CMS Response to Public Comments Received for CMS-10328

The Centers for Medicare & Medicaid Services (CMS) received two comments on the planned changes to CMS-10328. Below is a summary of and our response to the comments received.

Comment: One commenter maintained that the proposed Group Practice Information Form would be helpful because it would not require separate Physician Information Forms for each physician included in the disclosure when reporting noncompliance arising from the failure of a physician practice to qualify as a group practice under §411.352 ("group practice noncompliance"). The commenter requested that CMS no longer require separate Physician Information Forms for reporting other types of noncompliance involving multiple physicians, such as referrals from physicians with similar compensation arrangements or ownership or investment interests that fail to satisfy the requirements of an applicable exception. The commenter described the completion of individual Physician Information Forms as burdensome for disclosing parties where the facts of the noncompliance are the same for each physician who was (or was deemed to be) a party to the compensation arrangement or who had similar ownership or investment interest. The commenter suggested that CMS allow disclosing parties to detail the facts of a particular financial relationship and identify the physicians "involved in" the financial relationship in a single form (to be developed by CMS). The commenter suggested that, where the facts of the noncompliance are the same for each physician who was (or was deemed to be) a party to the compensation arrangement or who had similar ownership or investment interest, much of the physician-specific

information collected in the Physician Information Forms (such as the physician's name, National Provider Identifier, and physician organization, if applicable) could be collected in a spreadsheet identifying all the physicians who made prohibited referrals to the disclosing party.

Response: We agree with the commenter that the proposed Group Practice Information Form will facilitate the disclosure of group practice noncompliance. In response to the comment on the requirement that disclosing parties submit a separate Physician Information Form for each physician when disclosing other types of noncompliance, we note the following. First, we require a separate Physician Information Form for each physician only when it is necessary to adequately report violations of the physician self-referral law. The making of a prohibited referral is specific to an individual physician, as is the submission of claims to the Medicare program for designated health services improperly referred by that physician. We analyze noncompliance with the physician self-referral law on a physician-by-physician basis, and require the completion of separate Physician Information Forms to allow the agency to assess the nature and extent of noncompliance as required under Section 6409 of the Affordable Care Act. Second, the commenter's concerns are addressed in large part by the now-formalized special process for collecting information on physicians who stand in the shoes of their physician organization and are, therefore, deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization. Under the special process, a disclosing party may submit a *single* Physician Information Form that details the noncompliant compensation arrangement(s) between the entity and the

physician organization along with a separate listing of each physician who is deemed to have the same noncompliant compensation arrangement(s) with the entity as the physician organization and the period(s) of noncompliance for each physician. (This is current policy stated in a FAQ on the physician self-referral website, and is now incorporated in the "Instructions Regarding the Voluntary Self-Referral Disclosure Protocol Submission" at IV.A.2.c.)

In our experience administering the SRDP, the majority of self-disclosures that report noncompliance pertaining to multiple physicians in the same physician organization report either: (a) group practice noncompliance, or (b) arrangements that are deemed to be between entities and physicians under §411.354(c)(1)(ii) or (2)(iv). Taken together, the proposed Group Practice Information Form and the special rule for physicians who stand in the shoes of their physician organization will allow parties to report this type of noncompliance using a single form. We believe that the use of a single form is appropriate in these cases, because the physicians are part of the same physician organization, and, in the case of compensation arrangements where the stand in the shoes provisions apply, the individual physicians are deemed to have the same arrangement(s) with the entity as the physician organization.

In contrast, when a party discloses noncompliance with respect to its compensation arrangements with physicians who are not in the same physician organization, even if some of the factual details of the compensation arrangements are similar, the compensation arrangement with each physician are separate and distinct. In such

circumstances, for the reasons described above, we continue to believe that separate Physician Information Forms are necessary to report the specific facts and circumstance of each separate compensation arrangement. Likewise, when a group practice fails to satisfy the requirements of an exception in §411.355, such as the exception for in-office ancillary services at §411.355(b), the facts of each physician's prohibited referrals will differ, making separate Physician Information Forms necessary to adequately disclose the noncompliance with the physician self-referral law. To underscore this point, the instructions to the Group Practice Information Form have been clarified to explicitly state that the form may not be used by a physician practice that qualifies as a group practice under §411.352 or the medical practice of a physician in solo practice to report the entity's failure to satisfy the requirements of an applicable exception in §411.355, including the in-office ancillary services exception.

