

From: Leon Margolin <md@cpmiohio.com>

Sent: Monday, November 8, 2021 1:23 PM

To: Tierra Davis

Cc: Dave Merrill; Doug Merriman; Brian Thompson; Stacy Hanson; Glenn Prager; Jason Zurn; Robin Rogers

Subject: [External]

Dear Tierra,

I would like to formalize our discussion today in writing.

You call me today to provide the password for the CD attached to the CoventBridge letter and discuss the letter and my concerns.

You mentioned that the review was performed by a RN and not a physician (you did not disclose the name of the RN).

I explained that RN cannot legally make clinical recommendations on issues related to prescriptions of opioid substances based on federal and state laws. The recommendations made are in violation of the federal and state laws and regulations as described below and the Medicare integrity manual and cannot be implemented.

There are several additional violations we can prove.

Thank you for agreeing that the review process must be compliant with the Medicare integrity manual and understanding that until such compliance is established (like in the case of you letter your agency sent) the finding must be used until the validity and compliance with the federal and state laws and regulations as described below and Medicare integrity manual is established.

Thank you for committing to transfer these concerns to your legal department and promising a response.

Initial review of the attached letter shows that the opioid prescribing and distribution of the dangerous substances as per the attached license (Based on Ohio HB 93 law and SMBO and Ohio State Board of Pharmacy (BoPh) regulations), which is the main clinical service of our program was not mentioned by the reviewer even once.

Nor was mentioned NARX score review, nor the review of the original OARRS report review (Ohio state prescription monitoring report – individually obtained and reviewed for each patient and encounter), nor the Urine drug screen reviews, nor Flowchart of the SMBO Ohio Administrative Rule 4731-21-02; all those are the individual assessment for each patient encounter provided as part of the records. All these and other essential components were ignored by the auditor for all the encounters reviewed and are not mentioned in the letter.

It seems to us that the auditor had no knowledge or understanding of the clinical nature of the service we provide and the applicable state and federal regulations (HB-93, PMC cat. 3 regulations, SMBO OAR-4731-21-02 requirements, SMBO and BoPh, HHS, DEA, and CDC guidelines as above), therefore the recommendations of the auditor may not be compliant with the state and federal laws and regulations and create a serious patient safety concern.

For example, auditor labeled all the office visits as “medically not necessary”, since notes allegedly “did not indicate “new issues and problems” (page 4 and many other times in the letter). The auditor had no knowledge that the purpose of the visits is SBIRT compliance with the opioid prescribing and issuing new prescriptions (these are chronic pain patients). The auditor ignored the “new issues and problems” (individual review of the urine drug screen results, OARRS reports new medication prescriptions etc, and other parts of the records. We have more than 20 page note with 4-6 SAOPP pages and multiple individual evaluations for each patient for each visit (additional pages are part of the SBIRT monitoring and education and not “cloning”).

The auditor seems to advise us to avoid such visits and assessments or make them complementary to the procedures. This recommendation would violate the state and federal guidelines for opioid prescription and based on legal precedents in the state of Ohio and nationwide might be seen as criminal liability for a provider.

We humbly request an urgent review of this matter to avoid patient and staff safety concerns and significant legal liability.

As part of the compliance policy, we will have to add the auditor’s recommendations as specified in the attached letter and our response to patient charts and the office compliance policy and make it available to the regulatory, legal authorities, and coronary offices upon request.

The auditor blindly accused us on allegedly “cloning” “photocopying” all the documents, claiming that she had nothing but our word that the individual assessment was performed. There is nothing further from the truth. The OARRS (Ohio PMD) report has a patient-specific date and patient-specific data (data verified by the state), the urine screen reports were provided by the big national lab company (Aegis), the individual prescriptions can be verified by the pharmacy staff, cases were discussed with outside specialists, the assessments and the flowcharts are individualized signed by the patients and could not have been copied.

In addition, the auditor made multiple comments about the pain management procedures that indicate a lack of understanding that the procedures were done is an alternative and addendum to the chronic opioid medication use in accordance with the state and federal guidelines. I would like to emphasize that the Ohio PMC category three license certification (attached) requires the use of such procedures for this indication. Many Medicare and Medicaid HMO have online guidelines allowing 8 to 10 trigger point and other similar procedures a year.

I think it is important for everyone to understand the background of our office. We are in the "trenches" and at the forefront of the opioid epidemic fight (please see our publications and presentations on the website below). Our assessment is that over the last 10 years we have

identified and referred to addiction treatment close to 2000 individuals who otherwise could have been still abusing drugs today. The danger of defunding such services cannot be overestimated, it can lead to overdose morbidity and mortality. I arranged a few slides separately to demonstrate the real-life challenges we face.

As you know, our treatment protocols were endorsed by the national academy (AAPMR), several independent experts, and published in a peer-reviewed journal in cooperation with one of the top hospitals:

<https://cpmiohio.com/wp-content/uploads/2021/02/the-final-opioid-screening-article.x69810.pdf>
<https://cpmiohio.com/resources/>

In a sense, we are at the forefront of the “opioid epidemic” and COVID-19 fight. It is my duty to speak up for the patients and advocate for their safety. The threat of inappropriate denial of services is putting up hundreds of patients in danger of withdrawal and potential narcotic substance misuse and as well as the risk of COVID 19. This is especially concerning since most of our patients and staff is minorities and racial bias and disparity in healthcare are widely discussed and acknowledged (please find some patients' testimonials attached to the email).

Respectfully,

Dr. Margolin