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VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10328 (OMB Control Number: 0938-1106)
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-10328; CMS Voluntary Self-Referral Disclosure Protocol

Dear Sir or Madam:

We appreciate the opportunity to comment on CMS's proposed collection of information related to the Voluntary Self-Referral Disclosure Protocol ("SRDP"). The SRDP is an important tool to facilitate the resolution of actual or potential violations of the federal physician self-referral law. As attorneys who frequently advise clients on SRDP submissions, we appreciate the proposals CMS has made to clarify and streamline the SRDP process.[1]

We support the proposed changes. In particular, we support the proposal to create a new Group Practice Information Form to be used in place of individual Physician Information Forms where the reported noncompliance concerns the "group practice" definition at 42 C.F.R. § 411.352. We also support the proposal that would permit a disclosing party to submit a single Physician Information Form for all physicians who stand in the shoes of their physician organization. In addition, we support the proposal to eliminate the requirement to submit a hard copy of the certification statement. These changes would reduce burden while preserving CMS's ability to collect the information it needs to review and resolve SRDP submissions.

There are, however, several changes that CMS may wish to consider as it revises the SRDP forms. Our comments address the proposed Group Practice Information Form first, followed by the proposed revisions to the SRDP Disclosure Form.

A. Group Practice Information Form

1. Volume or value requirement at § 411.352(g) and special rule at § 411.352(i)

In discussing the "volume or value" requirement at § 411.352(g), the proposed Group Practice Information Form could be read to suggest that compensation that takes into account referrals *necessarily* violates the requirement at § 411.352(g) unless the designated health services are

[1] We comment in our individual capacity, not on behalf of any organization (including Bass, Berry & Sims PLC), nor in relation to any particular matter.

personally performed by the physician or are "incident to" the physician's personally performed services. Specifically, in Section I.A.1 of the form, beneath the first bullet point under the heading "*§ 411.352(g) Volume or value of referrals & § 411.352(i) Special rule for profit shares and productivity bonuses*," the form offers the following as an example of failure to satisfy the volume or value requirement at § 411.352(g):

> Certain members of the practice received productivity bonuses that took into account referrals for designated health services that were neither personally performed by the physicians nor incident to the physician's personally performed services.

Although the productivity bonuses in this example could result in the failure to satisfy the requirement at § 411.352(g), that is not necessarily the case. If the productivity bonuses satisfy the conditions of the special rule at § 411.352(i), the practice would satisfy the volume or value requirement at § 411.352(g). Productivity bonuses that take into account referrals can satisfy the conditions of the special rule at § 411.352(i) (and thus the volume or value requirement at § 411.352(g)) in either one of two ways. One, the productivity bonuses could satisfy a deeming provision at § 411.352(i)(2)(ii)(A)-(C). Or, two, the productivity bonuses could satisfy the conditions of the special rule at § 411.352(i) if: (i) the bonuses are paid "based on services that [the physician] has personally performed"; (ii) the bonuses are not "directly related to the volume or value of the physician's referrals"; and (iii) the bonuses are calculated in a reasonable and verifiable manner. *See* § 411.352(i)(2)(i)-(ii).[2]

We recognize that the form simply offers an example of how a disclosing party could describe noncompliance. Nevertheless, we believe it worthwhile to clarify this point two reasons. First, in our experience, the volume or value requirement at § 411.352(g) often is the reason a practice that intends to structure itself as a group practice fails to qualify as a group practice. Second, the effect of the special rule at § 411.352(i) is often misunderstood, and without this clarification this example could compound the issue.

CMS could clarify this example by inserting the following bold and underlined text:

> Certain members of the practice received productivity bonuses that took into account referrals for designated health services that were neither personally performed by the physicians nor incident to the physician's personally performed services **and cannot satisfy the conditions of the special rule at § 411.352(i) (because the productivity bonuses were directly related to the volume or value of the physician's referrals)**.

Alternatively, the form could offer examples of circumstances where a practice's compensation to its physicians takes into account referrals in a manner that does not satisfy the conditions of the special rule at § 411.352(i). This, for instance, could be due to the productivity bonus directly relating to the volume or value of referrals.

2. Effect of not satisfying a deeming provision of the special rule at § 411.352(i)

[2] *See* Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase I), 66 Fed. Reg. 855, 909-10 (Jan. 4, 2001).

In discussing the deeming provisions of the special rule at § 411.352(i), the Group Practice Information Form could be read to suggest, in several places, that the only way to satisfy the conditions of the special rule is to satisfy a deeming provision. It would be helpful for CMS to clarify that practices can satisfy the condition of the special rule at § 411.352(i) without satisfying one of its deeming provisions.

First, in Section I.A.1 of the proposed form, the second bullet point under the heading "*§ 411.352(g) Volume or value of referrals & § 411.352(i) Special rule for profit shares and productivity bonuses*," provides the following instruction:

> If the practice relied on one or more of the deeming provisions at § 411.352(i) to satisfy the requirement at § 411.352(g), but failed to satisfy the conditions of the relevant deeming provision, please describe the specific circumstances of the practice's failure to satisfy the relevant deeming provision in § 411.352(i) and provide the additional information as requested.

