Form Approved
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CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL

I. INTRODUCTION

The physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies; (2) prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third-party payer) for those referred services; and (3) establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (HHS) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

The Affordable Care Act (ACA), enacted on March 23, 2010, provides for the establishment of a voluntary self-referral disclosure protocol (SRDP), under which providers of services and suppliers may self-disclose actual or potential violations of the physician self-referral law, section 1877 of the Social Security Act (the "Act"). Section 6409(b) of the ACA grants the Secretary of HHS the authority to reduce the amount due and owing for all violations of the physician self-referral law. Section 6409(a)(3) of the ACA explicitly states that the SRDP is separate from the advisory opinion process related to physician referrals set forth in 42 C.F.R. §§ 411.370 through 411.389. Thus, a provider of services or supplier may not disclose an actual or potential violation through the SRDP and request an advisory opinion for conduct underlying the same arrangement(s) concurrently.

Section 6402 of the ACA establishes a deadline for reporting and returning overpayments by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. At the time the provider of services or supplier electronically submits a disclosure under the SRDP (and receives email confirmation from the Centers for Medicare & Medicaid Services (CMS) that the disclosure has been received), the obligation under section 6402 of the ACA to return the disclosed overpayment within 60 days will be suspended until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP. See 42 C.F.R. § 401.305(b)(2)(ii).

II. THE SRDP

The SRDP is open to all persons (as defined at § 401.303) who may have received an overpayment as a result of an actual or potential violation of section 1877 of the Act. For purposes of the SRDP, a person submitting a disclosure to the SRDP will be referred to as a "disclosing party." The fact that a disclosing party is already subject to Government inquiry (including investigations, audits or routine oversight activities) will not automatically preclude acceptance of a disclosure. The disclosure, however, must be made in good faith. A disclosing party that attempts to circumvent an ongoing inquiry or fails to fully cooperate during the self-disclosure process will be removed from the SRDP.

The SRDP cannot be used to obtain a CMS determination as to whether an actual or potential violation of the physician self-referral law occurred. As stated above and in section 6409(a)(3) of the ACA, the SRDP is separate from the CMS physician self-referral advisory opinion process. 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 to the SRDP with the intention of resolving its overpayment liability exposure for the conduct it identified. In keeping with these principles, for each disclosed noncompliant financial relationship, the disclosing party must either: (a) state that the financial relationship was noncompliant, or (b) state that, because it cannot confirm that the financial relationship complied with the physician self-referral law, it is certifying noncompliance with the law.

CMS will review the circumstances surrounding the matter disclosed to determine an appropriate resolution. In some instances, Medicare contractors may be responsible for processing any identified overpayment. CMS is not bound by any conclusions made by the disclosing party under the SRDP and is not obligated to resolve the matter in any particular manner. Nevertheless, CMS will work closely with a disclosing party that structures its disclosure in accordance with these SRDP instructions to reach an effective and appropriate resolution. As a condition of disclosing a matter pursuant to the SRDP, the disclosing party agrees that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settlement agreement. If the disclosing party withdraws or is removed from the SRDP, the disclosing party may appeal any overpayment demand letter in accordance with applicable regulations. Furthermore, disclosing parties agree that, if the disclosed matter is not resolved through the SRDP, [illegible] the initial

III. COOPERATION WITH THE INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (OIG) AND THE DEPARTMENT OF JUSTICE (DOJ)

Participation in the SRDP is limited to actual or potential violations of the physician self-referral law. OIG's Self- Disclosure Protocol is available for disclosing conduct that raises potential liabilities under other federal criminal, civil, or administrative laws. See 63 Fed. Reg. 58399 (Oct. 30, 1998); OIG's Open Letter to Health Care Providers, March 24, 2009. For example, conduct that raises liability risks under the physician self-referral law may also raise liability risks under OIG's civil monetary penalty authorities regarding the federal anti-kickback statute and should be disclosed through OIG's Self-Disclosure Protocol. Disclosing parties should not disclose the same conduct under both the SRDP and OIG's Self-Disclosure Protocol.

