit an estimate of the amount paid by Federal health care programs for the items or services associated with potential violations of the AKS and, if applicable, the Stark Law. A disclosing party may use the methodology in section III.B to calculate the estimate.
- ▶ Alternatively, a disclosing party may identify another reliable methodology to calculate this claims-based estimate and explain that methodology in its submission.
- ▶ ...a disclosing party must include the total amount of remuneration involved in each arrangement without regard to whether the disclosing party believes a portion of the total remuneration was offered, paid, solicited, or received for a lawful purpose.
- ▶ A disclosing party may also explain what it believes is the value of the financial benefit conferred under the arrangement and whether it believes any portion of the total remuneration should not be considered by OIG in determining an appropriate settlement of OIG's CMP authorities. Given the various legal authorities at issue, OIG has broad discretion in determining an appropriate resolution in these cases.

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## CORRECTIVE ACTION

- ▶ A description of the disclosing party's corrective action upon discovery of the conduct.
- ▶ A certification by the disclosing party, or, in the case of an entity, an authorized representative on behalf of the disclosing party, stating that to the best of the individual's knowledge, the submission contains truthful information and is based on a good faith effort to bring the matter to the Government's attention for the purpose of resolving potential liability to the Government and to assist OIG in its resolution of the disclosed matter.

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## DOJ INVOLVEMENT

- ▶ In some cases, disclosing parties may request release under the FCA, and in other cases, DOJ may choose to participate in the settlement of the matters. If DOJ participates in the settlement, the matter will be resolved as DOJ determines is appropriate consistent with its resolution of FCA cases, which could include a calculation of damages resulting from violations of the AKS based on paid claims.
- ▶ OIG will advocate that the disclosing party receive a benefit from disclosure under the SDP and the matter be resolved consistent with OIG's approach in similar cases. However, DOJ determines the approach in cases in which it is involved.

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## OIG MINIMUM SETTLEMENT AMOUNTS

- ▶ For **kickback**-related submissions accepted into the SDP, OIG will require a minimum **\$50,000** settlement amount to resolve the matter. This minimum amount is consistent with OIG's statutory authority to impose a penalty of up to \$50,000 for each such transaction and an assessment of up to three times the total remuneration. See section 1128A(a)(7) of the Act.
- ▶ **For all other matters** accepted into the SDP, OIG will require a minimum **\$10,000** settlement amount to resolve the matter. This minimum amount is consistent with OIG's statutory authority to impose a penalty of at least up to \$10,000 for each improper claim submitted as described in the CMPL, section 1128A(a) of the Act.

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**DOJ SELF REPORT  
9-47.120 - FCPA CORPORATE  
ENFORCEMENT POLICY**

- ▶ What elements are they looking for
- ▶ What release can they give-
- ▶ What release can they not give
- ▶ What role does CMS ply
- ▶ What role does HHS-OIG play
- ▶ Fallout

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**DOJ SELF REPORT  
9-47.120 - FCPA CORPORATE  
ENFORCEMENT POLICY**

- ▶ "...the FCPA Corporate Enforcement Policy is aimed at providing additional benefits to companies based on their corporate behavior once they learn of misconduct.
- ▶ When a company has (1) voluntarily self-disclosed misconduct in an FCPA matter,(2) fully cooperated, and (3) timely and appropriately remediated, (4) all in accordance with the standards set forth below, there will be a presumption that the company will receive a declination absent aggravating circumstances involving the seriousness of the offense or the nature of the offender.
- ▶ Aggravating circumstances that may warrant a criminal resolution include, but are not limited to, involvement by executive management of the company in the misconduct; a significant profit to the company from the misconduct; pervasiveness of the misconduct within the company; and criminal recidivism."

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## DEFINITIONS

► a. *Voluntary Self-Disclosure in FCPA Matters*

In evaluating self-disclosure, the Department will make a careful assessment of the circumstances of the disclosure. The Department will require the following items for a company to receive credit for voluntary self-disclosure of wrongdoing:

- The voluntary disclosure qualifies under U.S.S.G. § 8C2.5(g)(1) as occurring “prior to an imminent threat of disclosure or government investigation”;
- The company discloses the conduct to the Department “within a reasonably prompt time after becoming aware of the offense,” with the burden being on the company to demonstrate timeliness; and
- The company discloses all relevant facts known to it, including all relevant facts about all individuals substantially involved in or responsible for the violation of law.

