[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

[name and address redacted]

RE: Advisory Opinion No. CMS-AO-2008-01

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement (the "Proposed Arrangement") under which a hospital system (the "Requestor") would license a custom software interface (the "Physician Practice Interface") for use by the physicians on its medical staffs (and/or their physician practices) (the "Affiliated Physician Practices"). Specifically, you seek a determination as to whether the provision of the Physician Practice Interface results in a compensation arrangement within the meaning of section 1877(h)(1)(A) of the Social Security Act (the "Act") and, if so, whether the Proposed Arrangement satisfies the requirements of an exception to the prohibition on physician self-referral.

You have certified that all of the information provided in your request, including all supplementary materials and documentation, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of this information. If material facts have not been disclosed or have been misrepresented, this advisory opinion is without force and effect.

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement does not create a compensation arrangement as defined in section 1877(h)(1)(A) of the Act. We do not address whether the Proposed Arrangement satisfies the requirements of the exception in § 411.357(u) or any other exception to the physician self-referral prohibition.

This opinion may not be relied on by any persons other than [Name Redacted], the Requestor of this opinion, and is further qualified as set forth in section IV below and in 42 C.F.R. §§411.370 through 411.389.

I. FACTUAL BACKGROUND

The Requestor, a nonprofit corporation, owns and operates [number redacted] hospitals in [State redacted]. In [year redacted] and [year redacted], Requestor contracted with a third-party vendor (the "Vendor") to install a proprietary health care software information system (the "System"), customized to the Requestor's specific requirements, including a software interface engine that facilitates access by the custom Physician Practice Interface(s). Pursuant to the contract between the Requestor and the Vendor, the Vendor

provided software licenses to the Requestor that permit the Requestor and its controlled affiliates to use the System. Currently, the medical staffs of Requestor's [number redacted] hospitals have the option to view laboratory reports for the Requestor's patients over a protected internet connection to the System. The Proposed Arrangement would permit also the ordering or communicating of laboratory tests or procedures performed by the Requestor using the Physician Practice Interface(s).

Numerous physicians on the Requestor's medical staffs have begun to purchase and use electronic health records ("EHR") systems for their private practices. Requestor would like to integrate its System with individual information systems maintained by the Affiliated Physician Practices to promote the secure transfer of patient data between the parties. Integrating the System with each Affiliated Physician Practice requires the custom development of an interface that can extract data from the System and transfer it to the Affiliated Physician Practices' EHR systems. The Requestor may need to develop several versions of the Physician Practice Interface to accommodate the various EHR systems. The Requestor would limit the functionality of the Physician Practice Interface to the ordering or communicating the results of laboratory tests or procedures furnished by the Requestor.

Under the Proposed Arrangement, the Vendor would develop, and the Requestor would pay the development cost of, a Physician Practice Interface customized to the Affiliated Physician Practice's existing EHR software. Requestor would also purchase licenses to authorize Affiliated Physician Practices to use the Physician Practice Interface during the term of the Requestor's license agreement. Under the Proposed Arrangement, the Physician Practice Interface would be used only to order or communicate the results of tests and procedures furnished by the Requestor and could not be used for any purpose other than the ordering or communicating of the results of tests or procedures furnished by the Requestor. The Requestor has certified that the Physician Practice Interface cannot be applied or altered by an Affiliated Physician Practice to perform any alternative functions, nor may an Affiliated Physician Practice resell or otherwise transfer or assign its license to use the Physician Practice Interface to access Requestor's System. The Requestor has certified further that no other items or services would be provided to the Affiliated Physician Practices in connection with the Proposed Arrangement.

Requestor has received indications of interest in the Proposed Arrangement from Requestor's medical staff members, including several private, multi-specialty physician practices already affiliated with Requestor's hospitals.

II. LEGAL ANALYSIS

A. Law

Under section 1877 of the Act (42 U.S.C. § 1395nn), a physician may not refer a Medicare patient for certain designated health services ("DHS") to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the

entity furnishing the DHS from submitting claims to Medicare, the beneficiary, or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.[1]

In section 1877(h)(1)(A) of the Act, a compensation arrangement is defined as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C)." Section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the physician self-referral prohibition. Such remuneration includes "[t]he provision of items, devices, or supplies that are used solely . . . to order or communicate the results of tests or procedures for such entity." See also, the definition of "remuneration" at 42 C.F.R. § 411.351.

B. Analysis

According to the Requestor, the Physician Practice Interface: (1) would be used only to order or communicate the results of tests and procedures furnished by the Requestor; (2) cannot be modified to perform an alternate function; and (3) cannot be resold, transferred or assigned by an Affiliated Physician Practice. Therefore, we have determined that the Proposed Arrangement does not meet the definition of "compensation arrangement" for purposes of the statute's prohibition on physician self-referral as set forth in 1877(h)(1)(A). Our analysis is limited to the use of the Physician Practice Interface to order or communicate results of tests and procedures furnished by the Requestor. We make no determination as to compliance with the physician self-referral law should the Requestor and/or the Affiliated Physician Practices use the Physician Practice Interface for purposes other than those set forth herein.

III. CONCLUSIONS

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement does not constitute a compensation arrangement under Section 1877(h)(1)(A) of the Act. We have not considered, nor do we express an opinion about, whether or not the provision of the Physician Practice Interface constitutes prohibited remuneration outside the limitations discussed above in section II.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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[1] In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. 42 U.S.C. § 1396b(s).

- This advisory opinion is issued only to the Requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requestor of this opinion.

- This advisory opinion is applicable only to the statutory and regulatory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Requestor or the Affiliated Physicians, including without limitation, the Federal anti-kickback statute, section 1128(B)(b) of the Act (42 U.S.C. § 1320a-7b(b)).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services. The Centers for Medicare & Medicaid Services reserve the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. §§ 411.370 through 411.389.

Sincerely,

Jeffrey B. Rich, M.D., Director
Center for Medicare Management