Upon review of the disclosing party's submission(s), CMS will coordinate with OIG and DOJ. CMS may conclude that the disclosed matter warrants a referral to law enforcement for consideration under its civil and/or criminal authorities. When appropriate, CMS may use a disclosing party's submission(s) to prepare a recommendation to OIG and DOJ for resolution of False Claims Act, civil monetary penalty, or other liability. Accordingly, the disclosing party's initial decision regarding where to disclose a matter involving noncompliance with section 1877 of the Act should be made carefully.

Disclosing parties who currently have corporate integrity agreements (CIAs) or certification of compliance agreements (CCAs) with OIG should also comply with any disclosure or reportable event requirements under such agreements. Effective September 23, 2010, a reportable event solely related to a physician self-referral issue should be disclosed to CMS using the instructions set forth in this SRDP with a copy to the disclosing party's OIG monitor. Questions about any applicable CIA or CCA requirements should be directed to the disclosing party's OIG monitor.

IV. INSTRUCTIONS REGARDING THE VOLUNTARY DISCLOSURE PROTOCOL SUBMISSION

The disclosing party will be expected to make a submission as follows.

A. Required elements of a complete disclosure

The disclosing party must submit its disclosure using: (1) the SRDP Disclosure Form, (2) the Physician Information Form(s), and (3) the Financial Analysis Worksheet (unless the party is a physician-owned hospital disclosing noncompliance resulting **solely** from the failure to comply with § 411.362(b) (3)(C); see section IV.C for more details). The forms, including instructions for completing the forms, are attached to this document as an appendix. The disclosing party must submit all the information required by all the forms. The following is a brief summary of the forms and other materials that must be submitted to the SRDP. SRDP Disclosure Form: The SRDP Disclosure Form provides information about the disclosing party, including information regarding the disclosing party's history of abuse, pervasiveness of noncompliance, and steps to prevent future noncompliance. Physician Information Form(s): For each physician included in the disclosure, the disclosing party must submit a separate Physician Information Form providing details of the noncompliant financial relationship(s) between the physician and the disclosing party. Financial Analysis Worksheet: The Financial Analysis Worksheet quantifies the overpayment for each physician included in the disclosure who made referrals in violation of section 1877 of the Act. Effective March 14, 2016, the financial analysis is limited to the6-year look back period at § 401.305(f). The Financial Analysis Worksheet must be submitted in Microsoft Excel®-compatible format.Certification: The initial disclosure and any related supplemental submission must include a certification signed by the disclosing party or, in the case of an entity, its Chief Executive Officer, Chief Financial Officer, or other individual who is authorized by the disclosing party to disclose the matter to CMS and to certify the truthfulness of the information contained in the disclosure. The signed certification must state that, to the best of the individual's knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS' attention for the purpose of resolving the disclosed potential liabilities relating to the physician self-referral law.

In addition to all the required information, the disclosing party may submit an **optional** cover letter, including information that the party believes may be relevant to CMS' evaluation of the disclosure.

B. Instructions for submitting the disclosure

The complete disclosure and all relevant supporting documents must be submitted electronically to **1877SRDP@cms.hhs.gov**. In addition, a hard copy of the signed certification only must be sent to: Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop C4-25-02, Baltimore, MD 21244-1850. Submissions by facsimile will not be accepted.

When the disclosing party submits a disclosure electronically, CMS will immediately send a response email acknowledging receipt of the submission. After reviewing the submission, CMS will send a letter to the disclosing party or its representative either accepting or rejecting the disclosure. In some cases, CMS may request additional information prior to determining whether to accept or reject the disclosure.

C. Disclosure of noncompliance arising solely from the failure to comply with § 411.362(b)(3)(ii)(C)

Parties disclosing noncompliance arising **solely** from the failure of a physician-owned hospital to disclose physician ownership on any public website or in any public advertising must continue to use the special instructions, available at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

D. Obligation to update

If, after the disclosure is made to CMS, the disclosing party files for bankruptcy, undergoes a change of ownership, or changes the designated representative, the disclosing party must inform CMS of the changes within 30 days. Updates must be submitted by e-mail to the following address: **1877SRDP@cms.hhs.gov**. Include the word "UPDATE" in the subject of the e-mail.