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## FULL COOPERATION IN FCPA MATTERS

- Disclosure on a timely basis of (1) all facts relevant to the wrongdoing at issue, including: all relevant facts gathered during a company’s independent investigation; (2) attribution of facts to specific sources where such attribution does not violate the attorney-client privilege, rather than a general narrative of the facts; (3) timely updates on a company’s internal investigation, including but not limited to rolling disclosures of information; (4) all facts related to involvement in the criminal activity by the company’s officers, employees, or agents; and (5) all facts known or that become known to the company regarding potential criminal conduct by all third-party companies (including their officers, employees, or agents);

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## ELEMENT CONTINUED

- ▶ Proactive cooperation, rather than reactive; that is, the company must timely disclose all facts that are relevant to the investigation, even when not specifically asked to do so, and, where the company is or should be aware of opportunities for the Department to obtain relevant evidence not in the company's possession and not otherwise known to the Department, it must identify those opportunities to the Department;

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## CONTINUED

- ▶ Timely preservation, collection, and disclosure of relevant documents and information relating to their provenance, including (a) disclosure of overseas documents, the locations in which such documents were found, and who found the documents, (b) facilitation of third-party production of documents, and (c) where requested and appropriate, provision of translations of relevant documents in foreign languages;

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## CONTINUED

- ▶ Where requested and appropriate, de-confliction of witness interviews and other
- ▶ Investigative steps that a company intends to take as part of its internal investigation with steps that the Department intends to take as part of its investigation[1]; and

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## CONTINUED

- ▶ Where requested, making available for interviews by the Department those company officers and employees who possess relevant information; this includes, where appropriate and possible, officers, employees, and agents located overseas as well as former officers and employees (subject to the individuals' Fifth Amendment rights), and, where possible, the facilitation of third-party production of witnesses.

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## FALLOUT: *TIMELY AND APPROPRIATE REMEDiation IN FCPA MATTERS*

Demonstration of thorough analysis of causes of underlying conduct (i.e., a root cause analysis) and, where appropriate, remediation to address the root causes;

Implementation of an effective compliance and ethics program, the criteria for which will be periodically updated and which may vary based on the size and resources of the organization, but may include:

- ▶ The company's culture of compliance, including awareness among employees that any criminal conduct, including the conduct underlying the investigation, will not be tolerated;
- ▶ The resources the company has dedicated to compliance;
- ▶ The quality and experience of the personnel involved in compliance, such that they can understand and identify the transactions and activities that pose a potential risk; The authority and independence of the compliance function and the availability of compliance expertise to the board;
- ▶ The effectiveness of the company's risk assessment and the manner in which the company's compliance program has been tailored based on that risk assessment;
- ▶ The compensation and promotion of the personnel involved in compliance, in view of their role, responsibilities, performance, and other appropriate factors;
- ▶ The auditing of the compliance program to assure its effectiveness; and
- ▶ The reporting structure of any compliance personnel employed or contracted by the company.

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## CONTINUED

- ▶ Appropriate discipline of employees, including those identified by the company as responsible for the misconduct, either through direct participation or failure in oversight, as well as those with supervisory authority over the area in which the criminal conduct occurred;

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## CONTINUED

- ▶ Appropriate retention of business records, and prohibiting the improper destruction or deletion of business records, including implementing appropriate guidance and controls on the use of personal communications and ephemeral messaging platforms that undermine the company's ability to appropriately retain business records or communications or otherwise comply with the company's document retention policies or legal obligations; and

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## CONTINUED

- ▶ Any additional steps that demonstrate recognition of the seriousness of the company's misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct, including measures to identify future risks.

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## FINAL NOTES

- ▶ Where a company asserts that its financial condition impairs its ability to cooperate more fully, the company will bear the burden to provide factual support for such an assertion. The Department will closely evaluate the validity of any such claim and will take the impediment into consideration in assessing whether the company has fully cooperated.
- ▶ *Remediation*: In order for a company to receive full credit for remediation and avail itself of the benefits of the FCPA Corporate Enforcement Policy, the company must have effectively remediated at the time of the resolution.

