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From: **Leon Margolin** <leon3087@gmail.com>
Date: Sat, Feb 10, 2024 at 9:22 PM
Subject: Request for clarification/conflict with the HB-93 law; PMC c3; OAR-4731-21-02; OAC 4731-11-14(F)-(G)
To: <Whitney.Shaver@coventbridge.com>, Meghan Duvall <Meghan.Duvall@us.coventbridge.com>
Cc: Jessica Gustafson <JGustafson@thehlp.com>

Dear Whitney and Mrs. Duvall,

I would like to formalize our phone discussion with Whitney in writing and request clarification for your educational letter attached.

The educational recommendations of your letter can not be implemented since they contradict 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.

Ohio law explicitly requires frequent monitoring of opioid patients (*See e.g.*, OAC 4731-11-14(F)-(G)), which creates a catch-22 with the CoventBridge position.

Your letter mistakenly labeled most of our services as “medically unnecessary” while multiple state of Ohio mandatory audits clearly designate these services and records as mandatory and appropriate (please see the self-audit report below):
chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://cpmiohio.com/wp-content/uploads/2020/12/Self-Audit-report-Mike-Staples.x38675.pdf

The recommendations made in the letter violate the federal and state laws and regulations as described above and therefore acting on them or creating a demand letter would be not compliant with the the Medicare integrity manual and cannot be implemented

There is additional clear evidence that the auditor did not have a basic understanding of the services provided (for example types of ultrasound utilized and types of different urine screens in the pain management, the purpose of the visits, and the assessments) and therefore misapplied the local coverage determination and other regulations. For example, failure of the auditor to differentiate between the diagnostic ultrasound and the image guidance ultrasound (that we use) resulted in the mistaken conclusions in the letter.

As I mentioned in my letter in November 2021:

“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, 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, or the 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…

The auditor blindly accused us of allegedly “cloning” and “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.”

Most of the other concerns raised in the 2021 letter are still applicable to the new letter we have received.

Ms. Duvall promised to review these concerns, hover we never got a response.

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.

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). We assess 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), and 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" fight. It is my ethical 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. This is especially concerning since most of our patients and staff are minorities and racial bias and disparity in healthcare are widely discussed and acknowledged (please find some patients' testimonials attached to the email).

The CoventBridge position has devastating effects on pain specialists in Ohio, essentially handcuffing them from appropriately practicing pain management.

We have evidence of approximately 200+ patient complaints submitted by Ohio patients to Medicaid insurers regarding the lack of access to vital pain management services.

The CoventBridge policy has far-reaching implications, including a negative impact on opioid-related death and crime rates. While these are nationwide issues, Ohio is a key focal point of the opioid epidemic, with one of the highest death rates for years in the U.S. due to drug overdose. (https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm), Ohio experienced a 22% increase in drug-related overdoses. (https://ohiocapitaljournal.com/2021/07/15/new-data-fatal-overdoses-leapt-22-in-ohio-last-year/). Ohio-based pain medicine practices have also experienced increased criminal activity from drug-seeking patients, including property destruction, attempted break-ins, and assaults on staff. Many drug-seeking patients are lashing out due to lack of access to appropriate pain management services.

So long as CoventBridge and other insurers continue to target pain specialists by limiting their ability to provide medically necessary services to pain patients, the opioid-related death and crime rate will continue to rise, and our society will continue to face negative implications from the opioid epidemic. For example, every branch of the U.S. military has announced record-low recruitment this year due, in part, to the opioid epidemic. (*See* https://www.nbcnews.com/news/military/every-branch-us-military-struggling-meet-2022-recruiting-goals-officia-rcna35078

Respectfully,

Dr. Margolin