



June 8, 2011

COALITION STATEMENT IN OPPOSITION TO AB 3551/SB 4660

(Voiding of New York Anti-Self Referral Provisions Applicable to Clinical Laboratories)

This legislation would void provisions of the New York State anti-self referral law and is opposed for the following reasons:

- In enacting this anti-self referral law in 1992, the New York Legislature affirmed that the ordering of laboratory tests should be based exclusively on the patients' medical need and not on any financial incentives between the laboratory and the ordering health care practitioner. **This legislation would void certain protections against financial abuse and inducements for improper laboratory test ordering and referrals.**
- **This legislation would legalize a form of business arrangement, currently considered an unlawful kick back under New York law, whereby clinical laboratories could be impelled to offer or donate electronic health records systems to physicians that order clinical laboratory services.** The New York State Department of Health explicitly identified this "abusive business practice" finding that: "clinical laboratories are offering new EHRs and software packages as an inducement for practitioners to refer patient specimens for testing, resulting in a financial benefit conferred to the practitioner. This arrangement may influence the practitioner's choice of laboratory, rather than his or her relying on quality, timely access to results or the specific needs of patients. **As such, these arrangements have the potential to adversely impact competition, reduce quality of services, and risk potential overutilization of healthcare services, resulting in unnecessary increased overall healthcare costs.**" (Notice of the New York State Department of Health, September 27, 2010)
- In addition, this legislation may supersede other statutes applicable to the provision of laboratory services and that are necessary to protect against unprofessional medical practices, including: referring physician markups on laboratory services that they do not perform or supervise, fee-splitting, kick-back incentives, and

unnecessary over-utilization of laboratory services.¹ **There is no language in this legislation to ensure the continued applicability of these provisions. Thus, the reliance on the federal Stark law in this bill will provide a safe harbor for practices that would otherwise be banned in New York under these other statutes.**

- **Deference to federal exceptions may void or displace New York State direct billing requirements for pathology/laboratory services.** The federal Stark law, upon which this legislation is based, contains **exceptions** to the federal Medicare direct billing requirement for pathology services. Adoption of these federal exceptions will conflict with the State's current comprehensive requirement for direct billing of pathology/laboratory services (Public Health Law § 586.) **The New York State direct billing requirement provides patients and payers with protection against pathology/laboratory markups by physicians that do not perform or supervise these services.** Similar laws have been enacted in 18 states – most have been enacted in the last decade. The direct billing requirement in New York State law, and in other states, helps to control healthcare costs by denying improper financial incentives for ordering physicians to over-utilize pathology services for profit.
- This legislation would encourage the formation of physician in-office captive laboratories that are exempt from routine inspection by the NYS Department of Health (DOH) and are also exempt from laboratory personnel licensing standards, **thereby creating a potential for proliferation of laboratories subject to lesser state governmental oversight and with potentially lower quality.**

**American Association of Bioanalysts
American Clinical Laboratory Association
American Society for Clinical Pathology
College of American Pathologists
National Independent Laboratory Association
New York State Clinical Laboratory Association
New York State Society of Pathologists**

¹ These protections are found in Public Health Law § 579 (Laboratory Scope and Exceptions); Public Health Law § 586 (Payment for Pathology/Laboratory Services); Public Health Law § 587 (Prohibited Practices); Public Health Law § 4501 (Medical Referral Services Businesses Prohibited); Education Law § 6530 and § 6531 (Physician Professional Misconduct.)