**Michael E. Prevoznik**
Senior Vice President & General Counsel

February 16, 2018

Chairman Orrin Hatch
Ranking Member Ron Wyden
U.S. Senate Committee on Finance
219 Dirksen Office Building
Washington, D.C. 20510

Dear Chairman Hatch and Ranking Member Wyden:

Quest diagnostics appreciates the Senate Finance Committee's letter dated February 2, 2018 expressing its interest in ensuring that the Medicare and Medicaid programs can assist in combatting the opioid epidemic and provide beneficiaries with appropriate care. We appreciate the opportunity to submit comments.

Quest Diagnostics is the nation's leading provider of diagnostic information, and we manage the largest database of de-identified clinical laboratory data - 40 billion test results, with annual increases of 3 billion tests results. We partner with the Centers for Disease Control and Prevention (CDC) on a variety of projects to help shape public health policy for the good of all citizens. Approximately 70 percent of clinical decisions are based on diagnostic tests. Quest Diagnostics is in a unique position to assist policymakers in their effort to provide workable, cost-effective approaches to combatting the opioid epidemic, so that our communities and families no longer suffer from the devastation far too many Americans have experienced.

Most recent policy initiatives have focused on limiting the number of pills prescribed, decreasing the number of prescriptions actually written and developing or enhancing state prescription drug monitoring programs (PDMPs). Efforts to decrease opioid prescriptions have shown successes, but it is not enough - 2016 drug overdose deaths spiraled upward to an all-time high. It is clear that while these efforts are worthwhile and provide additional tools to combat opioid abuse, they have focused primarily on prescribing patterns. It is critically important that healthcare providers have accurate, comprehensive, objective information to manage the millions of patients who are appropriately prescribed opioids. *For a health surveillance program to be effective, it is important to understand not only prescribing patterns, but how patterns relate to actual patient drug use.*

- In 2016, the CDC released guideline recommendations concerning the prescribing of opioids and that providers use baseline urine drug testing before starting opioid therapy and appropriate follow up testing to assess use of prescribed drugs and non-use of non-prescribed or illicit drugs. The U.S. Department of Veterans Affairs and the U.S. Department of Defense have created similar evidence-based guidelines that also include baseline drug testing and periodic follow up testing. Most recently, the President's Commission on Combating Drug Addiction and the Opioid Crisis recognized the value of drug testing in helping providers assess the individual patient and as an aid in providing insight into drugs available in the larger community.



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- Quest Diagnostics supports the use of baseline testing and follow up testing as an additional risk assessment tool to assist providers in determining whether opioid therapy is appropriate for patients. While Quest Diagnostics fully supports the use of state PDMP prescribing information and additional data sharing to document the patient's prescribing history, only drug testing provides the objective information for what drugs the patient is actually taking at that moment or how well a patient may have adhered to the prescription. Put simply, drug testing information along with information from state-based prescription databases provides a more current, comprehensive picture of a patient's prescription drug and treatment history.

**Question 1: How can Medicare and Medicaid Payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimize the risk of developing Opioid Use Disorder (OUD) or other Substance Use Disorders (SUDs)?**

Medicare and Medicaid payment incentives should be used to support the implementation of evidenced based guidelines for prescribing opioids for chronic pain patients, including baseline and periodic follow-up drug testing as described in the CDC guidelines. As a trusted source of objective information, drug testing can significantly minimize the risk of developing OUD and SUD.

A. Drug Testing As an Objective Source of Information for Risk Assessment

Drug use and non-use information provides a unique insight into the breadth and depth of the ongoing opioid epidemic. Quest Diagnostics Health Trends reports track health conditions affecting a large number of Americans, and our 2017 Prescription Drug Monitoring Health Trends report[1] reveals continued drug use trends that are troubling, including:

- >50% of drug tests are inconsistent with drugs prescribed;
- 36% of inconsistent results are drugs not prescribed;
- dangerous drug combinations occur, both prescribed and non-prescribed; and
- all age groups, genders and health plan payer types are at risk for misuse.

Healthcare providers need to be aware of potentially dangerous drug interactions that occur beyond the prescription level. To understand the relationship between drugs prescribed and combinations of drugs actually used, we performed a study for the two drug classes that contribute to the rising overdose death rates - opioids and benzodiazepines. Both classes can depress breathing and combined use of these drugs can be dangerous and potentially fatal.

We believe our study published in the November 2017 issue of The Journal of Addition Medicine (JAM),[2] the official peer reviewed publication of the American Society of Addiction Medicine, is the first national examination of concurrent use of opioids and benzodiazepines based on both prescribing information *and* drug testing. Prior analysis of concurrent use of these drugs focused on prescribing information only and therefore did not identify situations where patients may

[1] To access the study, and view an interactive depiction of misuse trends by state, visit QuestPDM.com. A more detailed summary of this Study, as well as other Health Trends studies leveraging Quest Diagnostics database of 40 billion de-identified data points, is contained in Section III.

