

ЧТ, 17 ОКТ. 2019 г. В 05:52, Wilson, Christopher G. (CIV)
<Christopher.G.Wilson@usdoj.gov>:

Thank you Dr. Margolin. As you are represented by counsel, I'll respond through your attorneys.

CW

From: Leon Margolin <leon3087@gmail.com>

Sent: Thursday, October 17, 2019 7:56 AM

To: Wilson, Christopher G. (CIV) <chriwils@CIV.USDOJ.GOV>

Cc: Crites, Michael <michael.crites@dinsmore.com>; XXXXXXXXXX

Subject: Fwd: 2 additional expert reports/patient safety concern

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Comprehensive Pain Management Institute, LLC

Medical and Interventional Pain Management

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10/18/19

Attn: Christopher G. Wilson Esq.

By e mail: Christopher.G.Wilson@usdoj.gov

Dear Mr. Wilson,

Please find two additional expert letters attached. As we discussed during my PowerPoint presentation we have been fully compliant with the CID procedures, we have produced more than 35,000 documents and prepared a detailed PowerPoint presentation and we want to confirm our commitment of compliance in the future.

Our practice representative contacted AANEM and received a written clarification from Millie Sulk, JD, MPP, AANEM Health Policy Director stating that "AANEM does not have any "best practices" established for pain management" and that AANEM endorses AAPMR policies.

We provided a detailed study ABPMR (certifying body of AAPMR) that analyzed all the CID charts, provided a clear scientific proof of medical necessity and showed our full compliance with the state and national guidelines. This study was validated by the top experts in the field (Professor Kimura and Professor Wainepal).

We also provided independent certified billing and coding expert reviews (2012-2015) that confirm compliance of our billing practices.

In addition, I attached to this letter the expert report from Dr. William Vasilakis PhD who is a clinical pain psychologist, the former director of the department of Addiction Medicine at Lancaster Hospital) who treated most of the patients in the CID list and is closely familiar with our NCV/EMG consent policy and SBIRT/G code protocol.

I also attached expert letter of Michael Staples (former SMBO investigator and police detective) provides a detailed report based on onsite voluntarily self-audit that explains how our policies and practices (including EMG/NCV protocol and SBIRT protocol) are necessary to comply with the state law and SMBO regulations (of note MLN (ICN 904084) requires a physician to create the SBIRT protocol in compliance with the state law).

At the same time we are not aware of any expert opinions that lead the CID team investigation. This a very complex area of medicine that involves high risk vulnerable patients that cannot be evaluated based on the statistical extrapolations and financial objectives without proper clinical expert guidance.

For example, we find it concerning that we are challenged on the necessity of our SBIRT protocol(G codes) procedures that are required by the state law (please review Michael Staples attached) . At the same time, our practice is invited by the leading experts to present our SBIRT protocol procedures at the state and national meetings to other physicians in the field. These procedures include face to face time spent by physician and the nurse practitioners, more that 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines would not only significantly impact CPMI's ability to function as a business, but would also put an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of my peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality. The quality of care we provide resulted in several clinical awards (i.e. Patient Choice Award, Most Compassionate Doctor awards for several years, 2019 "Top 10" Ohio physician award in Pain Medicine) and referrals we get from major hospitals such as OSU Medical Center, Riverside, Grant, Mt Carmel, Adina Health and University Hospitals in Cleveland and even other pain management practices.

Our practice has already run into a 6 figure cost for this protracted investigation, productivity loss and significant time investment in the review and production of more than 35,000 documents that have already taken a toll on our ability to operate, manage records and treat our patients (as you know, we are a small independent practice).

Many of our patients are opioid-dependent, if their medications are not timely reviewed, this can cause patient morbidity incident to abruptly stopping treatment.

As you know, it is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death (overdose death rate in Ohio is the highest in the nation and is up more than 800% since 2013). The cost of the opioid epidemic is estimated as more the 600 billion nationwide, we run a low cost program that saved hundreds of thousands of dollars to Medicare by identifying and referring for addiction treatments hundreds of patients using our SBIRT protocol. We billed much lower rates than comparable hospital based programs and chose lower cost codes (i.e. G codes vs. office visit and time codes).

In summary, denial payments for the appropriate testing and screening procedures for drugs and alcohol puts in danger about several hundred high-risk patients. As we discussed during my PowerPoint presentation, as a physician and medical director that is committed to the ethical treatment and care of my patients, I have a duty and obligation to express these concerns without fear of retaliation.

I will enclose this letter to my compliance policy and will have to generate appropriate notes in the charts of the patients at risk and may need to take additional appropriate steps (as per state and federal guidelines) to ensure safety of this vulnerable patient population.

Our practice is in the forefront of the “opioid epidemic” fight. We hope to see Medicare and DOJ as an ally in this fight acting in compliance with the HHS 5 point strategy, rather than an adversary who tries to avoid payments for the appropriate services, so we can benefit the care and safety of our patients.

Sincerely,

Leon Margolin, M.D., Ph.D.