

UPDATED

OIG's Provider Self-Disclosure Protocol

Note: This notice, issued on April 17, 2013, updates the Provider Self-Disclosure Protocol.



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Updated OIG's Provider Self-Disclosure Protocol

SUMMARY: This notice, issued on April 17, 2013, updates the Provider Self-Disclosure Protocol.

FOR FURTHER INFORMATION CONTACT: Patrice S. Drew, Department of Health and Human Services, Office of Inspector General, Congressional and Regulatory Affairs, at (202) 619-1368.

I. Background

In 1998, the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) published the Provider Self-Disclosure Protocol (the SDP) at 63 Fed Reg. 58399 (October 30, 1998) to establish a process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud involving the Federal health care programs (as defined in section 1128B(f) of the Social Security Act (the Act), 42 U.S.C. 1320a-7b(f)). The SDP provides guidance on how to investigate this conduct, quantify damages, and report the conduct to OIG to resolve the provider's liability under OIG's civil monetary penalty (CMP) authorities. Over the past 15 years, we have resolved over 800 disclosures, resulting in recoveries of more than \$280 million to the Federal health care programs.

Since the original publication, we identified areas where additional guidance would be beneficial to the health care community and would improve the efficient resolution of SDP matters. To that end, we issued three Open Letters to Health Care Providers in 2006, 2008, and 2009. Since the last Open Letter, we continued to evaluate our SDP process. We also solicited comments about the SDP on June 18, 2012, and we received numerous helpful comments from the public. On the basis of our experience and the comments we received, we have decided to revise the SDP in its entirety at this time. This revised SDP supersedes and replaces the 1998 *Federal Register* Notice and the Open Letters, as described below.

A. Why Disclosure Is Important

For many years, OIG has emphasized the importance of dealing with the Federal health care programs with integrity. All members of the health care industry have a legal and ethical duty to do so. This duty includes an obligation to take measures to detect and prevent fraudulent and abusive activities, including implementing specific procedures and mechanisms to investigate and resolve instances of potential fraud involving the Federal health care programs. Whether as a result of voluntary self-assessment or in response to external forces, participants in the health care industry must be prepared

to investigate such instances, assess the potential losses suffered by the Federal health care programs, and make full disclosure to the appropriate authorities.

B. Benefits of Disclosure

We recognize that whether to disclose potential fraud to OIG is a significant decision. However, there are significant benefits to disclosing potential fraud to OIG that should make that decision easier.

First, we believe that good faith disclosure of potential fraud and cooperation with OIG's review and resolution process are typically indications of a robust and effective compliance program. As a result, we have instituted a presumption against requiring integrity agreement obligations in exchange for a release of OIG's permissive exclusion authorities in resolving an SDP matter. Since 2008, we have resolved 235 SDP cases through settlements. In all but one of these cases, we have released the disclosing parties from permissive exclusion without requiring any integrity measures.

Second, we believe that individuals or entities that use the SDP and cooperate with OIG during the SDP process deserve to pay a lower multiplier on single damages than would normally be required in resolving a Government-initiated investigation. The specific multiplier that we accept may vary depending on the facts of each case. OIG's general practice in CMP settlements of SDP matters is to require a minimum multiplier of 1.5 times the single damages, although we determine in each individual case whether a higher multiplier may be warranted.

Third, we believe that using the SDP may mitigate potential exposure under section 1128J(d) of the Act, 42 U.S.C. 1320a-7k(d). Section 1128J(d)(2) of the Act requires that a Medicare or Medicaid overpayment be reported and returned by the later of (1) the date that is 60 days after the date on which the overpayment was identified or (2) the date any corresponding cost report is due, if applicable. Any overpayment retained by a "person," as defined in section 1128J(d)(4)(C) of the Act after this deadline may create liability under the Civil Monetary Penalties Law (CMPL), section 1128A of the Act, and the False Claims Act (FCA), 31 U.S.C. 3729. In its Notice of Proposed Rulemaking, 77 Fed. Reg. 9179-9187 (February 16, 2012), the Centers for Medicare & Medicaid Services (CMS) proposes to suspend the obligation to report overpayments under section 1128J(d) of the Act when OIG acknowledges receipt of a submission to the SDP so long as the submission is timely made. CMS also proposes to suspend the obligation to return overpayments until a settlement agreement is entered into, or the provider or supplier withdraws or is removed from the SDP. As necessary, we will provide additional guidance on OIG's web site concerning section 1128J of the Act and the SDP after CMS issues its final rule.