V. VERIFICATION

Following the receipt of a disclosing party's submission, CMS will begin its verification of the disclosed information. The timeframe for CMS' verification effort will depend, in large part, upon the quality and thoroughness of the submissions received. Matters uncovered during the verification process, which are outside of the scope of the disclosure being verified, may be treated as new matters outside the SRDP.

To facilitate CMS' verification process, CMS must have access to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced. In the normal course of verification, CMS will not request production of written communications subject to the attorney-client privilege. However, there may be documents or other materials, which CMS believes are critical to resolving the disclosure that may be covered by the attorney-client privilege. CMS will discuss with a disclosing party's counsel ways to gain access to the underlying information without waiver of protections provided by an appropriately asserted claim of privilege.

CMS may request additional information, such as financial statements, income tax returns, and other documents, if needed. If additional information is requested, a disclosing party will be given at least 30 days to furnish the information.

VI. PAYMENTS

Because of the need to verify the information provided by a disclosing party, CMS will not accept payments of presumed overpayments determined by the disclosing party prior to the completion of CMS' review. However, the disclosing party may place funds in an interest-bearing escrow account to ensure adequate resources have been set aside to repay amounts owed.

While the matter is under CMS review, the disclosing party must refrain from making repayments relating to the disclosed matter to the Federal health care programs or their contractors without CMS' prior consent. If CMS consents, the disclosing party will be required to acknowledge in writing that the acceptance of the payment does not constitute the Government's agreement as to the amount of losses suffered by the programs as a result of the disclosed matter, and does not relieve the disclosing party of any criminal, civil, or civil monetary penalty liability, nor does it offer a defense to any further administrative, civil, or criminal actions against the disclosing party. We remind disclosing parties that section 1877(g)(2) of the Act requires that any amounts collected from individuals that were billed in violation of the physician self-referral law must be refunded to the individuals on a timely basis.

VII. COOPERATION AND REMOVAL FROM THE SRDP AND TIMELINESS OF DISCLOSURE

The disclosing party's diligent and good faith cooperation throughout the entire process is essential. Accordingly, CMS expects to receive documents and information from the disclosing party that relate to the disclosed matter without the need to resort to compulsory methods. If a disclosing party fails to work in good faith with CMS to resolve the disclosed matter, the lack of cooperation will be taken into account in CMS' resolution of the matter. Likewise, the failure to update CMS regarding changes in ownership, bankruptcy filing, or changes in the designated representative will be taken into account in assessing the disclosing party's cooperation. The intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to DOJ, OIG, or other Federal agencies and could, in itself, result in criminal and/ or civil sanctions, as well as exclusion from participation in the Federal health care programs. Furthermore, it is imperative for disclosing parties to disclose overpayments in a timely fashion once identified. As stated above, section 6402 of the ACA establishes a deadline for reporting and returning overpayments by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.

VIII. FACTORS CONSIDERED IN REDUCING THE AMOUNT OWED

The factors CMS may consider in reducing the amount otherwise owed include, but are not limited to: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; and (3) the cooperation in providing additional information related to the disclosure. Although CMS may consider these factors in determining whether reduction in any amounts owed is appropriate, CMS is not obligated to reduce any amounts due and owing. CMS will make an individual determination as to whether a reduction is appropriate based on the facts and circumstances of each disclosed actual or potential violation. The nature and circumstances concerning a physician self-referral violation can vary given the scope of the physician self- referral law and the health care industry. Given this variability, CMS evaluates each matter in order to determine the severity of the physician self-referral law violation and an appropriate resolution for the conduct.

Checklist of required items for a complete submission:

- ☐ SRDP Disclosure Form
- ☐ Physician Information Form(s) (one for each physician included in the disclosure who made referrals in violation of section 1877 of the Act)
- ☐ Financial Analysis Worksheet, submitted in Microsoft Excel®-compatible format
- ☐ Certification

The disclosing party may also submit an optional cover letter. All the items listed above (and the optional cover letter, if included) must be submitted electronically to **1877SRDP@cms.hhs.gov**. In addition, a hard copy of the certification **only** must be mailed to Division of Technical Payment Policy, ATTN: Provider and Supplier Self- Disclosure, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop C4-25-02, Baltimore, MD 21244-1850.

