STATE OF MICHIGAN
DEPARTMENT OF TREASURY
LANSING

RICK SNYDER
GOVERNOR

NICK A. KHOURI
STATE TREASURER

October 23, 2017

[redacted]

RE: Diagnostic Reagents Purchased by Clinical Laboratories and Hospitals

Dear [redacted]:

Thank you for your March 17, 2017, response to our request for additional information. You have requested a technical advice letter regarding the sales and use tax treatment of certain diagnostic reagents purchased by your clients, [redacted] and [redacted]. Your request meets the requirements for issuance of a Technical Advice Letter pursuant to Revenue Administrative Bulletin 2016-20.

Facts

[redacted] and [redacted] are full-service [redacted] laboratories owned by [redacted]. These laboratories use in vitro diagnostic products and equipment to provide accurate diagnoses for human diseases.

Diagnostic reagents are essential to in vitro diagnostic testing. Diagnostic reagents may be sold individually or as a component of in vitro diagnostic "kits." These kits will generally include multiple reagents or other control chemicals that must be applied to effectively perform the full diagnostic test. These kits may also include additional tangible personal property to perform the tests, which includes packaging, swabs, brooms, vials, pipettes, and other specimen collection materials. The price for each item within a kit is not always itemized on the resulting invoice.

While you have provided examples of these kits, you have not requested guidance regarding any particular diagnostic reagent or in vitro diagnostic kit purchased by [redacted] or [redacted]. Rather, you have requested guidance as to the Michigan tax treatment of diagnostic reagents generally. To the extent such an analysis requires an examination of the facts for a particular transaction, additional information is necessary. Factual differences between transactions could result in different tax treatments under the Michigan's General Sales Tax Act and Use Tax Act.

Analysis

The Michigan General Sales Tax Act[1] and the Michigan Use Tax Act[2] exempt the sale of prescription drugs and over-the-counter drugs that meet certain criteria. The statute defining exempt drugs reads in relevant part:

> Sales of drugs for human use that can only be legally dispensed by prescription, over-the-counter drugs for human use that are legally dispensed by prescription, or food or food ingredients, except prepared food intended for immediate human consumption. As used in this subdivision, "over-the-counter drug" means a drug that is labeled in accordance with the format and content requirements required for labeling over-the-counter drugs under 21 CFR 201.66.[3]

I. The Prescription Drug Exemption

The prescription drug exemption requires that a "drug" i) be intended for human use, and ii) be legally dispensed *only* by prescription. As discussed below, diagnostic reagents will qualify for the prescription drug exemption if the Food & Drug Administration (FDA) limits the reagent to prescription use only.

a. Diagnostic reagents are drugs for human use

"Drug" is defined as "a compound, substance, or preparation, or any component of a compound, substance, or preparation, other than food or food ingredients, dietary supplements, or alcoholic beverages, intended for human use that is 1 or more of the following:

(i) Recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or in any of their supplements.
(ii) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
(iii) Intended to affect the structure or any function of the body."[4]

In this regard, diagnostic reagents are a "drug" because they constitute a "compound, substance, or preparation" that is intended for the "diagnosis, cure, mitigation, treatment, or prevention of a disease" in humans. This is true even where the reagent is included as a component of a diagnostic kit or other medical device intended to diagnose, cure, mitigate, treat, or prevent a disease.[5] Consequently, diagnostic reagents are "drugs" as defined by the Michigan Sales and Use Tax Acts.

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[1] MCL 205.51 *et seq*.
[2] MCL 205.91 *et seq*.
[3] MCL 205.54g(1)(a); MCL 205.94d(1)(a).
[4] MCL 205.51a(h); MCL 205.92b(h).
[5] See also *Streamlined Sales and Use Tax Agreement*, adopted November 12, 2002, and amended through December 16, 2016, p. 100. Michigan's definition of "drug" is based on an identical definition set forth within the Streamlined Sales Tax Agreement. Additionally, the Compliance Review and Interpretations Committee (CRIC) of the Streamlined Sales Tax Governing Board has acknowledged that chemicals included within infectious disease testing kits qualify as a drug.

b. Diagnostic reagents may only be legally dispensed pursuant to prescription as determined by FDA review.

The prescription drug exemption is limited to drugs "that can *only* be legally dispensed by prescription."[5] Prescription means, in relevant part, an "order, formula, or recipe, issued in any form of oral, written, electronic, or other means of transmission by a licensed physician or other health professional [licensed, certified, or authorized under state law to practice a health profession]."[6] Thus, the prescription drug exemption is limited to drugs that require an order from a licensed health professional in Michigan to be dispensed, regardless whether a prescription is actually issued in a particular transaction.

Prescription and over-the-counter drugs are generally regulated by the FDA. In many cases, FDA regulations require a physician's order for the distribution of diagnostic reagents or kits containing diagnostic reagents. Indeed, medicinal products and medical instruments are generally subject to pre-market screening by the FDA. This screening process includes review of the marketing and distribution of the product and includes approval as to whether the product is "For Prescription Use Only."[7] Based upon the application and approval process of the FDA, any diagnostic reagent, or any kit containing a diagnostic reagent,[8] that is approved exclusively for prescription use meets the prescription requirement of the prescription drug exemption.

Because FDA pre-market approval may not be required in all circumstances, you also make alternative arguments for consideration. For example, you point out that reagents may only be sold to Clinical Laboratory Improvement Act (CLIA) laboratories and such labs are required by law to be operated by a state-licensed physician.[9] However, eligibility for the prescription drug exemption is premised upon whether a drug legally requires a prescription, and without regard to whether a prescription is actually issued in a particular transaction. That is, the fact that laboratories are operated by state-licensed physicians who may be issuing purchase orders is generally irrelevant. More importantly, because neither CLIA nor any other federal laboratory regulations directly require an order of a licensed physician in the sale of a reagent, the statutory requirement for the exemption is not met.