Finally, we commit to working with individuals and entities that use the SDP in good faith and cooperate with OIG's review and resolution process. OIG created the SDP to provide a specific and detailed process that can be relied upon by all participants in the

health care industry as one that OIG will consistently follow. As part of this commitment, we streamlined our internal process to reduce the average time a case is pending with OIG to less than 12 months from acceptance into the SDP. To further facilitate timely resolutions of SDP matters, we are changing the timeframe to submit the findings of the completed internal investigation and damages calculation from 90 days from acceptance into the SDP to 90 days from the date of the initial submission.

II. Eligibility Criteria and Guidance

This section explains the eligibility criteria for the SDP, including who may use the SDP and what conduct is and is not eligible for acceptance into the SDP.

A. Who May Use the SDP

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. For purposes of the SDP, we refer to all individuals or entities that make a submission to the SDP as "disclosing parties." 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. However, disclosing parties should not use the SDP to disclose conduct of another, unrelated party. OIG's hotline should be used to report potential misconduct of other parties (1-800-OIG-TIPS or <https://oig.hhs.gov/fraud/report-fraud/index.asp>).

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.

B. 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." OIG has

found that disclosing parties who avoid acknowledging that there is a potential violation are more likely to have unclear or incomplete submissions or unrealistic expectations about resolutions, which result in a lengthier review and resolution process. In addition, statements such as “the Government may think there is a violation, but we disagree” raise questions about whether the matter is appropriate for the SDP. The resulting back-and-forth over these issues can create unnecessary delays in reaching a resolution and may result in the disclosing party’s removal from the SDP.

C. Conduct Ineligible for the SDP

First, the SDP is not available for a matter that does not involve potential violations of Federal criminal, civil, or administrative law for which CMPs are authorized, such as one exclusively involving overpayments or errors. In this situation, the matter should be disclosed directly to the appropriate CMS or other responsible contractor under the payor’s voluntary refund process.

Second, the SDP is not available to request an opinion from OIG regarding whether an actual or potential violation has occurred. For example, a disclosure that broadly describes a business arrangement and requests a determination from OIG regarding whether the arrangement violates the AKS is not appropriate for the SDP. The Advisory Opinion process is the only vehicle to obtain an OIG opinion, as described at <https://oig.hhs.gov/compliance/advisory-opinions/index.asp>.

Third, 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.

D. Tolling the Statute of Limitations

As described above, one of the benefits of disclosure is that CMS has proposed that the time for repayment of an identified overpayment under section 1128J(d) of the Act will be tolled for the disclosing party. 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, except to the extent

that such defenses would have been available to the disclosing party had an administrative action been filed on the date of submission.

E. Corrective Action

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.

III. Submission Content

To be considered for admission into the SDP, the disclosing party must include the following information in its submission:

A. Requirements for All Disclosures

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.

Disclosures may be submitted through OIG's Web site at <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>. Disclosures may also be submitted by mail to the Chief of the Administrative and Civil Remedies Branch, Office of Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services, 330 Independence Avenue, SW, Cohen Building, Room 5527, Washington, DC 20201. Submissions by facsimile or other means will not be accepted. The narrative submission must include:

1. The name, address, type of health care provider, provider identification number(s), and tax identification number(s) of the disclosing party and the Government payors (including Medicare contractors) to which the disclosing party submits claims or a statement that the disclosing party does not submit claims.
2. 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.

3. The name, street address, phone number, and email address of the disclosing party's designated representative for purposes of the voluntary disclosure.
4. 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.
5. A statement of the Federal criminal, civil, or administrative laws that are potentially violated by the disclosed conduct.
6. The Federal health care programs affected by the disclosed conduct.
7. 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.
8. A description of the disclosing party's corrective action upon discovery of the conduct.
9. A statement of whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor. If the disclosing party has knowledge of a pending inquiry, it must identify any involved Government entity and its individual representatives. The disclosing party must also disclose whether it is under investigation or other inquiry for any other matters relating to a Federal health care program and provide similar information relating to those other matters.
10. The name of an individual authorized to enter into a settlement agreement on behalf of the disclosing party.
11. 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.

