

Revisions Crosswalk (CMS-10328)

Issue #	Page #	Section	Action to be performed	Changes to the Application	Reason for the Change
1.	1	I. Introduction, 1 st paragraph	Add new 1 st paragraph	Add: “The Affordable Care Act (ACA), enacted on March 23, 2010, provides for the establishment of a voluntary self-disclosure protocol, under which providers of services and suppliers may self-disclose actual or potential violations of the physician self-referral statute (section 1877 of the Social Security Act). The physician self-referral statute 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; 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 establishes a number of specific exceptions and grants the Secretary 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.”	Revised to clarify statutory language
2.	1	I. Introduction, 2 nd paragraph	Delete first sentence	Delete: “The Affordable Care Act (ACA) was enacted on March 23, 2010.”	Removed repetitive sentence

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3.	1	I. Introduction, 2 nd paragraph	Replace	<p>Replace:</p> <p>1) “an actual or potential” with “a”</p> <p>to the following sentence:</p> <p>“In establishing the amount by which an overpayment resulting from <u>a</u> violation(s) may be reduced, the Secretary may consider: the nature and extent of the improper or illegal practice; the timeliness of such disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers appropriate.”</p>	Clarified to reflect that reductions will only be made when CMS determines that an actual violation has occurred
4.	1	I. Introduction, 2 nd paragraph	Revise sentence	<p>Add :</p> <p>“related to physician referrals” to the following sentence:</p> <p>“Section 6409(a)(3) of the ACA explicitly states that the SRDP is separate from the advisory opinion process related to <u>physician referrals</u> set forth in 42 C.F.R. §§ 411.370 through 411.389.”</p>	Revised to clarify statutory language
5.	2	II. The SRDP, 1 st paragraph	Revise sentence	<p>Add:</p> <p>“acceptance of” to the following sentence:</p> <p>“The fact that a disclosing party is already subject to Government inquiry (including investigations, audits or routine oversight activities) will not automatically preclude <u>acceptance of</u> a disclosure.”</p>	Revised to clarify language

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6.	2	II. The SRDP, 1 st paragraph	Replace	<p>Replace “in” with “during” in the following sentence:</p> <p>“A disclosing party that attempts to circumvent an ongoing inquiry or fails to fully cooperate <u>during</u> the self-disclosure process will be removed from the SRDP.”</p>	Editorial Change
7.	2	II. The SRDP, 2 nd paragraph	Revise sentence	<p>Add:</p> <p>“above and” to the following sentence:</p> <p>“As stated <u>above and</u> in section 6409(a)(3) of the ACA, the SRDP is separate from the CMS physician self-referral advisory opinion process.”</p>	Editorial change
8.	2	II. The SRDP, 2 nd paragraph	Delete last sentence	<p>Delete:</p> <p>“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.”</p>	Editorial change
9.	2	II. The SRDP, 3 rd paragraph	Replace word	<p>Replace:</p> <p>“the protocol” with “SRDP”</p>	Editorial change
10.	3	III. Cooperation with OIG and the Department of Justice (DOJ), 2 nd paragraph	Replace word	<p>Replace:</p> <p>“refer” with “disclose” in the following sentence:</p> <p>“Accordingly, the disclosing party’s initial decision of where to <u>disclose</u> a matter involving non-compliance with section 1877 of the Social Security Act should be made carefully.”</p>	Editorial change

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11.	3	IV. A. Instructions Regarding the Voluntary Disclosure Submission,	Correct zip code	Replace: “21224” with “21244” in the sentence with the CMS address	Number correction
12.	4	IV. B (1)(d) Required Information Related to the Matter Disclosed	Replace words	Replace: 1) “issue” with “actual or potential violation”; and 2) “abuses” with “instances of non-compliance” in the following sentence: “The circumstances under which the disclosed matter was discovered and the measures taken upon discovery to address the <u>actual or potential violation</u> and prevent future <u>instances of noncompliance.</u> ”	Editorial change
13.	4	IV. B (1)(f) Required Information Related to the Matter Disclosed	Replace	Replace: “or through training” with “new training programs” in the following sentence: “..... (e.g., new accounting or internal control procedures, <u>new training programs</u> , increased internal audit efforts, increased supervision by higher management).”	Editorial change
14.	4	IV. B (1)(g) Required Information Related to the Matter Disclosed	Delete word	Delete: “and” after the (,) from the following parenthetical: (e.g., Securities and Exchange Commission, Internal Revenue Service)	Editorial change

