June 1, 2011

MEMORANDUM IN OPPOSITION
AB3551/SB4660

(In relation to referrals of patients for health or health related items or services)

The American Clinical Laboratory Association (ACLA) opposes AB 3551/SB 4660. ACLA is an association representing clinical laboratories throughout the country, including local, regional and national laboratories, virtually all of which are licensed by New York to provide services to New York residents and several of which are located in the State of New York. ***ACLA opposes AB 3551/SB4660 for the following reasons:***

1. <u>The legislation would weaken New York's important protections against health care fraud and abuse, in particular by expanding the in-office ancillary services exception.</u>

The New York health care practitioner referral law is currently one of the strongest in the nation and provides important protections against fraud and abuse of government health care programs. In several important respects, the current New York law is actually stronger than the federal version. Therefore, by conforming the New York referral law to the federal Stark law, this legislation would effectively weaken these protections because it would increase the leniency of the New York law.

In particular, the federal law's in-office ancillary services (IOAS) exception allows independent contractor relationships to qualify, whereas New York's IOAS exception currently requires an employer/employee relationship to qualify for the exception. In the laboratory context, under the more expansive federal IOAS exception, physicians are permitted to enter arrangements with pathologists as independent contractors to provide pathology services one day per week in the office of the billing physician so that the billing physician can refer pathology services to the contract pathologist at a discount and bill the Medicare program at the full fee schedule amount. The financial incentive created by these arrangements results in higher utilization of pathology services, financial abuse of the Medicare program, and poorer quality of care as physicians profit from these self-referrals. In New York, such arrangements are not permitted because the IOAS exception under New York law requires that the pathologist be a bona fide employee of the group practice. Requiring the physician supplying the services under the IOAS exception to be an employee reduces the risk of abuse, because the costs of employing a pathologist are usually higher than simply contracting with him on a "piece-work" basis. As a result, the potential profits are lessened and the attractiveness of these potentially abusive arrangements is reduced.

Enacting this legislation will lead to increased utilization of health care services and higher health care costs as physicians self-refer services performed by their independent contractors. For this reason, ACLA opposes AB 3551/SB4660.

2. <u>The legislation would allow entities to provide electronic health record systems to physicians, which induces them to choose a laboratory based on a kickback, not quality</u>.

Under the federal anti-kickback law, a safe harbor exists for the donation of up to 85 percent of the cost of installing an electronic health record (EHR) system in a physician's office. A similar exception exists under the federal Stark self-referral law. Therefore, as long as the requirements of the exception and safe harbor are met, no self-referral or anti-kickback issue is raised under federal law when a laboratory donates EHR technology to a physician. However, under current New York law such a gift is considered a kickback and a violation of the health care practitioner referral law, although many laboratories mistakenly believe that the New York law is preempted by the federal law.

The rationale behind New York's law is that a physician should choose a laboratory based on the quality of its services, not based upon an offer of free EHR software. Although it is improper under the federal exception for a laboratory to promise, or for a physician to demand, EHR software in exchange for referrals, it is clear that these rules are difficult to enforce or even to apply. As a result, the potential for abuse of the rules is always present. The potential for just this type of abuse was the reason that the federal Office of the Inspector General had substantial reservations about the federal EHR safe harbor and exception and one reason why the safe harbor and exception will "sunset" in 2013. Furthermore, the American Recovery and Reinvestment Act of 2009 (ARRA) provides substantial incentives for physicians to adopt EHRs, including higher reimbursement if they bill using EHR software. As a result, physicians should no longer need laboratories to assist them in purchasing this technology.

Finally, it is unclear how the referral law as amended by this legislation would interact with Section 34-2.9 of the New York Laboratory Business Practices regulations, which separately and specifically prohibits such donations of EHR technology under the authority of the New York anti-kickback statute, Section 587 of the New York Public Health Law.

Enacting this legislation will lead to laboratories competing on the basis of the kickbacks they can provide to physicians, rather than the quality of the services they perform. As a result, laboratory quality will suffer. For this reason, ACLA opposes AB 3551/SB4660.

3. <u>The Public Health Council would have specified additional exceptions to the health care practitioner referral law if they did not pose a substantial risk of abuse.</u>

The Public Health Council currently possesses the authority to specify in regulations additional exceptions to the self-referral prohibition. The fact that the Public Health Council has not adopted the federal exceptions is evidence that they are not warranted or that they pose a risk of abuse. Contrary to the current law, under which the Public Health Council must affirmatively act

to exempt a particular financial relationship from the prohibition, the legislation would presume that the federal exceptions do not pose a risk of abuse unless the Council determines otherwise. The current health care practitioner referral statute and regulations have been enacted to protect New York residents from payer and patient abuse and should not be amended simply to conform with federal law without consideration of the consequences.

Enacting this legislation will weaken the self-referral prohibition intended to protect New York residents from abusive practices by presuming that the federal Stark law's protections are sufficient. For this reason, ACLA opposes AB3551/SB4660.