B. Requirements for Conduct Involving False Billing

When a disclosure involves the submission of improper claims to Federal health care programs, the disclosing party must conduct a review to estimate the improper amount paid by the Federal health care programs (referred to as “damages”) and prepare a report of its findings that follows the requirements in this section. 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.

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. To avoid unreasonably large sample sizes, the SDP does not require a minimum precision level for the review of claims. As a result, the disclosing party may select an appropriate sample size to estimate damages as long as the sample size is at least 100 items. As a general rule, smaller sample sizes (closer to 100) will suffice where the population has a high level of homogeneity, and larger sample sizes will be necessary where the population contains a more diverse mixture of claim types. The disclosing party should keep in mind that a careful and complete definition of the population will assist in making accurate findings.

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.
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.

If the financial review was based upon a sample, the review report must also include the Sampling Plan that was followed. At a minimum, this includes:

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).

C. Requirements for Conduct Involving Excluded Persons

Many SDP submissions disclose the employment of, or contracting with, individuals who appear on OIG's List of Excluded Individuals and Entities (LEIE) (available online at <https://exclusions.oig.hhs.gov>). We are providing additional guidance here to help disclosing parties gather the necessary information for a complete disclosure.

Specific Information

In addition to providing the general information required by section III.A, the disclosure must provide the following information:

1. The identity of the excluded individual and any provider identification number.
2. The job duties performed by that individual.
3. The dates of the individual's employment or contractual relationship.
4. A description of any background checks that the disclosing party completed before and/or during the individual's employment or contract.
5. A description of the disclosing party's screening process (including any policy or procedure that was in place) and any flaw or breakdown in that process that led to the hiring or contracting with the excluded individual.
6. A description of how the conduct was discovered.
7. A description of any corrective action (including a copy of any revised policy or procedure) implemented to prevent future hiring of excluded individuals.

In addition, before disclosing the employment of an excluded individual, a disclosing party must screen all current employees and contractors against the LEIE. Once this has been done, the disclosing party should disclose all excluded persons in one submission.

Calculating Damages

Federal health care programs may not pay, directly or indirectly, for items or services furnished, ordered, or prescribed by excluded individuals or entities. If a disclosing party employed or contracted with an excluded person who was a direct provider, such as a physician or a pharmacist, and the items or services furnished, ordered, or prescribed by that person were separately billed to Federal health care programs, the disclosure must include the total amounts claimed and paid by the Federal health care programs for those items or services.

We understand that when an excluded individual provided items or services that are not billed separately to Federal health care programs, such as many items or services furnished by nurses, respiratory therapists, and billing and other administrative personnel, the damages amounts can be difficult to quantify. For purposes of resolving SDP matters involving such non-separately-billable items or services, we use the disclosing party's total costs of employment or contracting during the exclusion to estimate the value of the items and services provided by that excluded individual. The costs of employment or contracting include, but are not limited to, all salary and benefits and other money or items of value, health insurance, life insurance, disability insurance, and employer taxes paid related to employment of the individual (e.g., employer's share of FICA and Medicare taxes). This total amount should be multiplied by the disclosing party's revenue-based Federal health care program payor mix for the relevant time period. (If a disclosing party can measure the Federal payor mix for the department or unit in which the excluded person worked, it is appropriate to apply that payor mix. If the departmental payor mix cannot reasonably be measured, the disclosing party must apply the payor mix for the whole entity.) The resulting amount will be used, for purposes of compromising OIG's CMP authorities in a settlement, as a proxy for the amount paid and the single damages to the Federal health care programs resulting from the employment of the excluded individual. When the disclosing party is using a Federal payor mix, the disclosure must include a separate calculation for each Federal health care program. For example, if the disclosing party's Federal payor mix is 60 percent, the disclosure should break down how the Federal health care programs make up that 60 percent, such as 40 percent Medicare, 10 percent Medicaid State A, 5 percent Medicaid State B, and 5 percent TRICARE.

