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March 10, 2014

Bernice Hecker, M.D. Noridian Healthcare Solutions, LLC JE Part B Contractor Medical Director/s Attention: Draft LCD Comments P.O. Box 6783 Fargo, ND 58108-6783 policyb.drafts@noridian.com

## Re: DRAFT POLICY DL 34692 (LCD for Drugs of Abuse Testing)

Dear Dr. Hecker,

I am writing on behalf of the National Fibromyalgia & Chronic Pain Association in representation of our patient member constituents, many of whom are the victims of the "war on opioids," more specifically the many who have suffered at the hands of prescribing clinicians who more often than not, lack the necessary skills to interpret urine drug tests (UDTs) or who are prohibited from performing definitive testing.

The National Fibromyalgia & Chronic Pain Association recognizes that any advocacy for inconvenient urine or blood testing by our organization could create some misunderstanding among our constituents; however, we are also wise enough to comprehend that with good medicine comes appropriate monitoring (cholesterol panels, HgA1c, INR, UDT).

As we understand it, your policy does not advocate, and precludes payment for, specimen validity testing (SVT). While our organization does not pretend to have the scientific nor medical expertise to dispute these policies, we are aware that several clinicians and scientists throughout the United States and Canada have questioned your integrity on this decision as it seems to be skewed towards financial incentive rather than the best interest of our constituent affiliates and patients, and chronic pain patients as a whole. It is especially bothersome that you oppose payment to clinical laboratories for more accurate testing because of "unnecessary" costs; yet the costs to patients and society at large are wholly ignored.

While laboratory companies and third-party payers are busy bickering in the background, the patient voice is largely ignored. It is unconscionable that large health insurance companies profit from "patient care" but flout the very people who are the bane of their existence. How is it that a non-scientific, non-medical group such as ours can understand the negative impact and implications of non-definitive urine testing yet you cannot? We don't believe that to be the case; however, we do believe it is totally profit driven and selfish insofar as it will contribute to patient harm and maximize your profits. Furthermore, information access has made it less easy to assume patient ignorance at the hands of venal corporate revenue.

As we understand it, many clinical thought leaders, professional peer reviewed journals and resources recommend UDTs for an initial differential diagnosis regarding drug compliance, but they also concede that there is a large potential for false negative and/or false positive results in the absence of confirmatory testing by

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chromatography. While the dearth of definitive testing serves to vilify honest patients, allowing such tests serves to ratify their compliance. In either case, we acknowledge that UDTs are a part of the lives for chronic pain sufferers requiring treatment with controlled substances, and we are willing to live with that in support of clinician liability, public safety, and verified patient integrity.

The UDT does not definitively identify which drugs a patient has ingested, nor does it mitigate against haphazard sedative-hypnotic usage, keep patients safe from overdose, nor elucidate drug interaction risks. We want to pay for a test that returns useful information on which clinicians can rely for improved patient care and safety. Overriding a clinician's judgment for requesting UDT confirmatory testing by a third-party payer falls outside the scope of that payer, is unacceptable, and dangerous.

As a group, we believe the in-office immune assay (IA) urine drug test is outdated and can be manipulated for the benefit of illicit access to opioid medications, which ultimately has and continues to instigate harm for legitimate chronic pain patients. It doesn't take a Rhode Scholar to surf the Internet and find various paraphernalia specifically designed to beat these IA tests. Legitimate chronic pain patients are so afraid of losing their access to healthcare, they generally will comply with anything, and they don't understand many of the healthcare policies thrust upon them except whether or not their insurance will pay for a benefit. Moreover, inaccurate office tests that are misinterpreted are sometimes used by clinicians to oust honest patients who are otherwise labeled as "high maintenance," a characteristic often attributed to our fibromyalgia constituents because of comorbid depression, anxiety, sleep disorders, and inflammatory bowel syndrome.

In addiction medicine, patients receive more supportive attention when they have a positive UDT in terms of acknowledging the need for more help, generating a referral to behavior health, etc. What does the pain patient receive when a UDT yields an unexpected result? ... based on your policy, a discriminating kick to the curb!

It's time to stop the stigmatization of chronic pain patients and fairly assess criminality among chronic opioid users without hurting honest patients and frightening caregivers. Basically, you are encouraging clinicians to use an outdated model aligned with the judicial system which was designed to test for drugs of abuse, not the clinical testing necessary for treating legitimate patients. The sacrosanct clinician-patient relationships has been all but lost with the "opioid epidemic," and it is truly disheartening to those who are living in daily fear of losing assess to the very medications that allow some semblance of normalcy and function.

As a group we respectively request, and in fact plead with you, to take the responsible approach for UDT as outlined above. Help preserve this necessary component of healing and health by providing accurate and datadriven drug monitoring with definitive analyses that support the patient-doctor relationship rather than forcing a wedge between honest caregivers and patients.

Respectfully submitted,

hambers

Jan Favero Chambers, President & Founder National Fibromyalgia & Chronic Pain Association