

CMS Advisory Opinion Approves Parent and Wholly-Owned Subsidiary Qualifying as “Single Legal Entity” under the Stark “Group Practice” Definition

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The Centers for Medicare & Medicaid Services (“CMS”) released Advisory Opinion No. CMS-AO-2021-01 in June 2021, which gave the requestor the green light to provide designated health services (“DHS”) through wholly-owned subsidiaries while the parent and subsidiaries could qualify as a “single legal entity” under the “group practice” definition of the federal physician self-referral law (or “Stark Law”). As a result, the requestor is eligible for the in-office ancillary services (“IOAS”) exception to the Stark Law. This opinion is notable because CMS issues advisory opinions infrequently and, particularly given recent changes to the CMS advisory opinion regulations (as we wrote about [here](#)), other entities may use this opinion as guidance in forming similar arrangements.

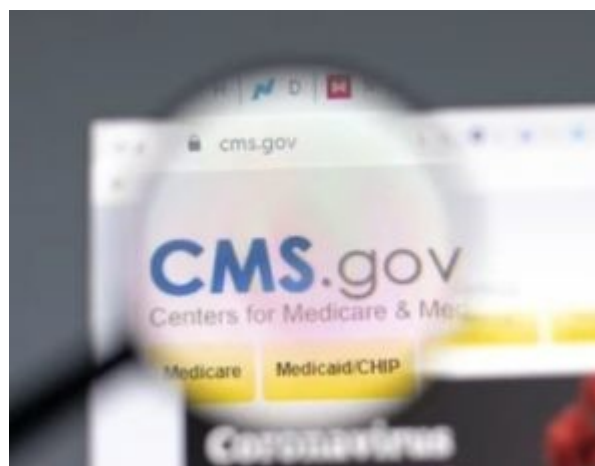
As background, under the IOAS exception, a physician practice may make referrals for DHS within the practice, but only if it qualifies as a group practice. The term “group practice,” defined in the Stark regulations, requires, among other things, that the practice is a “single legal entity” that operates “primarily for the purpose of being a physician group practice.” Accordingly, a “single legal entity” does *not* include physicians who are only informally affiliated for the purpose of sharing profits from referrals, but a single legal entity may itself own subsidiary entities. The recent advisory opinion focuses on whether a physician practice with wholly-owned subsidiary physician practices qualifies as a “single legal entity” for the purposes of the IOAS exception.

The Advisory Opinion

In short, the advisory opinion

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allows for a group practice with wholly-owned subsidiaries to provide services through those subsidiaries, even if the subsidiaries do not themselves qualify as group practice. The group practice and the subsidiaries, for purposes of the IOAS exception, qualify as a single legal entity.

The Arrangement

The requestor (“Group Practice”), was the sole owner of two subsidiary physician practices (the “Subsidiaries”). Group Practice was looking to provide services, including DHS, to patients, both directly and through the Subsidiaries. Group Practice attested that, while the Subsidiaries would retain their own Medicare enrollment and use billing numbers assigned to them to bill Medicare for items and services they furnish to beneficiaries, the material assets and business functions of the Subsidiaries would be transferred to Group Practice or the practice’s management company. The management company would provide non-clinical services to both Group Practice and the Subsidiaries. The revenue and expenses of the Subsidiaries would be attributed to Group Practice. Furthermore, the clinical employees and contractors of the Subsidiaries would become employees and contractors of Group Practice, and the patients served by the Subsidiaries would be considered patients of Group Practice.

Group Practice certified that it met all requirements of a group practice itself and that the arrangement with the Subsidiaries would meet all other requirements of a group practice, such as having centralized decision-making. The Subsidiaries did not qualify as group practices on their own, and Group Practice specifically sought to determine if it, in its arrangement with the Subsidiaries, could qualify as a “single legal entity” for the purposes of the group practice definition, thus meeting this requirement of the IOAS exception.

CMS Analysis

CMS found that Group Practice and the Subsidiaries would qualify as a single legal entity. In concluding this, CMS focused heavily on two aspects of the relationship: (1) the revenue and expenses of the Subsidiaries would be attributed to Group Practice, and (2) the clinical employees and contractors of the Subsidiaries would become employees and contractors of Group Practice. CMS found the first factor to be adequate even though the Subsidiaries maintained their own Medicare enrollments and payor contracts separate from Group Practice.