Obligation to update: Disclosing parties are reminded of the obligation to update the disclosure if the disclosing party files for bankruptcy, undergoes a change of ownership, or changes its designated representative. The update must be submitted electronically to **1877SRDP@cms.hhs.gov** within 30 days of the change. Include the word "UPDATE" in the subject line of the e-mail.

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SRDP DISCLOSURE FORM: CMS-10328

I. DISCLOSING PARTY

1. Legal Business Name

2. "Doing Business As" name (if applicable)

3. Address

City	State	Zip code

4. CMS Certification Number (CCN)	5. National Provider Identifier(s) (NPI)	6. Tax Identification Number (TIN)

7. Is the disclosing party affiliated with a network or system? Note: If multiple entities from a network or system are submitting self-disclosures, each entity that is separately enrolled in Medicare must submit a separate disclosure.

◯ Yes ◯ No

If yes, provide the name of the network or system:

II. DESIGNATED REPRESENTATIVE

1. Name

2. Address

City	State	Zip code

3. Phone Number(enter numbers only)	4. Email

III. PERVASIVENESS OF NONCOMPLIANCE

For purposes of the SRDP, pervasiveness means how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians.

Determine the type(s) of noncompliance being disclosed (i.e., compensation arrangement failing to satisfy an applicable exception at § 411.357, ownership or investment interest failing to satisfy an applicable exception at § 411.356, or the provision of services failing to satisfy an applicable exception at § 411.355), and report the pervasiveness of the noncompliance relative to the disclosing party's similar financial relationships (in the case of compensation arrangements or ownership or investment interests) or similar services furnished (in the case of DHS that failed to meet an applicable exception at § 411.355). When reporting more than one type of noncompliance, the pervasiveness of the noncompliance may be reported by type of noncompliance or in the aggregate. For disclosures of noncompliant compensation arrangements, do not include arrangements involving nonmonetary compensation or medical staff incidental benefits in the determination of the pervasiveness of the noncompliance, unless the disclosed noncompliance resulted from a failure to comply with § 411.357(k) or § 411.357(m).

The following examples may be helpful. The hospital has numerous compensation arrangements with physicians. We estimate that the noncompliant compensation arrangements disclosed herein represent less than 3 percent of all financial relationships with physicians. Six of the hospital's 30 call coverage arrangements (20 percent) failed to satisfy the requirements of the exception for personal service arrangements at § 411.357(d) or fair market value compensation at § 411.357(l). The hospital had no other financial relationships with referring physicians. The hospital has 25 physician owners. Each physician owner had an ownership or investment interest during the entire lookback period. One of the physician owners was not authorized to perform services at the hospital as required at § 411.356(c)(3)(i) for a period of six months during the lookback period. In 150 instances during a six-month period, the group practice failed to provide the notice required at § 411.355(b)(7). We reviewed the medical records and determined that this represents approximately 10 percent of the services subject to the notice requirement that were furnished by the group practice during the same six-month period. The physician practice provided nonmonetary compensation to 50 referring physicians who were not part of the physician practice during calendar year 2015. The physician practice exceeded the annual limit on nonmonetary compensation with respect to two physicians. Neither physician returned the excess nonmonetary compensation during the period established at § 411.357(k)(3).

Note on the application of the "stand in the shoes" provisions at § 411.354(c): The "stand in the shoes" provisions determine how arrangements with physician organizations should be counted. If there is a compensation arrangement with a physician organization, the arrangement is deemed to be an arrangement with all the physicians who stand in the shoes of the physician organization. For example, assume that a party is disclosing a noncompliant lease arrangement with a physician organization, and that the organization consists of three owners (mandatorily standing in the shoes of the organization pursuant to § 411.354(c)(ii)(B)) and two non-owners who are not permissively standing in the shoes of the organization. For purposes of the SRDP, this should be counted as three arrangements, because the arrangement with the organization is deemed to be an arrangement with the physicians standing in the shoes of the organization.