Comment: One commenter noted that, under the currently approved collection of information, CMS accepts electronic submission of the SRDP Forms and related materials, but requires a hard copy of the signed certification to be mailed or otherwise physically delivered to CMS. The commenter requested that CMS permit the entire submission, including the signed certification, to be submitted electronically.

Response: Under the proposed updates to the SRDP, a signed certification remains a necessary element of a complete disclosure. See the SRDP Disclosure Form IV.A.2.e. However, disclosing parties are no longer required to mail or otherwise physically deliver

to CMS the signed certification in hard copy format. The entire SRDP submission may now be submitted electronically.

Comment: One commenter who generally supported the Group Practice Information Form stated that the instructions for reporting the failure to satisfy the "volume or value" requirement at §411.352(g) and the special rules for profit shares and productivity bonuses at §411.352 could be clarified in certain respects to avoid potential misunderstandings. First, the commenter asserted that the SRDP instructions could be read to suggest that compensation that takes into account the volume or value of referrals *necessarily* violates the requirement at §411.352(g) unless the designated health services are personally performed by the physician or are "incident to" the physician's personally performed services. To address this potential misunderstanding, the commenter suggested that we explicitly state that compensation that takes into account the volume or value of referrals may satisfy the requirement at §411.352(g) if the conditions of the special rules at §411.352(i) are satisfied. Second, the commenter asserted that the SRDP instructions could be read to suggest that the only way to satisfy the special rules for profit shares and productivity bonuses at § 411.352(i) is to satisfy one of the deeming provisions in §411.352(i). To correct this potential misunderstanding, the commenter suggested several minor revisions to the instructions.

Response: As a preliminary matter, we note that the SRDP Forms provide instructions on how to disclose overpayments arising from violations of the physician self-referral

law. The instructions to the SRDP Forms are not intended to provide guidance on the application of or compliance with the physician self-referral law.

With respect to the commenter's first point, we agree that a physician practice may avoid noncompliance with the requirement at §411.352(g) if it meets the conditions of the special rules at §411.352(i). To avoid any potential misunderstanding identified by the commenter, we are adding the language indicated in italics to the following example of how to report failure to satisfy the 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 *and the productivity bonuses did not meet the conditions of the special rule at §411.352(i)*."

With respect to the commenter's second point, we agree that a physician practice is not required to meet the conditions of a deeming provision in §411.352(i)(1)(iii) or §411.352(i)(2)(ii) in order for the share of overall profits or a productivity bonus not to be directly related to the volume or value of the recipient physician's referrals under §411.352(i). However, we do not believe that it is necessary to modify the proposed Group Practice Information Form. The instructions pertaining to the special rules at §411.352(i) request specific information from physician practices that *relied* on one or more of the deeming provisions in §411.352(i)(1)(iii) or (2)(ii) to satisfy the volume or value requirement at §411.352(g). If a physician practice otherwise met the conditions of the special rules at §411.352(i), then the practice would not have to rely on the deeming

provisions. To the extent that a physician practice did not rely on one of these deeming provisions, it is not necessary for the practice to provide this information.

Comment: One commenter stressed that the proposed Group Practice Information Form will reduce burden for parties disclosing group practice noncompliance, and added that that the form, in general, is well-tailored to gather necessary information and is not unduly burdensome. However, the commenter objected to the following specific request for information on the Group Practice Information Form: for disclosures where a physician practice failed to qualify as a group practice under §411.352 because one or more physicians in the practice received productivity bonuses based on services not personally performed by the physician or services not "incident to" such personally performed services, the proposed Group Practice Information Form requests information regarding the total number of unique designated health services CPT/HCPCS codes billed by the practice, and the number of designated health services CPT/HCPCS codes for which physician(s) received productivity bonuses that were neither personally performed by the physicians nor services "incident to" such personally performed services. According to the commenter, this requirement would impose significant administrative burden on disclosing parties while yielding very little insight into the nature and extent of the disclosed noncompliance with the physician self-referral law. In particular, the commenter contended that the number of CPT/HCPCS codes billed by a physician practice often has more to do with the specialties of the physicians in the practice than the extent of noncompliance.

