[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: CMS Advisory Opinion No. CMS-AO-2017-01

Dear [name redacted]:

We write in response to your request for an advisory opinion regarding an arrangement under which [name redacted] ("Requestor" or "you") would provide certain pop-up notifications alerting physicians of various potential issues ("Laboratory Alerts") on Requestor's free web-based portal ("Portal"), which is used for ordering and reporting the results of diagnostic tests (the "Arrangement"). Requestor would provide the Laboratory Alerts free of charge to physicians who make referrals to Requestor for designated health services payable by Medicare ("Referring Physicians"). You seek a determination as to whether the addition of Laboratory Alerts to the Portal would constitute "remuneration" that gives rise to a "compensation arrangement" under section 1877(h)(1) of the Social Security Act (the "Act").

You certified that all of the information provided in your request, including all supplementary materials and information, is true and correct and constitutes a complete description of the relevant facts and arrangements between the parties. In issuing this opinion, we relied solely on the facts and information you 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 Arrangement would not result in "remuneration" to Referring Physicians and, therefore, the Arrangement would not create a compensation arrangement between Requestor and Referring Physicians within the meaning of section 1877(h)(1) of the Act.[1]

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

[1] We express no opinion as to whether physicians who receive the Portal with Laboratory Alerts at no cost are prohibited from making referrals to the Requestor for designated health services under section 1877(a) of the Act. Our opinion is limited to the question of whether the provision of Laboratory Alerts at no cost via the Portal constitutes "remuneration" giving rise to a compensation arrangement under section 1877(h)(1) of the Act.

I. FACTUAL BACKGROUND

Requestor is a for-profit corporation providing diagnostic testing services throughout the United States. Requestor currently provides its Portal without Laboratory Alerts to Referring Physicians free of charge.[2] The Portal is used for electronic test order management and secure messaging between Requestor and Referring Physicians. Requestor proposes to add Laboratory Alerts to the Portal, and would continue to provide the Portal to Referring Physicians free of charge. The Laboratory Alerts would be limited to issues relating to the particular test results being reported to a Referring Physician. That is, a Laboratory Alert would not provide general clinical recommendations, drug interaction warnings, or any other information not tied directly to the laboratory results with which it is provided. The Laboratory Alerts may recommend follow-up, repeat, or additional testing, where appropriate, based on industry-standard, peer-reviewed guidelines. For example, a Laboratory Alert may recommend that a particular laboratory test result warrants follow-up testing in 90 days or that a definitive identification test is available if clinically indicated.

Requestor certified that, other than patient-related information (*e.g.*, prior test results and demographic data), all the content provided in the Laboratory Alerts is available in the public domain, and that Referring Physicians may access the content without cost through channels other than the Laboratory Alerts. For example, scientific literature supporting a recommendation in a Laboratory Alert could also be found using a free Internet search engine. Requestor further certified that all the information and recommendations to be provided in the Laboratory Alerts would be based on peer-reviewed guidelines from well-recognized medical organizations, such as the National Institutes of Health, American Cancer Society, and College of American Pathologists.

The Laboratory Alerts would be removed from the Portal by the sooner of the date that the Referring Physician orders the recommended follow-up testing (if follow-up tests have been recommended) or 14 days after the Referring Physician first receives the Laboratory Alert. The test results are stored on the Portal indefinitely. If the patient receives a recommended follow-up or additional test, the test results would be available through the Portal. If a Referring Physician orders a test but the patient does not have the test performed, Requestor does not notify the physician that the test has not been performed or resend the Laboratory Alert.

A Referring Physician has the ability to turn off a particular alert rule or a set of rules grouped by disease condition if the physician does not want to receive Laboratory Alerts. When a Referring Physician attempts to order a test based on a Laboratory Alert recommendation, the Portal would display all the tests that may address the recommendation. However, there is no "select all" option, and the Referring Physician must individually select each test to be performed.

[2] [Footnote redacted. The information in the original footnote contained identifying information associated with the requestor and does not relate to the legal analysis or conclusion of this advisory opinion.]

II. LEGAL ANALYSIS

A. Law

Under section 1877 of the Act and the regulations in 42 C.F.R. § 411.350 et seq. (collectively, the "physician self-referral law"), a physician may not refer a Medicare beneficiary 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. The physician self-referral law also prohibits an entity from submitting claims to Medicare, the beneficiary, or any other entity for DHS that are furnished as a result of a prohibited referral.

In section 1877(h)(1)(A) of the Act, "compensation arrangement" is defined as "any arrangement involving any remuneration" between a physician (or an immediate family member of such physician) and an entity furnishing DHS. Section 1877(h)(1)(B) of the Act defines "remuneration" to include "any remuneration, directly or indirectly, in cash or in kind." However, under section 1877(h)(1)(C)(ii) of the Act, "remuneration" does not include "[t]he provision of items, devices, or supplies that are used solely to—(I) collect, transport, process, or store specimens for the entity providing the device or services, or (II) order or communicate the results of tests or procedures for such entity."