[2] See https://journals.lww.com/journaladdictionmedicine/fulltext/2017/12000/Concurrent_Use_of_Opioids_and_Benzodiazepines__.3.aspx

not have used their prescribed drugs or patients may have used non-prescribed drugs. *Our study results Jar exceeded previous estimates of the rate at which opioids and benzodiazepines were combined based on prescription drug monitoring databases alone. This suggests that prescription drug monitoring databases and monitoring programs do not fully reflect the extent to which individuals combine these drug classes in the United States.*

The key findings of our 48 state study of 231,000 prescription drug monitoring drug tests from 144,000 patients (prescribed at least one drug and co-tested for opioids and benzodiazepines) include:

- Prescribing information submitted with test requests indicated 11.2% of patients were concurrently *prescribed* both opioids and benzodiazepines (this compares favorably with 9.6 percent concurrent opioid and benzodiazepines prescribing patterns reported in a previous analysis of millions of patients filling prescriptions for both drug classes); but
- 25.8% of drug test results were positive for concurrent *use* of opioids and benzodiazepines.

Therefore, PDMP prescribing data alone will greatly underestimate the extent to which patients combine prescribed and non-prescribed drugs that may have dangerous consequences.

While some patients may be appropriately prescribed both opioids and benzodiazepines, the Quest Diagnostics study results of concurrent use of opioids and benzodiazepines are a significant public health warning because more than 30 percent of opioid-related deaths also involved benzodiazepines, according to the CDC. It is no surprise that, in August 2016, the FDA issued a "boxed warning" of prescription opioids and benzodiazepines that alerted prescribers to the dangers of concurrent drug use.

Thus, drug testing enhances patient safety by:

- alerting providers that a patient may not be taking prescribed medication(s) and may be a possible diversion risk;
- augmenting existing subjective tools (e.g. patient medical history, risk assessment, etc.) that providers use to determine patient risk for drug use;
- supporting the observation that patient self-reporting of drug use has limited validity in that it can fail to detect drug use problems that are revealed by drug testing;
- assisting healthcare providers with making evidence-based decisions prior to and throughout treatment, including whether to choose non-opioid therapy or opioid therapy and referral for OUD or SUD treatment; and,
- helping to maintain the healthcare provider-patient relationship and trust by de-stigmatizing "drug testing" through mandatory drug-testing.

B. CDC Guideline Concerning Drug Testing and State Adoption

We are working to encourage all states to adopt drug testing guidelines similar to the CDC opioid prescribing recommendations for baseline and appropriate periodic follow up testing. PDMP prescribing data is an important tool but cannot detect actual drug use.

Recommendation 10 of the 'CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016' requires drug testing as a component for Assessing Risk and Addressing Harms of Opioid Use. Incorporating drug tests into patient management can lead to earlier clinical

interventions when clinicians are able to detect initial/early prescription misuse, potential drug diversion, dangerous drug combinations, and patients progressing to using illicit drugs. The specific guidance issued by the CDC states:

> [W]hen prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

The President's Commission on Combatting Drug Addiction and the Opioid Crisis also acknowledged the importance of drug testing, noting in its report:

> While progress has been made in training prescribers and fostering the adoption of prescribing guidelines such as the CDC guideline, the Commission has learned that not all states have adopted the guideline, not all physicians are aware of them, and sound opioid prescribing guidelines are far from universally followed. For example, while the CDC guideline, as well as guidelines from the VA and the Department of Defense (DOD), recommend clinicians use baseline and periodic urine testing as part of a comprehensive plan to ensure the safe and effective use of opioid therapies, not all states have placed sufficient emphasis upon the utility of medication screenings. In the current crisis, drug testing not only allows providers to assess proper use of prescribed medications in individual patients, but it would also be part of a broader solution in fighting the opioid crisis, as it can provide a snapshot of controlled prescription drugs and illicit drugs available in a community. (p49)

States are also recognizing the importance of drug testing, and have approached this issue in different ways. Some like Oregon have adopted the CDC guideline (with the addition of Oregon-specific issues). The Commonwealth of Virginia has, through regulation, created stricter standards than the CDC guideline for baseline and follow-up testing.

According to a survey of state Medicaid Directors by the Kaiser Family Foundation, Medicaid programs have begun to adopt the guideline for parts of their Medicaid populations. However, even if states have adopted the guideline there is no available information to know that they are being implemented. See https://www.kff.org/other/state-indicator/states-reporting-adoption-of-the-cdc-opioid-prescribing-guideline/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D

C. Medicare Payment for Services

Your committee must ensure appropriate Medicare and Medicaid payment for testing OUD and SUD risk-relevant patients for use of prescribed drugs and non-use of non-prescribed or illicit drugs. Drug testing provides the only objective tool that providers can use to evaluate actual drug use.