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15.	4	IV. B (1)(h) Required Information Related to the Matter Disclosed	Replace words	Replace: 1) “entity” with “agency or contractor”; and 2) “or” with “and the” in the following sentence: “If the disclosing party has knowledge of a pending inquiry, identify any such Government <u>agency or contractor</u> , <u>and the</u> individual representatives involved, if known.”	Editorial change
16.	4	IV. B (1)(h) Required Information Related to the Matter Disclosed	Add	Add: “, if known” to the end of the following sentence: “If the disclosing party has knowledge of a pending inquiry, identify any such Government agency or contractor, and the individual representatives involved, <u>if known.</u> ”	Editorial change
17.	4	IV. B (1)(h) Required Information Related to the Matter Disclosed	Delete word	Delete: “any” between “inquiry for” and “other matters” in the following sentence: “The disclosing party must also disclose whether it is under investigation or other <u>inquiry for</u> 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.”	Editorial change

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18.	5	IV. B(2) Financial Analysis	Revise sentence	<p>Change the following sentence from:</p> <p>“As part of its initial submission, the disclosing party will be expected to conduct a financial analysis, and then report its findings to CMS.”</p> <p>To:</p> <p>“As part of its initial disclosure submission, the disclosing party must conduct a financial analysis relating to the actual or potential violation(s) of the physician self-referral law, and report its findings to CMS.”</p>	Clarified the term “financial analysis”
19.	5	IV. B(2) Financial Analysis	Replace subsection c	<p>Add:</p> <p>“c. Set forth the total amount of remuneration a physician(s) received as a result of an actual or potential violation(s) based upon the applicable “look back” period.”</p>	Revised to clarify the information that should be submitted
20.	5	IV. B(2) Financial Analysis	Make old subsection c, subsection d and revise	<p>Create new subsection d and revise the following sentence from:</p> <p>“Provide a summary of auditing activity undertaken and a summary of the documents relied upon.”</p> <p>To:</p> <p>“d. Provide a summary of any auditing activity undertaken and a summary of the documents the disclosing party has relied upon relating to the actual or potential violation(s) disclosed.”</p>	Revised to clarify the information that should be submitted

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21.	5	IV. C Certification	Replace word	<p>Replace “any” with “the disclosed” in the following sentence:</p> <p>“The disclosing party, or in the case of an entity its Chief Executive Office, Chief Financial Officer, or other authorized representative, must submit to CMS, along with all submissions, a signed certification stating 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 <u>the disclosed</u> potential liabilities relating to the physician self-referral law.”</p>	Editorial change
22.	5	V. CMS’ Verification	Delete lower case “s” from the section title	<p>Delete:</p> <p>“s” from “CMS’s Verification”</p>	Grammar correction
23.	5	V. CMS’ Verification	Revise sentence	<p>Change the following sentence from:</p> <p>“There may be documents or other materials, however, that may be covered by the work product doctrine, but which CMS believes are critical to resolving the disclosure.”</p> <p>To:</p> <p>“However, there may be documents or other materials, which CMS believes are critical to resolving the disclosure, that may be covered by the work product doctrine.”</p>	Editorial change

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24.	5	V. CMS' Verification	Replace word	<p>Replace:</p> <p>“the need to waive the” with “waiver of” in the following sentence:</p> <p>“CMS is prepared to discuss with a disclosing party’s counsel ways to gain access to the underlying information without <u>waiver of</u> protections provided by an appropriately asserted claim of privilege”</p>	Editorial change
25.	6-7	VIII. Factors Considered in Reducing the Amounts Owed	Replace word	<p>Replace:</p> <p>“has no obligation to” with “is not obligated to” in the following sentence:</p> <p>“While CMS may consider these factors in determining whether reduction in any amounts owed is appropriate, CMS <u>is not obligated</u> to reduce any amounts due and owing.”</p>	Editorial change
26.	7	PRA Disclosure Statement	Replace word	<p>Replace:</p> <p>“Maryland” with “MD” in the last sentence with the CMS address</p>	Editorial change