See <https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations#9-28.200>

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## WHY WOULD YOU CHOOSE ONE METHOD OVER ANOTHER?

- ▶ Ease of filing
- ▶ Reduction of audit risk
- ▶ Tolling the 60 Day reporting liability
- ▶ Stark Release
- ▶ Anti-kickback (civil) release
- ▶ Anti-kickback criminal release
- ▶ False Claims/Reverse False Claims release

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## 60 DAY RULE

- ▶ “Section 1128J(d) of the Act defines overpayment to include any funds that a person receives or retains to which the person is not entitled after applicable reconciliation. In the case of a non-covered service, as well as others, the amount to which the person is entitled is zero.”

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## AMOUNTS

- ▶ “In **circumstances where a paid amount exceeds the appropriate payment** amount to which a provider or supplier is entitled, the overpayment is the difference between the amount that was paid and the amount that should have been paid.
- ▶ In addition, there are **instances where payment is made for an item or service specifically not payable** under the Act (for example, claims resulting from Anti-Kickback Statute or physician self-referral law violations or claims for items and services furnished by an excluded person), or where the payment was secured through fraud. In these types of situations, the overpayment typically consists of the entire amount paid.”

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## DUTY REASONABLE INQUIRY

- ▶ "...in some cases, a provider or supplier may receive information concerning a potential overpayment that creates a duty to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider or supplier then has 60 days to report and return the overpayment.
- ▶ On the other hand, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider or supplier knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment."

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## "DELIBERATE IGNORANCE"

- ▶ "The final rule states that 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.
- ▶ A person should have determined that the person received an overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.
- ▶ "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." See CMS-6037-F

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## REASONABLE INQUIRY

- ▶ “If the reasonable inquiry reveals an overpayment, then the provider has 60 days to report and return the overpayment. On the other hand, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider or supplier knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment.”

See revised § 401.305(a) and (b) in the final rule

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## TIMING

- ▶ “...we adopt the standard of reasonable diligence and establish that this is demonstrated through the timely, good faith investigation of credible information, which is at most 6 months from receipt of the credible information, except in extraordinary circumstances....
- ▶ ...A total of 8 months (6 months for timely investigation and 2 months for reporting and returning) is a reasonable amount of time, absent extraordinary circumstances affecting the provider, supplier, or their community.”

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## RINGING THE BELL

- ▶ “The 60-day time period begins either when the reasonable diligence is completed and the overpayment is identified or on the day the person received credible information of a potential overpayment if the person fails to conduct reasonable diligence and the person in fact received an overpayment.
- ▶ **This standard**, as well as the requirement to conduct a timely, good faith investigation in response to obtaining credible information of a potential overpayment, **provide "bright line" standards** that should assist providers and suppliers in structuring their compliance programs to comply with the rule.”

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## CALCULATIONS

- ▶ We understand that a common way to conduct an audit is to use a probe sample and then incorporate that probe sample into a larger full sample as the basis for determining an extrapolated overpayment amount.
- ▶ In the probe sample, **it is not appropriate for a provider or supplier to only return a subset of claims identified as overpayments and not extrapolate the full amount of the overpayment.**
- ▶ We believe that in most cases, the extrapolation can be done in a timely manner consistent with the identification requirements of this rule and that the provider or supplier should not report and return overpayments on specific claims from the probe sample until the full overpayment is identified.

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## HOW WOULD YOU CONDUCT THE REVIEW AND REPAYMENT WITH THE METHOD YOU WANT IN MIND ?

- ▶ Audit and review standards
- ▶ Documented, accepted, followed by government?
- ▶ Performed by Compliance, legal, both?
- ▶ C- Suite input?
- ▶ Long term impact; extrapolation or not?

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## JUDGMENTAL VS EXTRAOLATION

- ▶ Probe audit, scope methodology and result use
- ▶ 60 Day comment on Judgmental and Duties to pursue review
- ▶ Extrapolation-minimum claims set per Medicare Integrity Manual and documentation requirements

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## HOW WOULD IT CHANGE YOUR DOCUMENTATION REQUIREMENTS

- ▶ Legal Privilege and Work Product Privilege
- ▶ Audit standards
- ▶ Review Standards
- ▶ OIG-Self Report Standards--insert
- ▶ DOJ standards-- review manual and insert

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## QUESTIONS?

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