D. Requirements for Conduct Involving the Anti-Kickback Statute and Physician Self-Referral Law

Another large category of SDP submissions relates to potential violations of the AKS (including conduct that violates both the AKS and the Stark Law). This section provides further guidance to help disclosing parties gather the necessary information for complete disclosure.

Specific Information

In this section, we provide additional guidance on submitting the information described in section III.A. 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. In the past, some disclosing parties have failed to include this acknowledgment in their submissions to the SDP while others have phrased their acknowledgments as suggestions that OIG could view the disclosed conduct as potential violations. OIG will not accept any disclosing party into the SDP that fails to acknowledge clearly that the disclosed arrangement constitutes a potential violation 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. The description should include the participants' identities, their relationship to one another to the extent that the relationship affects their potential liability (e.g., hospital-landlord, referring physician-tenant); the payment arrangements; and the dates during which each suspect arrangement occurred. Further, the disclosure should explain the relevant context and the features of the arrangement that raise potential AKS or both AKS and Stark Law liability.

Below are several examples of the type of information OIG finds helpful in assessing and resolving disclosed conduct involving potential AKS and, if applicable, Stark Law violations. These illustrations are by no means comprehensive or exclusive; rather, they reflect some common issues that have arisen in SDP submissions. For example:

1. How fair market value was determined and why it is now in question.
2. Why required payments from referral sources, under leases or other contracts, were not timely made or collected or did not conform to the negotiated agreement and how long such lapses existed.
3. Why the arrangement was arguably not commercially reasonable (e.g., lacked a reasonable business purpose).
4. Whether payments were made for services not performed or documented and, if so, why.
5. Whether referring physicians received payments from Designated Health Service entities that varied with, or took into account, the volume or value

of referrals without complying with a Stark Law exception. Finally, the submission must describe the corrective action taken to remedy the suspect arrangement(s), as well as any safeguards implemented by the disclosing party to prevent the conduct from reoccurring.

Calculating Damages

AKS compliance is a condition of payment of the Federal health care programs. Under section 1128B(g) of the Act, claims that include items or services resulting from an AKS violation constitute false or fraudulent claims for purposes of the FCA. Stark Law compliance is also a condition of payment under section 1877 of the Act. 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.

Consistent with OIG's CMPL authorities, 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. For purposes of resolving SDP matters, we generally exercise this discretion by compromising our CMP authorities for an amount based upon a multiplier of the remuneration conferred by the referral recipient to the individual or entity making the referral. While this is our general approach, OIG's determination of the appropriate settlement amount depends on the facts and circumstances of each matter. We generally use this remuneration-based methodology in the SDP as an incentive to encourage disclosure of potential AKS violations. OIG's use of a remuneration-based methodology in the SDP settlement context does not govern OIG's position in other situations, such as Government-initiated investigations, in which the Government may use any legally supportable measure of damages, multipliers, and penalties.

IV. Resolution

Resolution of a matter in the SDP depends on cooperation, realistic expectations, and clear communication between OIG and the disclosing party. This section provides some basic information about successful resolution of SDP matters.

A. Cooperation Is Essential

The benefits of self-disclosure, such as a speedy resolution, lower multiplier, and an exclusion release without integrity agreement obligations, depend on the disclosing party's willingness to work cooperatively with OIG throughout the process.

Cooperation includes, for example, conducting a thorough investigation, submitting all necessary information, communicating through a consistent point of contact, being responsive to OIG requests for additional information, and being willing to pay a penalty or multiplier of damages for self-disclosed conduct. Disclosing parties who fail to cooperate with OIG in good faith will be removed from the SDP.

B. OIG Coordination With DOJ on Civil Matters

OIG will coordinate with the Department of Justice (DOJ) on in resolving SDP matters. If OIG is the sole agency representing the Federal Government, the matter will be settled under OIG's applicable CMP authorities. 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.