Note on violations arising from the failure to satisfy the requirements necessary to qualify as a group practice. The exception for physician services at § 411.355(a) is available only to DHS entities that qualify as group practices. The exception for in-office ancillary services at

§ 411.355(b) is available only to DHS entities that qualify as group practices and to physicians in solo practice. If the disclosed noncompliance arises from the failure of an entity to satisfy the requirements of § 411.352, the financial relationships between the entity and its physician owners, employees and contractors should be analyzed under § 411.356 (for ownership or investment interests), § 411.357 (for compensation arrangements) or both. For example, assume a physician organization has five physician owners and two non-owner physician employees; the five owners each receive shares of overall profits divided per capita and compensation in the form of salaries; the employees receive compensation in the form of salaries and productivity bonuses on services furnished incident to their personally performed services; and the physician owners and employees make referrals to the physician organization for DHS provided in the office. If the physician organization does not qualify as a group practice, the in-office ancillary services exception is not available. The disclosing party must then determine whether an applicable exception at § 411.356 or § 411.357 is satisfied for each financial relationship between the entity and a referring physician. In this example, the physician owners of the physician organization may have both noncompliant ownership interests and noncompliant compensation arrangements. The physician employees have noncompliant compensation arrangements. For purposes of the SRDP, these financial relationships should be analyzed and reported as noncompliant ownership interests (i.e., failure to satisfy an exception at § 411.356) and noncompliant compensation arrangements (i.e., failure to satisfy an exception at § 411.357). Do not analyze and report the financial relationships as potential violations of § 411.355.

The following examples illustrate the application of the "stand in the shoes" provisions and the failure to qualify as a "group practice" to the report of pervasiveness: During each year of the lookback period, the disclosing entity was a party to approximately 100 compensation arrangements with referring physicians or their immediate family members, after considering the application of the "stand in the shoes" rules. During the lookback period, the disclosing entity was a party to approximately 300 compensation arrangements, after considering the application of the "stand in the shoes" rules, as some arrangements lasted more than one year. These included compensation arrangements for the rental of office space, call coverage arrangements, medical directorships, and other personal service arrangements. The disclosed noncompliance relates to a total of eight compensation arrangements (two directly with individual physicians and one with a six-owner physician organization). The eight arrangements were noncompliant for a total of 90 out of 576 potential months during the lookback period (8 arrangements x 72 months each in the lookback period). During two calendar years, the physician practice compensated its physicians in a manner that did not comply with § 411.352(g). The physician practice paid productivity bonuses and profit shares that were determined in a manner that directly related to the volume or value of physicians' referrals of DHS to the physician practice. Because the physician practice cannot satisfy the requirements for a group practice, the in-office ancillary services exception is unavailable to it. The compensation arrangements with the physician practice's five employed physicians failed to satisfy the requirements of the exception at § 411.357(c) (or any other exception). The ownership or investment interests of the physician practice's three owners do not meet the requirements of any exception at § 411.356. Therefore, eight of eight financial relationships between the physician practice and its employed physicians and physician owners were noncompliant for the entirety of the two calendar years.

Report the pervasiveness of the noncompliancein the space provided below. The disclosing party may also provide additional details and context to help CMS evaluate the pervasiveness of the noncompliance.

IV. OTHER COMPLIANCE ISSUES AND ACTIVITIES

1. **Current government inquiry:** Indicate whether the disclosing party has knowledge that the disclosed conduct is under current inquiry by a Government agency or contractor. If the disclosing party has knowledge of an inquiry, identify the Government agency or contractor, and the individual representatives involved, if known. The disclosing party must also disclose whether it is under investigation or other inquiry for other matters relating to a Federal health care program, including any matters it has disclosed to other Government entities, and provide similar information relating to those other matters.

   Current government inquiry: ◯ Yes ◯ No

   If yes,explain:

2. **History of similar conduct:** State whether the disclosing entity has a history of conduct similar to that being disclosed or any prior criminal, civil or regulatory enforcement action against it.

   History of similar conduct: ◯ Yes ◯ No

   If yes,explain:

3. **Steps taken to prevent future noncompliance:** State whether the disclosing party has taken any steps to prevent future noncompliance. If yes, briefly summarize what steps, if any, the disclosing party has taken. If no, briefly explain why the disclosing party believes that additional steps are not necessary.

   Steps to prevent future noncompliance: ◯ Yes ◯ No

   Explain:

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PHYSICIAN INFORMATION

For each physician included in the disclosure, you must submit a **separate** Physician Information Form providing details of the noncompliant financial relationship(s) between the physician and the disclosing party. Additional Physician Information Forms are available on the CMS website.

