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Advancing Excellence

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April 30, 2014

Chairwoman Ramirez
Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

RE: Health Care Workshop, Project No. P131207

Dear Chairwoman Ramirez,

The College of American Pathologists (CAP) appreciates the opportunity to comment in follow up to our attendance at the Examining Health Care Competition workshop last month. The CAP is a medical society serving more than 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and the worldwide leader in quality assurance. The CAP advocates for accountable, high-quality, and cost-effective patient care. The CAP's Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide.

In our comments below, we will address those areas covered both in the workshop and FTC's published questions of greatest relevance and impact on pathology in the context of health care competition in the order they appear in the Federal Register notice.

Professional Regulation of Health Care Providers/Innovations in Health Care Delivery

Pathologist Practice -- Laboratory technologists, pathologists assistants, and Ph.D. laboratory scientists are critically important in the delivery of laboratory services in the health care system. As important as these professionals are, by virtue of their training and clinical experience which is far more limited than pathologists, they cannot truly serve as "pathologists extenders" in the way that nurse practitioners and physician assistants serve as "physician extenders" in many direct patient care settings.

The clinical interpretation of laboratory tests and offering of clinical consultations requires a complete medical patient assessment and requisite clinical training that only pathologists can provide. Pathologists, as physicians, can provide the more extensive key diagnostic and patient management services for which they are trained. At a very basic level, laboratory technologists, pathologists, and Ph.D. laboratory scientists are trained to perform different tasks that do not necessarily overlap with pathologists.

Interstate Practice – CAP supports the right of each state, through licensure, to regulate the practice of medicine in order to protect the health and welfare of its citizens. CAP believes that a pathologist who engages in the interstate practice of pathology, including telepathology

(defined below), and issues a pathology diagnosis that is contained in the patient's medical record should have a full, unrestricted license to practice medicine from the state in which the patient presents for diagnosis or where the specimen is taken or image is made.

The CAP defines telepathology as the practice of anatomic or clinical pathology whereby diagnosis is enabled through digital or electronic communication technology whenever the pathologist is not in the physical presence of the patient's specimen. Telepathology is the practice of the pathology component of telemedicine.

Intra-specialty consultation from an out-of-state pathologist should not require in-state licensure provided that the consultation is at the request of an in-state pathologist licensed within the state and if the consultation is reflected in a pathology report issued by an in-state pathologist. Similarly, pathologists examining specimens and/or slides from a case that has been previously reported, such as might occur when a patient is referred to a treatment center in another state, need only to be licensed by the state within which the examination occurs. A requirement for licensure in these ad hoc situations will impede occasional second opinion consultations that are inherently part of the practice of pathology for equivocal diagnostic findings. For pathologists with very specialized expertise these requests may come from across the nation but are not frequent enough, nor ongoing, so as to feasibly warrant their licensure in all fifty states. Thus, occasional intra-specialty consultation, between pathologists, should not be impeded by licensure for the out-of-state pathologist to the detriment of patient care.

Advancements in Health Care Technology

Electronic Health Records (EHR) Donations -- CAP applauds the final rulings of the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS), released December 23, 2013, removing "laboratory companies" as protected donors of electronic health records (EHR) services and items under the applicable anti-kickback statute safe harbor and Stark exception. While the rules extended the safe harbor and exception until the end of 2021, they excluded "laboratory companies" from the types of entities that may donate EHR items and services, thereby eliminating the abusive business practices that had been associated with these donations.

The CAP had long been opposed to laboratories as donors of EHRs, calling attention to the anti-competitive behavior and abuses associated with EHR donations sought by referring physicians from laboratories. When laboratories were included as protected donors, EHR donations were frequently quid pro quo arrangements for referrals, not whether a laboratory offered the best service, satisfaction and turnaround time. Referral decisions were therefore premised on the richest EHR donation over quality, timely provision of test results and the best interests of patients.

Prior to the release of the final rules, in response to requests for clarification of EHR donations under existing law made by state pathology societies working in concert with the CAP beginning in 2010, nine states (Connecticut, Massachusetts, New York, New Jersey, Missouri, West Virginia, Pennsylvania, Tennessee and Washington) had exerted their authority under each state's anti-kickback law to prohibit or limit EHR donations by clinical laboratories to referring physicians.

Electronic Transactions - Days after the March 27, 2014 effective date of the removal of laboratories as protected donors under the anti-kickback statute safe harbor, OIG issued Advisory Opinion No. 14-03 finding an arrangement requiring a laboratory to pay a per-order fee for each test the EHR vendor transmits to the laboratory to pose more than a minimal risk of fraud and abuse. Under the arrangement, the laboratory's per test fee declined with volume/frequency of referrals. Referring physicians that did not order laboratory tests from a

laboratory contracted with the EHR vendor for the per test fee, were also charged a transmission fee.

While OIG acknowledged the efficient exchange of health information as a laudable goal, it concluded the arrangement generated prohibited remuneration under the anti-kickback statute for which OIG could potentially impose administrative sanctions. OIG was particularly concerned about the material effect the arrangement could have on referral decisions. This concern arises from representations made by the requestor of the opinion that some of the referring practices indicated they would discontinue their historical laboratory referral patterns if the laboratory did not enter into the arrangement with the vendor. CAP applauds OIG's continued recognition of abuses in this space and calls them to FTC's attention underscoring their anti-competitive effects.

