May 31, 2011

Donald S. Clark
Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Submitted electronically via: https://ftcpublic.commentworks.com/ftc/acoenforcementpolicy

Re: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

Dear Secretary Clark :

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), representing community clinical laboratories, we welcome the opportunity to provide comments on the Federal Trade Commission (FTC) and Department of Justice (DOJ) proposed enforcement policy regarding the application of the antitrust laws to health care collaborations among otherwise independent providers and provider groups who are approved to participate as Accountable Care Organizations (ACO) under the Medicare Shared Savings Program.

AAB and NILA represent the owners, directors, supervisors, and technologists of independent, regional and community clinical laboratories who currently work in contract arrangements with physician practices, outpatient care settings, skilled nursing facilities, and home health care agencies. Given the focus and approach of the proposed statement of enforcement policy, we are concerned that the FTC and DOJ may not understand the importance of ensuring there is sufficient oversight in place to examine the implications of ACO arrangements on the broader health care market, including clinical laboratories. We are concerned there may be a false perception that this part of the medical care delivery system does not lend itself to competitive concerns, and that there may be a fundamental lack of understanding on the subsequent effect such arrangements could have on Medicare beneficiaries and commercially insured patients from anticompetitive harm in relation to these types of services. We do not believe the proposed statement of policy issued by the agencies addresses these issues, and submit the following background information and comments for consideration.

ACO Contracting Arrangements and Implications on Laboratories

There are a multitude of clinical laboratories in the market, ranging from large publicly-traded laboratories to hospital-based laboratories to physician-owned laboratories to independent regional and community laboratories. For approved ACO arrangements, in which either a hospital or the physician practice with which it joins have an in-house laboratory, there could be a

significant challenge for regional and community laboratories. If the ACO in this example opts not to contract out for any additional laboratory services, then regional and community laboratories will not have the opportunity to compete for business. This is of particular concern in rural and small communities where community laboratories already have a far more limited market in which to compete.

For hospitals that seek to enter joint venture ACO arrangements with large publicly-traded laboratories in an effort to quickly grow market share through those ACO arrangements, particularly in ACO arrangements that involve commercial payers, regional and community laboratories are concerned about the ability or opportunity to fairly compete for contract work.

For those hospitals and physician practices that form ACO arrangements and put out bids to contract for laboratory services, there must also be oversight to ensure fair competition for such services. ACO arrangements currently being considered by the government, including those that would permit the bundling of services, may provide a disadvantage to smaller laboratories who cannot then offer competitive bids to the ACO.

Medicare Market Share and Laboratory Services

The FTC and DOJ also need to consider the impact such contracting arrangements will have on patients, particularly Medicare beneficiaries – whether an ACO arrangement is focused on the Medicare fee-for-service population exclusively, or on both Medicare and patients served by commercial payers. The laboratory market is skewed when it comes to who predominantly cares for the Medicare population. While the two largest independent (publicly-traded) laboratories in the United States have approximately 63 percent of the independent laboratory market (based on total revenue, 2009 data), only 10-12 percent of those labs' business is Medicare Part B business. There are major segments of the laboratory market that are only served by regional and community laboratories, including those that serve a large number of vulnerable Medicare beneficiaries -- nursing homes and home health are leading examples.

Many regional and community laboratories are small businesses, currently receiving between 40-80 percent of their revenue through Medicare. This market allocation for laboratory services has remained consistent over time, as patients who are homebound or living in nursing homes are rarely ambulatory and cannot visit a physician's office or laboratory service center for routine, essential tests. This vulnerable population of Medicare beneficiaries relies upon the services provided by regional and community clinical laboratories with the ability and practice of deploying medical professionals to their place of residence to collect specimens and perform tests.

Potential Competitive Effects

One significant focus within antitrust statute is on predatory pricing in relation to pricing below average marginal cost. Oversight of pricing arrangements within any ACO structure that incorporates laboratory services is of critical importance. The need for this is demonstrated through a recently settled legal suit in California where Quest Diagnostics, the state's largest provider of medical lab testing, was alleged to have offered doctors, hospitals, and clinics deeply discounted prices for lab tests in return for referrals. Higher prices were allegedly charged to other payers, including Medi-Cal, the state's Medicaid program, in order to make up the difference. This situation was first identified by a community laboratory that claimed it was unable to

compete in the marketplace because of Quest's unfair business practices, including offering rates far lower than what the community lab was charging Medi-Cal based on the state's fee schedule. The community laboratory (*qui tam* plainfiff) found it could not compete in a significant sector of the marketplace where laboratories such as Quest offered doctors, hospitals, and clinics far lower rates than they were charging Medi-Cal. The community lab in this case believed it had no choice but to either offer the same discounted prices in order to be competitive, which were not sustainable to stay in business, or break the law. The settlement, announced on May 20, 2011, resulted in Quest returning $241 million to the state of California and the *qui tam* plaintiff.

In addition, in the commercial marketplace a number of large HMO's have entered into "sole-source" contracts with the two largest publicly-traded laboratories for clinical laboratory services, essentially blocking other independent laboratories from directly providing services to these HMOs. While HMOs are not fully developed ACOs, most possess many of the characteristics that ACOs will have.

Primary Service Area Analysis

The FTC and DOJ have outlined a way to determine whether an ACO is likely to raise competitive concerns by evaluating the ACO's share of services in each ACO participant's Primary Service Area (PSA). However, it seems that this analysis focuses exclusively on physician services. Given the issues raised earlier in these comments, we recommend that the FTC protect competition in relation to laboratory services by applying the same PSA share analysis of 30 percent, 31-50 percent, and greater than 50 percent for laboratory services. Thus, even if the ACO's joint PSA share is less than 30 percent, it should not be found to meet the safety zone criteria if the PSA share of laboratory (and possibly other ancillary) services is greater than 30 percent.

Similarly, the rules on not entering into exclusive arrangements with commercial payers should also apply to laboratory services. If a laboratory has an exclusive or preferred arrangement with a commercial payer, the ACO cannot enter into a contract with that laboratory because it would automatically cause the laboratory's PSA share to become anticompetitive.

Conclusion

The regional and community laboratories, which predominantly serve the needs of rural and small communities and of Medicare beneficiaries specifically, is very concerned about having antitrust and other oversight protections in place to ensure laboratories are not unfairly displaced through any ACO contracting arrangements. We represent viable competitors, but without proper oversight to address competitive effects around geographic market share and pricing, we are concerned that the result would be in fewer laboratory providers being able to remain in the market.

Sincerely,

Mark S. Birenbaum, Ph.D.
Administrator