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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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December 7, 2015

Dr. Patrick Conway
Deputy Administrator for Innovation and Quality
Chief Medical Officer
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Conway:

Thank you for appearing before the Subcommittee on Health on November 17, 2015, to testify at the hearing entitled "Examining the Regulation of Diagnostic Tests and Laboratory Operations."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 21, 2015. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to graham.pittman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Marsha Blackburn

1. Dr. Conway, rather than having an either/or approach to testing oversight, might there be another option?

2. The American College of Medical Genetics and Genomics has proposed a risk-based oversight system for regulation of genetic Laboratory Developed Tests which entails CLIA enhancement and uses a third-party review system for tests being offered. Since the majority of the work requiring scientific and medical genetic expertise would be performed by 3rd parties, if CMS were to implement such a model, how many additional FTE's would CMS/CLIA need?

The Honorable Michael C. Burgess

1. In a June 2006 GAO Report, the GAO indicated that the CLIA program "had a carryover balance of $70 million" as of September 30, 2005. Please detail for the Committee the current funding status of the CLIA program, including a breakdown of revenues (i.e. user fees or other appropriations) and outlays (i.e. detailing administrative outlays, salary outlays, and those outlays attributable to inspection activities, or other) in 2014, and whether the CLIA program still maintains a carryover balance.

2. Regarding CMS-conducted laboratory inspections under CLIA, please provide the following:
    a. The primary inspection objectives for an inspector;
    b. The number of CMS laboratory inspections conducted per year (not including those inspections conducted by deemed organizations); and
    c. The number of inspection findings by CMS per year that the agency would deem as "serious," that "create a probability of risk to patients," or that warrant the sanctioning or closure of a CLIA laboratory. Additionally provide a categorical breakdown of the types of such findings.

3. Dr. Conway's written statement indicates that "CMS does not have a scientific staff capable of determining whether a test is difficult to successfully carry out or likely to prove detrimental to a patient if carried out improperly." However, as CMS acknowledges on CMS.gov, "[t]he objective of the CLIA program is to ensure quality laboratory testing." How does CMS accomplish this mission without the ability to determine whether a test is difficult to carry out or likely to harm a patient?

4. During the hearing, Dr. Conway indicated that seven organizations are currently deemed authorities under CLIA. Please provide the following:
    a. The names of each of the deemed authorities;
    b. The number of inspectors fielded by each organization as compared to CMS;
    c. The types of expertise and qualifications of the inspectors of each organization as compared to inspectors fielded by CMS;

d. The number of laboratory inspections per year, per organization as compared to CMS; and
e. A description of how inspections by a deemed organization may differ from an inspection conducted by CMS.

5. CMS materials indicate that the States of New York and Washington have "CMS approved laboratory program(s)." Please provide the following:
   a. Describe the difference in these state laboratory programs from those under CLIA.
   b. Further, the Committee understands New York State also inspects laboratories that are not located in New York State but provide services on patient samples originating in New York. How do these inspections and policies differ and intersect with CMS CLIA operations?

6. On April 16, 2015, the FDA and CMS announced the formation of the "Task Force on LDT Quality Requirements." Please provide the following:
   a. The scope of the Task Force's work;
   b. When findings or conclusions of the Task Force will be made public and, if not to be made public, the rationale for not making public;
   c. The anticipated time period the Task Force is expected to operate; and
   d. The extent to which the Task Force is coordinating with industry, and/or provider, and/or patient stakeholders.