I. Physician Information:

1. Physician Name

2. Physician NPI

3. Physician Organization, if applicable

Physician Organization TIN	Physician Organization NPI

4. Noncompliant **compensation** arrangement(s) with the physician (See § 411.357)

◯ Yes ◯ No

4.a. Total number of noncompliant compensation arrangements with the physician during the lookback period

4.b. Are any of the disclosed noncompliant compensation arrangements deemed to be arrangements with the physician because the physician stands in the shoes of a physician organization under § 411.354(c)(1) or § 411.354(c)(2)?

◯ Yes ◯ No

5. Noncompliant **ownership or investment** interest of the physician (See § 411.356)

◯ Yes ◯ No

5.a. Direct or indirect ownership or investment

◯ Direct ◯ Indirect

6. Noncompliant designated health **services** provided pursuant to referrals made by the physician (See § 411.355)

◯ Yes ◯ No

II. Noncompliant compensation arrangement (§ 411.357), noncompliant ownership or investment interest (§ 411.356), Noncompliant designated health services provided pursuant to referrals made by the physician (§ 411.355)

Provide the details required below regarding the noncompliant ownership or investment interest, the noncompliant compensation arrangement, or the prohibited DHS referred by the physician.

Special instructions for disclosures of multiple noncompliant financial relationships with a single physician: In certain circumstances, there may be more than one reason why DHS referred by a physician violated section 1877 of the Act. For example, the disclosing party may have had a noncompliant equipment lease arrangement with a physician and a noncompliant call coverage arrangement with the same physician during the lookback period. If there are multiple reasons why DHS referred by the physician violated section 1877 of the Act, complete a duplicate of this section for each reason by clicking the box labeled**"Click here to add another reason for noncompliance involving the samephysician" at the end of this form.**

A. NARRATIVE EXPLANATION

1. Nature of the compensation arrangement, ownership or investment interest, or noncompliance resulting from the provision of prohibited services:

For compensation arrangements:

Describe the items, space, equipment, and/or services provided under the arrangement. For example, for a medical directorship arrangement, describe the typical duties and responsibilities of the director and the number of hours per week, month, or year that the physician performed such services. Describe the rate of compensation or the amount of remuneration provided under the arrangement (for example, the monthly rental charge for a lease of office space, the rate of payment for call coverage, or the cash value of nonmonetary compensation). If the rate of compensation changed at some point during the disclosed period of noncompliance, explain when it changed, the amount it was changed to, and why it was changed. Provide any additional information that the disclosing party believes is relevant and/or necessary to understanding the nature of the arrangement.

For ownership or investment interests:

Describe the physician's ownership interest in the DHS entity making the disclosure. For disclosures involving physician ownership of hospitals, state whether the physician's ownership interest is in the entire hospital, as opposed to a distinct part or department of the hospital. See 42 CFR § 356(c)(3)(iii). Provide any additional information that the disclosing party believes is relevant and/or necessary to understanding the nature of the ownership interest.

For noncompliance with an applicable services exception:

Describe the circumstances surrounding the provision of the prohibited services. For example, if you are disclosing a failure to satisfy the requirements of the in-office ancillary services exception at § 411.355(b), explain who furnished and supervised (if applicable) the DHS, where the services were furnished, how the services were billed, and the type of services furnished. Provide any additional information that the disclosing party believes is relevant.

Nature of noncompliant compensation arrangement, noncompliant ownership or investment interest, or noncompliant DHS furnished pursuant to referrals made by the physician.

2. Nature of noncompliance: Explain the nature of the noncompliance.

Explanation of the noncompliance:

If you are disclosing the failure to comply with an applicable exception at § 411.356 (exceptions for ownership or investment interests) or § 411.357 (exceptions for compensation arrangements), explain why the financial relationship failed to comply with the physician self-referral law. For example, if a lease arrangement was not signed by a physician lessee but otherwise complied with an applicable exception, the disclosing party could state that "the lease arrangement was not signed by the physician lessee." If you are disclosing the failure to comply with an applicable exception at § 411.355 (excepted services), explain why the DHS provided did not satisfy the requirements of the applicable exception. Describe any potential causes of the incident or practice. Provide any additional information that the disclosing party believes is relevant and/or necessary to understanding the nature of the noncompliance.