What This Means for Physician Practices

Reliance on Advisory Opinions

On January 1, 2020, the Stark regulations regarding advisory opinions were revised. Prior to this revision, only the entity requesting the advisory opinion and others who were parties to the specific arrangement could rely on the opinion. Under the revised advisory opinion regulations, the Secretary of HHS will not pursue sanctions against other entities who did *not* make the request for the opinion and who are not parties to the specific

arrangement, as long as their arrangement is "*indistinguishable in all its material aspects*" from an arrangement which received a favorable advisory opinion from CMS. See our detailed analysis of the revised advisory opinion regulations [here](#).

This means that other physician practices outside of Group Practice and the Subsidiaries can make referrals to wholly-owned subsidiaries if such arrangements are indistinguishable in all material aspects from the one described in the opinion and otherwise meet the requirements of the group practice definition and IOAS exception. Below is a brief list and description of factors that would likely be considered material to this arrangement, and thus necessary for physician practices seeking to rely on Advisory Opinion No. CMS-AO-2021-01.

Referrals to Subsidiaries

1. Parent-Subsidiary Relationship

The parent-subsidiary relationship is a key factor in the "single legal entity" analysis. As stated above, physicians that are only informally affiliated do *not* qualify as a group practice. Further, the advisory opinion expressly states that Group Practice and the Subsidiaries qualify as a single legal entity "provided that [Group Practice] is the sole owner of the Subsidiaries." However, it is not necessary for the subsidiary physician practice itself to qualify as a group practice.

Below are two diagrams: Diagram 1 illustrates affiliated entities that do *not* qualify as a group practice, and Diagram 2 illustrates the parent-subsidiary relationship that CMS deemed appropriate in the advisory opinion.



Diagram 1: Entities A and B are only affiliated and do not qualify as a single legal entity.

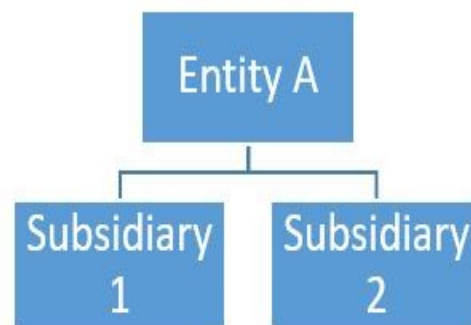


Diagram 2: Entity A wholly owns Subsidiaries 1 and 2, and the three entities together may qualify as a single legal entity.

2. Revenue and Expenses Attributed to Parent

Given the emphasis CMS put on the framework of Group Practice and the Subsidiaries' revenue and expenses, this element would likely be considered material. Therefore, subsidiary revenue and expenses should be attributed to the group practice if the entities are looking to qualify as a single legal entity.

However, as mentioned above, it is not necessary for a subsidiary physician practice to bill Medicare under the parent. A subsidiary may have its own Medicare number and bill separately from the parent, as long as the revenue and expenses of the subsidiary are ultimately attributed to the parent.

3. Employees and Contractors are Those of the Parent

Similarly, if a subsidiary's employees and/or contractors are not considered to be the employees and/or contractors of the group practice, it is unlikely that the arrangement would fall within the exception, because this, too, was a focus of the opinion and thus is likely material from CMS's point of view.

Conclusion

Following issuance of Advisory Opinion No. CMS-AO-2021-01 and recent regulatory changes regarding reliance on advisory opinions, parent physician practices may make referrals for DHS to wholly-owned subsidiary practices as a single legal entity if all other elements of the group practice definition and IOAS exception are met. This advisory opinion only addresses the definition of a single legal entity. Entities must ensure that the other elements of the group practice definition and IOAS exception to the Stark Law are also met if they choose to form a parent/subsidiary referral relationship.

Please contact the authors or your regular Dorsey attorney with any questions.

Summer Associate Hannah McCallum provided substantial assistance in the drafting of this article.