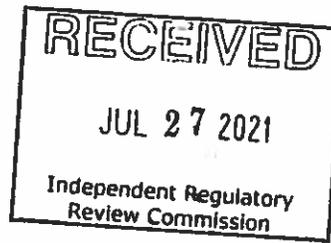


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July 26, 2021

Meg Snead
Acting Secretary
Pennsylvania Department of Human Services
625 Forster Street
Harrisburg, PA 17120

RE: Proposed Rulemaking concerning Interrelationships of Providers published July 26, 2021

Dear Secretary Snead,

On behalf of Quest Diagnostics, we appreciate the opportunity to offer comments in support of the proposed rule concerning Interrelationship of Providers. Quest Diagnostics is the world's leading provider of diagnostic information services and works with one in three adult Americans and half the physicians and hospitals in the United States annually. We are particularly proud of our presence in Pennsylvania, which includes over 2,600 employees, labs in Pittsburgh and Horsham, and 163 patient service centers. With our robust infrastructure in Pennsylvania, we service over 36,000 physicians, 156 hospitals, and handle over 46,000 Commonwealth patient specimens daily.

Further, Quest Diagnostics has been at the forefront of the response to COVID-19 in Pennsylvania since we launched our first laboratory-developed COVID-19 molecular test in March 2020. Since that time, our commitment to the state during the pandemic has never wavered, as we have already conducted statewide over 2.4 million viral PCR tests and approximately 105,000 serology tests to detect antibodies.

We applaud the Commonwealth's efforts to support more coordinated and integrated health care within Medical Assistance (MA) Programs. However, we are writing to respectfully request that the Department clarify that nothing contained in its proposed rulemaking concerning the interrelationship of providers shall be construed to override the important consumer protections contained in Act 122 of 2013.

Through the enactment of the Clinical Laboratory Act of 1951 and the adoption of anti-kickback rules in both the Public Welfare's Code (55 PA Code Section 1101.51 (Ongoing Responsibility of Providers)) and the Health Code (28 PA Code Section 5.71 (Restrictions on Solicitations)) as they pertain to in-state permitted clinical laboratories, Pennsylvania has long prohibited clinical laboratories from giving kickbacks and other forms of remuneration to physicians to induce specimen referrals. Specifically, PA laws, rules and regulations have prevented labs from placing specimen collectors in physicians' offices.

Act 122 of 2013 codifies the Department of Welfare's anti-kickback regulation in the Clinical Laboratory Act of 1951 to make it clear that regardless of whether the clinical lab is licensed by the Commonwealth state, another state or has a Clinical Laboratories Improvement Act license; absolutely no lab is permitted to engage in long held illegal conduct in this Commonwealth. Because Act 122 of 2013 expressly prohibits the placement of laboratory personnel—including phlebotomists, processors, laboratory staff, specimen collectors and other laboratory personnel in a provider's office, it is necessary to clarify that nothing contained in the proposed rulemaking could be construed to usurp any of the important consumer protections contained in Act 122 of 2013 in the context of MA Programs. as it pertains to MA programs.

Thank you for the opportunity to comment on the proposed regulation. Please do not hesitate to contact me at (201) 602-3993 or David.M.Reiner@questdiagnostics.com if you have any questions or require additional information.

Sincerely,

David M. Reiner

David M. Reiner
Sr. Director, State Government Affairs