NOTE: The disclosing entity must either: (a) certify that the financial relationship was noncompliant (or that the services failed to satisfy an applicable exception at § 411.355), or (b) state that, because it cannot confirm that the financial relationship complied with the physician self-referral law, it is certifying noncompliance with the law.

Nature of noncompliance narrative

3. Method of cure or termination: Describe how the financial relationship was brought back into compliance or otherwise terminated.

If the financial relationship was ongoing at the time the disclosing party discovered the noncompliance, explain the steps that the disclosing entity took to either bring the financial relationship back into compliance or terminate the financial relationship. For example, if a personal service arrangement was out of compliance because it was not set out in writing, state whether the parties cured the noncompliance by executing a writing or terminating the arrangement. NOTE: If the parties brought the arrangement into compliance by executing a signed writing covering the arrangement, CMS may request copies of the signed writing and other additional information regarding the arrangement. If the arrangement was terminated prior to the discovery of the noncompliance, state when the arrangement was terminated and the circumstances under which it was terminated. For example, a lease arrangement may have terminated prior to the discovery of the noncompliance because the physician lessee vacated the property.

Method of cure or termination:

B. RELEVANT DATES

1. **Period(s) of noncompliance:** Provide the date range(s) of the noncompliance. The party must provide a date range for the entire period of noncompliance, even if the noncompliance began prior to the 6-year lookback period.

2. **Date of discovery:** Provide the date that the party determined that it received an overpayment because it failed to comply with the physician self-referral law. See § 401.305(a)(2).

C. COMPENSATION ARRANGEMENTS ONLY

For compensation arrangements only, complete lines 1 through 6 below. Do not complete lines 1 through 6 for noncompliant ownership or investment interests or failure to satisfy the requirements of a service exception. The entries for lines 1 through 6 are based on certain common requirements of a number of exceptions for compensation arrangements. To complete the entries, determine which exception applies to the disclosed compensation arrangement. For example, for a lease of office space, the exception at § 411.357(a) would be applicable; for a call coverage arrangement, the exceptions at § 411.357(d) and § 411.357(l) are potentially applicable. After determining the applicable exception, state whether the requirements in lines 1 through 6 are either satisfied or not satisfied; if the applicable exception does not require this element, enter N/A. For example, the exception for the rental of office space imposes the requirements in lines 1 through 5 below, but not the requirement in line 6; thus, a party disclosing a noncompliant arrangement for the rental of office space must answer "yes" or "no" to lines 1 through 5 and "N/A" to line 6."

1. Satisfies the requirement that compensation is **set in advance:** State whether the amount of compensation was **set in advance**, if required by an applicable exception. (See, e.g., § 411.357(a)(4)).

◯ Yes ◯ No ◯ N/A

2. Satisfies the **volume or value of referrals or other business generated** requirement: State whether the compensation arrangement satisfied the volume or value of referrals or other business generated requirement, if applicable. (See, e.g., § 411.357(a)(5)(i)).

◯ Yes ◯ No ◯ N/A

3. Satisfies the **fair market value** requirement: State whether the compensation arrangement satisfied the relevant fair market value requirement, if applicable. (See, e.g., § 411.357(a)(4)).

◯ Yes ◯ No ◯ N/A

4. Satisfies the **commercial reasonableness** requirement: State whether the compensation arrangement satisfied the commercial reasonableness requirement, if applicable. (See, e.g., § 411.357(a)(6)).

◯ Yes ◯ No ◯ N/A

5. Satisfies the **reasonable and necessary** requirement: State whether the compensation arrangement satisfied the reasonable and necessary requirement, if applicable. (See, e.g., § 411.357(a)(3)).

◯ Yes ◯ No ◯ N/A

6. Satisfies the **Federal and State law** requirement(s): State whether, to the best of the disclosing party's knowledge, the compensation arrangement satisfied the **compliance with Federal and State law** requirements, if applicable. (See, e.g., § 411.357(d)(1)(vi)).