Concerning Electronic Interface Renewal Fees - Finally, over the course of the last year, CAP has heard from pathologist members about renewal fees they are being charged by EHR vendors that rise to the level to price gouging to maintain the interface that is the lifeblood of the flow of health information to and from the laboratory and ordering physicians. The inability to interface with the referring physicians' EHR creates roadblocks that are completely at odds with federal initiatives to expand EHR and interoperability, avoid duplicate services, further population health management, maintain competition, and a host of other objectives to reform the delivery system including most importantly, improving patient care.

Measuring and Assessing Quality of Health Care

As both a physician society and the worldwide leader in quality assurance, the CAP supports and is committed to efforts to improve the quality of care. Pathologists, by virtue of their capabilities and roles, and training intrinsically already coordinate care and execute many of the objectives and functions both public and private programs have aimed at increasing integration to improve patient care and the patient care experience overall. In addition, laboratory testing provides essential information that influences the delivery of health care and measurement of outcomes. The contributions of pathologists, though, have not been easily captured through current performance measurement reporting mechanisms and/or episodes of care.

The current Medicare Physician Quality Reporting System (PQRS) has made it exceedingly difficult to develop measures applicable to pathologists that fit its program design. Within the limitations of the current system, CAP has created five measures included in 2013 PQRS. CAP proposed three additional PQRS measures upon the request of the National Quality Forum that are now being considered for the 2015 PQRS. Given pathology's unique characteristics, many CAP members have no applicable measures in the current PQRS measure set. In particular, pathologists who sub-specialize in certain areas of pathology have no measures that apply to their subspecialties and therefore no mechanism to participate.

Pathologists' contributions, in many instances, apply to a patient population as a whole, but are not readily associated with an individual patient. Pathologists play a key role in patient safety particularly with testing protocols and accurate diagnosis. They are also integral to care coordination as key sources of information. This has presented an operational impediment under existing programs. The unique contribution to quality health care provided by pathologists may require a unique mechanism to measure them in the PQRS and other quality-based programs.

CAP has offered to work with the Centers for Medicaid and Medicare Services (CMS) to develop measures relevant to our specialty and to the patients we serve. These measures may be broader than just the individual physician and encompass the laboratories where the pathologists practice. They would also result in quality improvement by affecting not only pathology and laboratory medicine, but health systems, population health and patient safety.

Pathology/Laboratory Billing Transparency

The CAP supports public policies that require the disclosure to the patient or payer of actual charges for pathology and laboratory services when the charges for such services are not directly made by the provider of the service. This position is supported by the American Medical Association under its ethics policy (E-6.09) that calls upon physicians to furnish patients with the identity of the laboratory or physician providing the service and the actual amount charged for laboratory/pathology services when billed by a physician who has not supervised or performed the service.

Most recently, the CAP, in 2011, submitted comments to CMS, urging CMS to require in their federal rule making entitled the "*CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Report*," a requirement for all ordering clinicians to disclose to patients the identity of the laboratory providing services to the patient. CMS declined to mandate this disclosure in their final rule-making on this topic.

Disclosure of actual pathology/laboratory charges by physicians who order, but who do not perform or supervise these services will deter what the CAP considers to be financially exploitative and improper business practices whereby ordering physicians surreptitiously markup the actual cost of these services when billing patients or payers. Twenty-five states have outlawed this "markup billing" practice on certain pathology services as defined under state law. These 25 states are: Arizona, California, Colorado, Connecticut, Florida, Massachusetts, Michigan, Nevada, New Jersey, New York, Rhode Island, Louisiana, Ohio, Oregon, South Carolina, Tennessee, Illinois, Indiana, Iowa, Maryland, Montana, Kansas, Utah, Virginia, and Washington.

In addition to these 25 states, Delaware, Nebraska, North Carolina, Pennsylvania, Texas, and Vermont have all enacted laws that require physician disclosure to patients or payers of these markup practices included in the disclosure of the actual cost of pathology services when billed by ordering clinicians. These laws are: Del. C. 24 § 1769; R.R.S. Neb. § 38-2062; N.C. Gen. Stat. § 90-70; Pennsylvania 63 P.S. § 426.3; 24; Tex. Occ. Code § 166.002; 26 V.S.A. § 1354 (13).

However, in the remaining nineteen states this billing abuse can occur and is not required to be transparent to payers or patients through any state mandated disclosure requirement. In our view, the compelling public policy interest for the FTC is based upon the fact that patients in these 19 states may be subject to financially exploitative billing practices, conducted by physicians not involved in the performance or supervision of pathology/laboratory services; and that such markup practices are wholly surreptitious in nature and improperly and arbitrarily inflate the cost of these services.

Thank you for considering our comments. We greatly appreciate the opportunity to provide the Commission with input on health care competition as it has affected pathologists and their practicing in the broader health care delivery system particularly in the areas of professional regulation, electronic transactions, quality measurement, and transparency. If you have questions or need additional information, please contact Sharon L. West, J.D. at swest@cap.org.