However, pursuant to the Protecting Access to Medicare Act of 2014 ("PAMA"), CMS promulgated revised reimbursement schedules for clinical laboratory testing services provided under Medicare for 2018, 2019 and 2020. Under the revised Medicare Clinical Laboratory Fee Schedule, reimbursement for clinical laboratory testing is scheduled to be reduced by up to 30% over the 2018-2020 time period. PAMA calls for further revision of the Medicare Clinical

Laboratory Fee Schedule for years after 2020, based on future surveys of market rates; further reduction in reimbursement may result from such revisions. In addition, Medicaid rates tied to PAMA will also accordingly decline.

Unfortunately, these cuts are exacerbated because CMS failed to follow a Congressional directive to implement a market-based laboratory payment system. Although Congress directed CMS to conduct a market-based refresh of the Medicare Clinical Laboratory Fee Schedule (CLFS) under PAMA, the sample of data CMS collected to inform the refresh was grossly flawed and was from less than 1% of the laboratories paid under the CLFS. CMS excluded almost all hospital outreach laboratories and most physician office laboratories in the survey. This flawed approach resulted in grossly inaccurate and lower rates in the new CLFS which are not market-based. Although the Congressional Budget Office (CBO) scored Medicare program spending reductions to clinical laboratories under PAMA at $1.0B over the first 3 years of implementation, the rates that CMS published in late 2017 will reduce reimbursement to clinical laboratories by a staggering $3.6B.

As a result of PAMA, smaller laboratories that serve rural and more expensive settings, such as nursing homes, will be forced to reduce service or exit the laboratory market altogether. These laboratories simply will not be able to sustain these drastic reimbursement reductions. These reimbursement cuts will threaten access to critical laboratory services for the most vulnerable Medicare and Medicaid beneficiaries as implementation plays out over the next several years. Moreover, they come at a time when the critical information that laboratory testing provides in the fight against the opioid epidemic is needed the most.

CMS needs to fix PAMA to properly follow the Congressional intent. This will help ensure Medicare and Medicaid provide appropriate reimbursement for drug testing provided in conformance with the CDC Guidelines to minimize the risk of patients developing OUD or SUD.

D. Implementing Use of the Guidelines Within Medicare and Medicaid

In addition to ensuring adequate payment for drug testing, the Medicare and Medicaid programs should encourage implementation of the CDC recommendation concerning drug testing for chronic care patients.

Medicare Advantage plans should be required to ensure providers are following the CDC opioid prescribing guideline. The most recent call letter promotes this concept, but making it a requirement in statute to require Medicare Advantage plans to ensure, when appropriate, the CDC recommendations are followed - or that state laws that exceed the CDC guideline are followed - would assist Medicare patients in having the same evidenced-based care as other patients. Creating a quality incentive for physicians to follow the guidelines would assist in applying the guideline to fee for service patients as well.

Medicaid 1115 waivers also offer an opportunity to ensure access to appropriate drug testing as the CDC recommends and that Medicaid funds are used in a cost effective manner to combat opioid misuse. As states seek Medicaid waivers to increase treatment capacity or for other approaches to the opioid epidemic in their state, CMS should be required to provide guidance to ensure that drug testing following the CDC guideline is included. This would assist in the rapid adoption of the guideline.

**Question 6. What can be done to improve data sharing and coordination between Medicare, Medicaid and state initiatives such as the prescription drug monitoring programs?**

Quest Diagnostics wholeheartedly supports the development of state-based prescription drug monitoring programs (PDMPs) and supports expanding data sharing among the state programs. Private sector data can augment POMP information and assist CMS and state Medicaid programs to more rapidly and timely identify changes in the epidemic as it evolves, including local and regional changes. Our data can be tailored to assist federal health programs so they can assist in staying ahead of the problems.

Our Health Trends™ research derives clinically significant public health insights that enable policy makers and health care practitioners to take information-based actions that improve the health care of Americans. Quest Health Trends studies have been published in peer- reviewed medical journals as well as by the company as a public service. These expansive reports cover wide ranges of medical conditions including diabetes, kidney and heart disease, lead poisoning and drug use. The Quest Drug Testing Index has been utilized by government employers and policy makers for more than 29 years. For the past six years, Quest Diagnostics has published the annual Prescription Drug Monitoring Report as an industry update of more than 3,000,000 drug test results that are focused on the clinicians who prescribe controlled medications and monitor patients for compliance.

We would be happy to partner with Congress and CMS and use our data to assist them in identifying trends as needed to ensure the Medicare and Medicaid populations benefit from early identification of how this epidemic evolves.

Quest Diagnostics looks forward to working with you to find cost effective ways Medicare and Medicaid can prevent patients from opioid misuse and address those who have unfortunately become addicted.

Sincerely,

Michael E. Prevoznik
Senior Vice President and General Counsel