In the 1998 Proposed Rule, we interpreted the term "solely" to mean that the donated items must be used "solely for the purposes listed in the statute." We stated that "[w]e do not believe an item or device meets this requirement if it is used for any purposes besides these." 63 Fed. Reg. 1659, 1694 (Jan. 9, 1998).[3] We also explained that the donated items should be used "solely for the entity that provided them," and gave as an example a fax machine that is "integral to, and used exclusively for, performing the outside entity's work." 63 Fed. Reg. 1694. In our final rule entitled "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements," we affirmed that the same principles apply to limited-use interfaces used to store and share patients' laboratory results. 78 Fed. Reg. 78751, 78759 (Dec. 27, 2013).

B. Analysis

Requestor seeks a determination that the addition of Laboratory Alerts to the Portal, which is provided to Referring Physicians free of charge, does not create a compensation arrangement within the meaning of section 1877(h)(1) of the Act. We conclude that the added functionality of Laboratory Alerts does not create a compensation arrangement because the Laboratory Alerts, as integrated into the Portal, will be used solely in connection with "order[ing] or communicat[ing] the results of tests or procedures [for the Requestor]."[4]

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[3] In our 2015 Physician Self-referral Updates, 80 Fed. Reg. 70886, 71321 (Nov. 16, 2015), we clarified that "remuneration" does not include the provision of an item, device, or supply that is used for more than one of the purposes listed in section 1877(h)(1)(C)(ii), so long as it is not used for any other purposes.

[4] The Requestor has not asked us to opine, and we express no opinion, on whether the provision of the Portal *without* the added functionality of Laboratory Alerts creates a compensation arrangement between Requestor and the physicians to whom it is provided. Our opinion applies only to the added functionality of Laboratory Alerts. In

In Phase I of our rulemaking, we responded to a comment regarding whether a laboratory may provide medical waste disposal supplies and services free of charge if the services would be provided only for medical waste generated in connection with the collection, transportation, processing, or storage of specimens. 66 Fed. Reg. 856, 949 (Jan. 4, 2001). We stated that Section 1877(h)(1)(C)(ii) of the Act—

> does not specifically allow laboratories to furnish physicians and group practices with medical waste disposal supplies and services at no charge. However, we believe that supplies and the disposal of items used solely in connection with the collection of specimens for this clinical laboratory are part of the process the laboratory engages in when it collects, transports, and processes specimens. If a laboratory can provide a needle for collection and it can take away the specimen, we believe that the laboratory can also take away the needle and other items that are used in the process. However, we do not believe this exception covers the disposal of needles or other waste items that have been used by the physician practice for other purposes.

Id.

According to the Requestor, the Portal is used for electronic test order management and secure messaging between Requestor and Referring Physicians. In our view, Laboratory Alerts made available on the Portal will be used solely in connection with the ordering and communicating of test results for the Requestor. Laboratory Alerts are provided to Referring Physicians when test results are communicated via the Portal. The information provided in the Laboratory Alert is limited to issues relating to the specific test results being reported. For example, where a test result detects a possible abnormality, a Laboratory Alert may inform physicians of an additional test that will provide definitive identification. As the example illustrates, the purpose of Laboratory Alerts is not to provide the physician with general information that may or may not have any bearing on a patient's test results. Rather, Laboratory Alerts provide the physician with an enhanced test result that assists the physician in determining which additional tests, if any, should be ordered for a patient, given the specific results of the patient's test.

An essential consideration in our analysis is that Laboratory Alerts assist physicians in the deliberative process of determining which additional tests, if any, to order from Requestor. In this context, we believe that safeguards are necessary to ensure that the Laboratory Alerts are used solely to communicate and order tests, as opposed to being used also to encourage overutilization or medically unnecessary or duplicative testing. Requestor certified that the Portal, as equipped with Laboratory Alerts, includes such safeguards. First, the recommendations for additional testing provided in Laboratory Alerts will be based on industry-standard, peer-reviewed guidelines. Second, Laboratory Alerts are not overly intrusive, and they do not override the physician's independent judgment. Where multiple additional tests are

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addition, we do not opine on whether the provision of Laboratory Alerts constitutes remuneration in any other context than as an integrated part of an item, device, or supply that is used solely for ordering or communicating the results of tests.

recommended, there is no "select all" button. Likewise, physicians have the ability to turn off Laboratory Alerts for a particular disease condition. Third, the information provided in Laboratory Alerts is available free of charge from other sources. Thus, Laboratory Alerts do not incent a physician to order additional tests in order to gain access to information for which he or she would otherwise have to pay.

III. CONCLUSION

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement does not result in remuneration to Referring Physicians and, therefore, does not create a "compensation arrangement" that implicates the physician self-referral law. Our analysis is limited solely to the furnishing of Laboratory Alerts by Requestor to Referring Physicians on Requestor's Portal. We have not considered, nor do we express an opinion about, any other relationships between Requestor and Referring Physicians.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- 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 Requestor or Referring Physicians, including, without limitation, the Federal anti-kickback statute, section 1128(B)(b) of the Act.

- 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 in 42 C.F.R. §§ 411.370 through 411.389.

Sincerely,

Elizabeth Richter
Deputy Director
Center for Medicare

cc: [name redacted]