To avoid potential confusion, CMS could clarify this instruction by inserting the following bold and underlined text:

> If the practice relied on one or more of the deeming provisions at § 411.352(i) to satisfy the requirement at § 411.352(g), but failed to satisfy the conditions of the relevant deeming provision **(and did not otherwise satisfy the conditions of the special rule at § 411.352(i), e.g., because the share of overall profits or productivity bonus, as applicable, was directly related to the volume or value of the physician's referrals)**, please describe the specific circumstances of the practice's failure to satisfy the relevant deeming provision in § 411.352(i) and provide the additional information as requested.

Second, the first bullet point under the heading "*§ 411.352(i)(1)(iii)(C) or § 411.352(i)(2)(ii)(C)*" in the same section of the proposed form provides the following instruction:

> If the practice relied on the deeming provisions at § 411.352(i)(1)(iii)(C) or § 411.352(i)(2)(ii)(C) to ensure compliance with the requirement at § 411.352(g), but failed to meet the conditions of the deeming provision because revenues derived from designated health services were 5 percent or more of the practice's total revenues, or the portion of those revenues distributed to any physician in the practice exceeded 5 percent of his or her total compensation from the practice, please provide the following information . . . .

As with the first instruction, CMS could clarify this language by inserting the following bold and underlined text:

> If the practice relied on the deeming provisions at § 411.352(i)(1)(iii)(C) or § 411.352(i)(2)(ii)(C) to ensure compliance with the requirement at § 411.352(g), but failed to meet the conditions of the deeming provision because revenues derived from designated health services were 5 percent or more of the practice's total revenues, or the portion of those revenues distributed to any physician in the practice exceeded 5 percent of his or her total compensation from the practice **(and the practice cannot otherwise satisfy the conditions of the special rule at § 411.352(i))**, please provide the following information . . . .

Third, the first bullet point under the heading "*§ 411.352(i)(2)(i)*" in the same section of the proposed form provides the following instruction:

> If the practice failed to qualify as a group practice under § 411.352 because physician(s) in the practice received productivity bonuses based on services not personally performed by the physician(s) or services not "incident to" such personally performed services, please describe the methodology used to calculate physician productivity bonuses and provide the following information . . . .[3]

As with the first two, CMS could clarify this instruction (and clarify that services referred to in the first use of the term "services" are the designated health services) by inserting the following bold and underlined text and removing the stricken-through text:

> If the practice failed to qualify as a group practice under § 411.352 because physician(s) in the practice received productivity bonuses based on **designated health** services not personally performed by the physician(s) or services not "incident to" ~~such~~ personally performed services **(and the productivity bonuses cannot otherwise satisfy the conditions of the special rule at § 411.352(i)(2)**, please describe the methodology used to calculate physician productivity bonuses and provide the following information . . . .

We believe these clarifications could prevent confusion and facilitate a correct understanding of the effect of not satisfying a deeming provision of the special rule at § 411.352(i). Alternatively,

[3] The proposed Group Practice Information Form makes similar statements under the three subheadings "*Number of designated health services CPT/HCPCS codes*," "*Revenues derived from designated health services*," and "*Number of affected physicians in the practice*." Although clarifying the language under the main heading "*§ 411.352(i)(2)(i)*" would also serve to clarify similar statements under each subheading, it may still be worthwhile to clarify these statements under the subheadings. Under the subheading "*Revenues derived from designated health services*," for instance, the proposed Group Practice Information Form requests two pieces of information: (1) the practice's total revenues derived from designated health services, and (2) the "revenues derived from designated health services for which physician(s) received productivity bonuses that were neither personally performed by the physician[s] nor services "incident to" such personally performed services." We believe the second piece of information is likely intended to elicit only revenues from designated health services furnished pursuant to noncompliant referrals, and not revenues from designated health services for which productivity bonuses were paid in a compliant manner.

the Group Practice Information Form could plainly state that failing to satisfy the conditions of a deeming provision, standing alone, does not result in failure to satisfy the conditions of the special rule at § 411.352(i) and that, instead, parties must analyze whether the profit share or productivity bonus can nonetheless satisfy the conditions of the special rule.

3. Reporting the CPT/HCPCS codes for all designated health services

As noted above, we support the Group Practice Information Form. In particular, we believe the proposed form will reduce the burden on parties disclosing group practice-related noncompliance. We also believe that, in general, the proposed form is well tailored to gather necessary information and is not unduly burdensome.