For the same reason, the provisions related to Medicare and Medicaid reimbursement are equally unpersuasive. Indeed, although a prescription may be required for individuals to secure Medicare and Medicaid reimbursement, such a requirement is only relevant to recipients eligible to seek reimbursement and do not constitute a requirement applicable to the sale of the drug in all cases.[10] Thus, third party reimbursement provisions plainly do not meet the statutory standards for the prescription drug exemption.

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[5] MCL 205.54g(1)(a); MCL 205.94d(1)(a) (emphasis added).
[6] MCL 205.51a(n); MCL 205.92b(n).
[7] See e.g., 809.10(e).
[8] *Guidance for Industry and FDA Staff – Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions* ("FDA does not consider [reagents designed to be used in a specific assay or instrument) to be an ASR but rather an [in vitro diagnostic device] or [in vitro diagnostic device] component not covered by the ASR rule.").
[9] 21 CFR 809.30(f).
[10] MCL 205.54g(1)(a); MCL 205.92b(h).

Accordingly, based on the federal regulation of diagnostic reagents, the Department will look to FDA pre-market approval to determine whether a reagent can *only* be legally dispensed pursuant to a prescription.

II. The Over-the-Counter Drug Exemption

To meet the requirements for the over-the-counter drug exemption, an "over-the-counter drug" must be i) for human use, and ii) legally dispensed by prescription. Although the over-the-counter drug exemption is similar to the prescription drug exemption, the exemption differs in that it applies only to "over-the-counter drugs."[11] An over-the-counter drug is a "drug that is labeled in accordance with the format and content requirements required for labeling over-the-counter drugs under 21 CFR 201.66."[12] 21 CFR 201.66 establishes the general format and content requirements of labels for products that are regulated as over-the-counter drugs by the FDA.[13] In this regard, in vitro diagnostic reagents are regulated by the FDA as medical devices rather than over-the-counter drugs.[14] Consequently, the labeling requirements for such products, including those applicable to both analyte specific reagents[15] and general purpose reagents,[16] are established according to the provisions of 21 CFR 809.10.[17] Thus, because in vitro diagnostic reagents are not labeled in accordance with the provisions of 21 CFR 201.66, such reagents will not qualify as "over-the-counter drugs" eligible for the over-the-counter drug exemption.

III. Applying the Exemption to Transactions Involving Diagnostic Reagents

As you note, diagnostic reagents can be sold individually or as part of an in-vitro diagnostic kit or other medical device. Sufficient information has not been presented to allow for a determination as to any specific reagent or kits purchased by [redacted] or [redacted]. Without knowledge of the details of any particular transaction, the Department can only provide general guidance applicable to all transactions.

a. Standalone Sales of Diagnostic Reagents

As noted above, standalone sales of certain diagnostic reagents approved for prescription use by the FDA are eligible for the Michigan prescription drug exemption. FDA pre-market approval documents will generally be conclusive in establishing that a reagent can only be legally dispensed pursuant to a prescription for purposes of the prescription drug exemption.

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[11] MCL 205.54g(1)(a); MCL 205.94d(1)(a) (emphasis added).
[12] *Id.*
[13] 21 CFR 201.66.
[14] 21 USC 321(h) (defining device to refer to "an instrument, apparatus, implement, machine, contrivance, *in vitro reagent*, or other similar or related article" that meets certain requirements); 21 CFR 809.3 ("In vitro diagnostic products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.").
[15] 21 CFR 809.10(e)(1)(i)-(xi).
[16] 21 CFR 809.10(d)(1)(i)-(ix).
[17] 21 CFR 801.10.

b. Sales of Diagnostic Kits that include Diagnostic Reagents.

Sales of diagnostic kits often include reagents, chemicals, and other tangible personal property required to properly administer the kit. In some cases, these kits may separately state the cost of the diagnostic reagent. Where the invoice for a kit separately states the price for each item of tangible personal property in the kit, sales tax is required to be remitted only on taxable items. Diagnostic reagents that qualify for the prescription drug exemption will be exempt if separately itemized.

However, some in vitro diagnostic kits may be sold for a single lump sum price. In Michigan, when taxable and exempt tangible personal property are sold as one inseparable unit (i.e., a single mixed transaction), the "incidental" test will be applied to determine if the entire transaction is taxable or exempt.[18] This is a multi-factor test which considers all of the following factors in determining the taxable status of the transaction:

i. what the buyer sought as the object of the transaction,
ii. what the seller or service provider is in the business of doing,
iii. whether the goods were provided as a retail enterprise with a profit-making motive,
iv. whether the taxable tangible goods were available for sale without the non-taxable goods,
v. the extent to which intangible services have contributed to the value of the taxable item(s) transferred, and
vi. any other factors relevant to the particular transaction.[19]

Consequently, you will need to apply the "incidental" test to the diagnostic kits in order to determine the taxability of the kits.

This letter is limited to the facts described herein. If you have any questions regarding this letter, please feel free to contact me at 517-373-3210.

Sincerely,

Michael A. Eschelbach, Director
Bureau of Tax Policy

[18] *Catalina Marketing Sales Corp v Department of Treasury*, 470 Mich 13 (2004) (holding that the incidental to the service test is applicable to transactions that involve single mixed transactions of taxable tangible personal property and nontaxable services). *See also*, CRIC Interpretive Opinion Recommendation 2007-01 ruling that sales of infectious disease kits as part of a bundled transaction are taxed based upon the laws in each particular state.
[19] *Id.* at 26.