Response: We appreciate the commenter's general support for the proposed Group Practice Information Form, but we disagree with its assessment of the request for information regarding CPT/HCPCS codes billed by the physician practice. We believe that, in most cases, the information requested regarding CPT/HCPCS can be collected fairly easily by a query of the practice's billing or electronic health records software. We also believe that the ratio of the total number of CPT/HCPCS codes billed by the physician practice to the number of CPT/HCPCS codes that formed the basis for improper productivity bonuses provides useful information regarding the extent of the disclosed noncompliance, as well as the extent of the harm the physician self-referral law is intended to prevent. In our administration of the SRDP, we have reviewed many disclosures where improper productivity bonuses were paid based on a handful of CPT/HCPCS codes representing a very small percentage of the designated health services provided by the physician practice. This information, coupled with requested information regarding revenues derived from designated health services and the number of affected physicians in the practice, provides a comprehensive overview of the failure of the physician practice to qualify as a group practice, and is crucial to our ability to assess the nature and extent of noncompliance by the physician practice.

We are aware that, in some instances, the requested information regarding CPT/HCPCS codes may be impossible or extremely burdensome to collect. Therefore, we have modified the instruction regarding this information to state that the information should be provided "if available." We also accept reasonable estimates made by the physician practice.

Comment: A commenter commended CMS for not requiring a report on the pervasiveness of noncompliance when disclosing group practice noncompliance using the Group Practice Information Form. The commenter requested that CMS no longer require information on pervasiveness—defined in the SRDP Disclosure Form as how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians—for any type of disclosed noncompliance with the physician self-referral law. According the commenter, information regarding the pervasiveness of noncompliance is not useful in evaluating the extent of noncompliance. In addition, according to the commenter it is unduly burdensome for disclosing parties to collect information on other financial relationships that are similar to the disclosed financial relationship, especially for large organizations or for lengthy periods of noncompliance. The commenter also stated that the requirement that disclosing parties report the pervasiveness of the noncompliance raises questions about whether the parties have a duty to audit other financial relationships when submitting a self-disclosure to the SRDP.

The commenter requested that, if CMS retains the required report on pervasiveness, CMS should explicitly allow for qualitative statements on the pervasiveness, such as "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."

Response: We continue to believe that the report on pervasiveness provides important information necessary to assess the extent of noncompliance as required under section 6409 of the Affordable Care Act. For example, assume Hospital A employs five physicians, and the employment arrangements for all five physicians do not satisfy the requirements of any applicable exception in §411.357. Assume also that Hospital B employs 100 physicians, and the hospital discloses that compensation arrangements with five of the physicians do not satisfy the requirements of any applicable exception in §411.357. If we did not collect information on other similar financial relationships—in this example, employment arrangements between the hospitals and physicians—then the extensiveness of the noncompliance at Hospital A and Hospital B would appear to be roughly similar (in both cases, there are five noncompliant employment arrangements). However, we believe that the fact that 100 percent of the employment arrangements at Hospital A failed to satisfy the requirements of an applicable exception, while only 5 percent of the employment arrangements at Hospital B did so, indicates that the noncompliance was more extensive at Hospital A.

Regarding the burden of collecting information on pervasiveness, we believe that most entities maintain this information and that it can be accessed without undue burden by querying the entity's accounts payable or accounts receivable, as applicable, for physician vendors, lessees, or purchasers. We also accept reasonable estimates of the pervasiveness of reported noncompliance. We have modified the instructions for the SRDP Disclosure Form to explicitly state that reasonable estimates are accepted. Lastly,

the report on pervasiveness does not impose a separate or independent duty to audit other financial relationships between the entity and physicians.

In response to the commenter's suggested description of pervasiveness of noncompliance, we continue to believe that quantitative assessments of the number of similar financial relationships provide the clearest and least ambiguous information on pervasiveness. A statement as to the number and general types of financial relationships (e.g., rental of office space, employment, medical director services, etc.) reviewed as a part of comprehensive due diligence and the number of noncompliant financial relationships discovered in this process, similar to that suggested by the commenter, may be submitted as a report of the pervasiveness of noncompliance.

Comment: One commenter objected to the following statement in section IV.A.2.b of the SRDP Disclosure Form: "Note that the physician services exception at §411.355(a) and the in-office ancillary services exception at §411.355(b) are available only to a physician practice that qualifies as a group practice under §411.352." According to the commenter, this statement could imply that the exception for in-office ancillary services is not available to a physician in solo practice. The commenter asked CMS to clarify that this exception is available to physicians in solo practice.

Response: The commenter is correct that the exception for in-office ancillary services at §411.355(b) is available to physicians in solo practice. To address the concern raised by the commenter, in place of the sentence cited by the commenter, the instructions in

section IV.A.2.b now read, in relevant part: “Note that, if a physician practice consists of two or more physicians and does not qualify as a group practice under §411.352, the practice may not rely on the exception for physician services at §411.355(a) or the exception for in-office ancillary services exception at §411.355(b).”