July 26, 2013

Palmetto GBA Part B - J1 MAC
P.O. Box 1252
Augusta, GA 30903-1252

Subject: IOM 100-04, Ch16, § 10

Dear Dr. Jeter:

The American Academy of Pain Medicine (AAPM) and the American Association for Clinical Chemistry (AACC) strongly object to your recent decision to stop reimbursing for specimen validity testing (SVT). We believe the rationale for this decision, namely "the results of this testing are not used in the management of the beneficiary's medical problem," is inaccurate and, if implemented, could jeopardize patient care. Ensuring that patient samples are unadulterated provides the physician with vital information for making timely, accurate and cost-effective decisions impacting patient care.

The provision of pain management is a vital medical principle, and opioids are a necessary component to relieve pain in select patients (Noble *et al*. 2010). At the same time, the prescribing of opioids presents concerns for public health via diversion to nonmedical use, misuse by patients, and rising numbers of pharmaceutical overdose deaths (Jones 2012, Ives *et al.* 2006, Jones *et al*. 2010). Therapeutic success depends, in part, on precise patient adherence to the treatment regimen; however, research shows frequent discrepancies in this area (Michna *et al.* 2007). Additionally, physicians who prescribe are frequent targets for people who seek opioids to use illegally, and deception is often difficult to detect (Jung & Reidenberg 2007). As a result, each prescriber bears a responsibility to do everything possible to ensure opioids are used only as directed and only by the patients for whom they are prescribed.

Urine drug testing (UDT) is one of the tools used to monitor appropriate compliance with a treatment plan that includes controlled substances. UDT, used in conjunction with other monitoring measures, plays an important role in helping providers accomplish therapeutic success and reduction of societal harm. SVT provides additional information which can assist a physician who is trying to interpret urinary drug concentrations or UDT results. For example, excessive fluid intake can substantially dilute urinary drug concentrations and result in false-negative immunoassay screening results. Therefore, pain management programs use SVT results to correctly determine the legitimacy of the original UDT result. The SVT results (i.e. specific gravity and/or creatinine) can also be used to normalize the drug/metabolite concentrations in urine (Cone *et al.* 2009).

UDT plays a very important role in the management of pain patients. In fact, several clinical practice guidelines (American Society of Interventional Pain Physicians 2012, American Academy of Pain Medicine 2013, Veteran's Administration/ Department of Defense 2010) currently recommend UDTs for pain management patients to decrease prescription drug abuse or illicit drug use. UDT results are used to verify compliance/adherence to prescribed therapy, identify the use of undisclosed drugs, discourage drug misuse, and identify patients with abuse/addiction problems. The correct interpretation of UDTs mediated by SVT is important since the UDT results are ultimately used to manage the patients' medical care and pain treatment plan.

Urine testing is used because of ease of collection, the window of metabolite presence, speed of turn-around, and accessibility of laboratories that provide the testing. Other specimen samples are possible, but are not universally available. However, compared to saliva, hair or sweat testing, urine is the easiest to adulterate or substitute. Observed urine collection improves accuracy but is still not one hundred percent free of error. In addition, observed urine collection requires time and personnel that are not available in a busy clinic. Thus, the clinician depends on SVT by the lab to determine the legitimacy of the sample. Marketing of products and ways to "beat a drug test" continues to grow. In September 2002, a Google search on that phrase yielded 158,000 hits while in July 2012 the same search yields over 55,200,000 results in 0.3 seconds (Bush 2008; current Google search performed July 10, 2013)

The importance of SVT has also been emphasized in the current "Mandatory Guidelines for Federal Workplace Drug Testing Programs" which was most recently revised on April 13, 2004 and requires specific urine specimen validity tests. The Federal Workplace Drug Testing Program Guidelines were updated to include SVT because there are numerous ways which have been advertised and become available to the general public to mask drugs present in a urine sample. The new Federal guidelines state that laboratory's must:

a. Determine the creatinine concentration on every specimen,
b. Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL,
c. Determine the pH on every specimen,
d. Perform one or more validity tests for oxidizing adulterants on every specimen,
e. Perform additional validity tests when the following conditions are observed: 1) abnormal physical characteristics, 2) reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (i.e. non-recovery of internal standards, unusual response), or 3) possible unidentified interfering substance or adulterant.

In conclusion, SVT is a critical component of UDT and is necessary for appropriate interpretation of UDT results. Failing to reimburse for SVT effectively invalidates UDT as a monitoring tool for safe opioid prescribing. The lack of SVT will severely limit the ability to safely prescribe opioids and other medications for higher risk patients, those for whom the monitoring is most crucial. The American Academy of Pain Medicine and the American Association for Clinical Chemistry strongly encourage Palmetto to reconsider their decision regarding reimbursement for SVT so that pain medicine physicians can continue to provide the safest care possible for their patients.

Respectfully,

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President, American Academy of Pain Medicine

Robert Christenson, PhD, DABCC, FACB
President, American Association for Clinical Chemistry

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