One exception, however, is the requirement that appears under the subheading "*Number of designated health services CPT/HCPCS codes*." The proposed form would require the disclosing party to report the total number of unique designated health services CPT/HCPCS codes billed by the practice and the number of CPT/HCPCS codes for which physicians received noncompliant productivity bonuses. Tallying up to six years of CPT/HCPCS codes of services that are designated health services (some categories of which, of course, are not defined by CPT/HCPCS code) would add significant administrative burden on parties disclosing noncompliance without providing clear benefit to CMS. The number of CPT/HCPCS codes of designated health services a practice furnishes may have more to do with the specialties of its physicians than the extent of noncompliance. Moreover, counting CPT/HCPCS codes reveals little, if anything, about the significance of noncompliant referrals for designated health services relative to compliant referrals for designated health services. Here, we believe the burden outweighs the benefit of gathering the data.

B. SRDP Disclosure Form

1. Pervasiveness of noncompliance

The SRDP Disclosure Form requires a description of the "pervasiveness of noncompliance"—that is, the disclosing party must provide a description of how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians. The form suggests that a disclosing party should accomplish this by tallying up all similar financial relationships between the disclosing party and physicians.

The proposed revisions would not materially alter this requirement, except that in the case noncompliance arising solely from the failure to qualify as a group practice under § 411.352, the disclosing party would no longer be required to describe the pervasiveness of noncompliance on the SRDP Disclosure From. Instead, the disclosing party would simply complete the Group Practice Information Form, which, in the words of the proposed SRDP Disclosure Form, already "collects all the required information on pervasiveness." We agree, and we believe that the Group Practice Information Form's approach offers a more practical means of reporting the pervasiveness of noncompliance than does the SRDP Disclosure Form.

With respect to the SRDP Disclosure Form's suggestion to tally all similar financial relationships, it is unclear whether this sort of quantitative information justifies the burden of preparing it. There is no statutory requirement that CMS collect this information. And identifying all of the relevant financial relationships between the disclosing party and physicians during the time period in

question can be a significant undertaking, particularly where the disclosing party is a large organization or the period of noncompliance is long. Furthermore, the value of the denominator is not clear. That one physician practice reporting a noncompliant compensation arrangement has twice as many compensation arrangements with physicians as another physician practice that reports a substantially similar issue does not bear on the extent of the noncompliance. Nor is it fair to conclude that noncompliance was more pervasive in a physician practice in which one of two compensation arrangements failed to comply with the physician self-referral law than a hospital in which five of one hundred compensation arrangements failed to comply. The pervasiveness question also raises questions about the duty of the disclosing party to audit other financial relationships in the course of making an SRDP submission.

We ask that, in light of its experience evaluating and resolving SRDP submissions, CMS consider whether the information obtained in response to the pervasiveness question justifies the heavy burden it places on disclosing parties. If CMS chooses to retain the pervasiveness question for disclosures not related solely group practice noncompliance issues, it may wish to consider whether it would elicit the information it needs by including among the examples in the SRDP Disclosure Form one or more statements that are qualitative in nature, not quantitative (e.g., the disclosed arrangement was the only noncompliant financial relationship identified during the course of a due diligence review that involved all of the disclosing party's financial relationships with physicians), or by expressly stating that qualitative statements suffice. Qualitative statements, the accuracy of which are certified by the disclosing party, can provide just as much insight into the pervasiveness of noncompliance as quantitative analyses.

2. <u>Availability of the in-office ancillary services exception</u>

The SRDP Disclosure Form could be read to suggest that the in-office ancillary services exception at § 411.355(b) is unavailable to solo practitioners. Specifically, section IV.A.2.b of the SRDP Disclosure Form describes the in-office ancillary services exception as being "available only to a physician practice that qualifies as a group practice under § 411.352." Although this is true in the vast majority of cases, it is not universally true. It could be beneficial for CMS to clarify that solo practitioners can rely on the in-office ancillary services exception, as can a physician who wholly owns his or her practice (even if the practice employs or contracts with additional physicians).[4] CMS could clarify this statement by inserting the following bold and underlined text and removing the stricken-through text:

> Note that the physician services exception at § 411.355(a) **<u>is available only to a physician practice that qualifies as a group practice under § 411.352,</u>** and the in-office ancillary services exception at § 411.355(b) ~~are~~ **<u>is typically</u>** available only to a physician practice that qualifies as a group practice under § 411.352.

A statement to this effect may avoid confusion. Alternatively, the SRDP Disclosure Form could state that the effect of failing to qualify as a group practice under § 411.352 may preclude the practice from relying on the in-office ancillary services exception.

[4] *See, e.g.*, Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16053, 16071 (Mar. 26, 2004) (discussing when a solo practitioner can satisfy the requirements of the in-office ancillary services exception).

* * *

Thank you for your consideration of these comments. Again, we appreciate the proposals CMS has made to clarify and streamline the SRDP process, and we support the thrust of the proposed changes. Our comments are intended only to bring to CMS's attention certain issues that it may wish to consider as it revises the SRDP forms. Please do not hesitate to contact us if you have any questions.

Sincerely,

/s/ Travis G. Lloyd

Travis G. Lloyd

/s/ Justin K. Brown

Justin K. Brown