C. OIG Coordination With DOJ on Criminal Matters

OIG encourages disclosing parties to disclose potential criminal conduct through the SDP process. OIG's Office of Investigations investigates criminal matters, and any disclosure of criminal conduct through the SDP will be referred to DOJ for resolution. As in civil cases referred to DOJ, OIG will advocate that the disclosing parties receive a benefit from disclosure under the SDP.

D. OIG Coordination With the SRDP

Disclosing parties need to decide whether OIG's SDP or CMS's SRDP is the appropriate protocol to disclose potential Stark Law violations. Both protocols should not be used for the same arrangement. As stated above, disclosing parties must analyze each arrangement to determine whether the arrangement raises potential violations of the AKS, the Stark Law, or both. If the arrangement raises a potential violation of only the AKS or of both the AKS and the Stark Law, the arrangement should be disclosed to OIG under the SDP. If the arrangement raises a potential violation of only the Stark Law, the arrangement should be disclosed to CMS under the SRDP. OIG coordinates with

CMS on the review and resolution of matters disclosed to either agency as appropriate. However, OIG does not participate in SRDP settlements.

E. Minimum Settlement Amounts

While OIG does not demand an admission of liability in settlement agreements, disclosing parties should expect to pay above single damages for disclosed conduct that potentially violates Federal law. OIG's general practice is to require a minimum multiplier of 1.5 times the single damages, although in each case, we determine whether a higher multiplier is appropriate. As a general practice, for purposes of settlement in the SDP, OIG applies this multiplier to the amount paid by Federal health care programs, not the amount claimed.

To better allocate disclosing party and OIG resources in resolving matters through the SDP and to promote transparency and realistic expectations in the SDP process, we require minimum settlement amounts for self-disclosed matters. 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. These minimum amounts account for Federal health care program damages and any relevant multiplier.

In the unusual instance when OIG determines that no potential fraud liability exists for conduct disclosed under the SDP, OIG will refer the matter to the appropriate payor for acceptance of the overpayment and no CMP release will be provided.

F. Financial Inability To Pay

In some situations, disclosing parties may be unable to pay otherwise appropriate settlement amounts. In preparing the disclosure, disclosing parties should determine whether an inability to pay may be an issue. If a disclosing party asserts that it cannot pay a proposed settlement amount (*i.e.*, damages plus a multiplier or penalty amount), OIG will require extensive financial information, including audited financial statements, tax returns, and asset records. Disclosing parties must certify to the truthfulness and completeness of the financial disclosure. In addition to submitting the financial forms, disclosing parties should include an assessment of how much they believe they can afford to pay.

Disclosing parties should raise potential inability-to-pay issues at the earliest possible time, preferably in the SDP submission. Doing so enables OIG to promptly send the disclosing party the financial disclosure forms and consider that information in determining an appropriate resolution.

G. Overpayment Reconciliation

If, prior to resolving an SDP matter, a disclosing party refunds an overpayment related to the same conduct disclosed under the SDP, OIG will credit the amount paid toward the ultimate settlement amount. However, OIG is not bound by any amount that is repaid outside the SDP process. OIG may question the methodology of the overpayment calculation, particularly if the disclosing party estimated the overpayment amount by some method other than as described in the SDP. If OIG disputes the methodology used to calculate the overpayment, OIG may require the disclosing party to redo the review or conduct an independent damages review, which may result in a damages or overpayment amount that is higher than the disclosing party's estimate. Moreover, even if OIG agrees with the methodology used to calculate the overpayment, the disclosing party should expect to pay a multiplier on the damages under the SDP.

H. FOIA Implications of Disclosure

Disclosing parties should clearly identify any portion of their submissions that they believe are trade secrets or are commercial, financial, privileged, or confidential and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Information identified as exempt must meet the criteria for exemption from disclosure under FOIA as determined by an OIG FOIA officer. Consistent with the Department of Health and Human Services' FOIA procedures, set forth in 45 C.F.R. Part 5, OIG will make a reasonable effort to notify a disclosing party prior to any release by OIG of information submitted by a disclosing party and identified upon submission by a disclosing party as trade secrets or as commercial, financial, privileged, or confidential under the FOIA rules. With respect to such releases, a disclosing party will have the rights set forth at 45 C.F.R. § 5.65(d).