◯ Yes ◯ No ◯ N/A

FINANCIAL ANALYSIS WORKSHEET: CMS-10328

I. INSTRUCTIONS FOR THE FINANCIAL ANALYSIS WORKSHEET

A. Financial analysis:

The disclosing party must provide a financial analysis of the potential overpayment based on the 6-year lookback period at § 401.305(f). (Unless otherwise requested by CMS, disclosing parties are not required to report the actual amount of remuneration between the parties). The financial analysis worksheet must be submitted in Excel®-compatible format. For each physician included in the disclosure, the worksheet must include the following:

Physician's name Physician's NPI Date that the overpayment associated with the physician was identified (see § 401.305(a)(2) for the definition of "identified") Overpayment arising from the physician's prohibited referrals, itemized by calendar year (i.e., January through December)

For the yearly itemization of the overpayment, the Worksheet must include 7 columns, each covering an entire calendar year, even if the 6-year lookback period only falls in a portion of a particular calendar year, and even if the disclosing party did not receive an overpayment during a particular calendar year.

Example: Assume a party identifies an overpayment on May 14, 2016. The 6-year lookback period for this overpayment is May 14, 2010 through May 13, 2016. The Worksheet must include columns for the following calendar years: 2010, 2011, 2012, 2013, 2014, 2015, and 2016. For calendar year 2010 the disclosing party need only report prohibited referrals from May 14, 2010 through December 31, 2010, and for calendar year 2016 the disclosing party need only report prohibited referrals from January 1, 2016 through May 13, 2016. For disclosures involving multiple physicians with overpayments identified on different dates, use the same table for all physicians. If necessary, add columns for additional calendar years to account for the 6-year lookback period for each physician.

Example: Assume a party is disclosing 2 noncompliant arrangements, one identified on December 10, 2016 and the other on January 15, 2017. The Financial Analysis Worksheet must include columns for calendar years 2010 through 2017. If there are no overpayments in a particular year (for example, if the financial relationship was compliant during that year, if there were no prohibited referrals for that year, or if there was no financial relationship between the parties for that year), leave the worksheet cell blank. There must be a final, total overpayment column for each physician, and the table must also include a row calculating total overpayment amount for all physicians covered by the disclosure.

B. Methodology:

The Excel®-compatible Financial Analysis Worksheet must include a text box describing the methodology used to set forth the overpayment. The disclosing party must also indicate whether estimates were used, and, if so, how they were calculated.

Example: The following Financial Analysis Worksheet illustrates the required formatting for the Excel®compatible work sheet. In this example, assume a disclosure was submitted on April 10, 2016 disclosing noncompliant arrangements with Drs. A, B, and C. In addition, assume the following: For Dr. A, there was no noncompliant financial relationship between the disclosing party and Dr. A prior to May 1, 2013; the noncompliance was cured in 2015; and the overpayment was identified on February 18, 2016. For Dr. B, the noncompliance began in 2009, prior to the opening of 6-year lookback period; the noncompliance was not cured until 2016; and the overpayment was identified on March 24, 2016. For Dr. C, there was a noncompliant financial relationship between Dr. C and the disclosing party prior to 2010, but Dr. C did not make prohibited referrals to the disclosing party until October 2011; the arrangement terminated in 2015, and the overpayment was identified on April 5, 2016.

II. SAMPLE FINANCIAL ANALYSIS WORKSHEET:

Physician Name	NPI	Date Over-payment Identified	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	TOTAL
Dr. A	xxxxxxxxxx	2/18/16	$ -	$ -	$ -	$ 100,000.00	$ 100,000.00	$ 100,000.00	$ -	$ 300,000.00
Dr. B	xxxxxxxxxx	3/24/16	$ 25,000.00	$ 10,000.00	$ 75,000.00	$ 50,000.00	$ 50,000.00	$ 50,000.00	$ 10,000.00	$ 270,000.00
Dr. C	xxxxxxxxxx	4/5/16	$ -	$ 5,000.00	$ 25,000.00	$ 20,000.00	$ 20,000.00	$ 20,000.00	$ -	$ 90,000.00
									Total:	$ 660,000.00

Methodology: Actual data was used to determine the overpayment; estimateswere not used.