The Honorable Greg Walden  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515  

Dear Mr. Chairman:

Thank you for your recent letter regarding the House Energy and Commerce Committee’s continued interest in examining the opioid epidemic in the United States, and specifically your concern with patient brokering and substance use disorder treatment centers, as described in the articles you included with your letter. The Department of Health and Human Services (HHS) and its agencies, including the Substance Abuse and Mental Health Services Administration (SAMHSA), share your concern and outrage about these individuals and organizations that are exploiting those with opioid and other substance use disorders seeking treatment.

Attacking the opioid crisis on multiple fronts is one of HHS Secretary Tom Price’s top priorities. HHS has identified five specific strategies to address the opioid crisis: improving access to treatment and recovery services including the full range of medication-assisted treatment, promoting targeted availability and distribution of overdose-reversing drugs, strengthening our understanding of the epidemic through better public health and data and reporting, providing support for cutting edge research on pain and addiction, and advancing better practices for pain management.

Improving access to reputable, evidence-based treatment facilities is critical. Similarly, preventing and investigating fraudulent treatment programs and patient brokers that are taking advantage of vulnerable patient population is equally vital to our work. The role of patient brokers is coming under scrutiny via news outlets and through some State Attorneys General offices. As discussed in our answers below to your specific questions, HHS is committed to taking action where appropriate and considers addressing this issue as a top priority.

I am pleased to respond to your questions on behalf of Secretary Price.

Questions

1. Has HHS or any of its agencies examined the problem of patient brokers? If so, please discuss findings and observations.

Response:
The issue of patient brokering was discussed at the SAMSHA “Ethical and Quality Issues in Residential Substance Use Disorder Treatment” working group meeting held July 5
and 6, 2017. The discussion was within the context of broader concerns about residential treatment program practices in states. The purpose of the meeting was to identify areas of concern with residential substance use disorder treatment programs and discuss recommended solutions, tools, and resources.

SAMHSA is reviewing the recommendations identified in the meeting to address patient brokering and other ethical and quality issues affecting residential substance use disorder treatment to determine next steps.

In addition, SAMHSA is working with the Addiction Policy Forum to develop materials aimed at family members to educate them on what to look for in treatment facilities, and we hope to have these materials available to the public next year. These materials can further address patient brokering as an issue. SAMHSA is also working with the states to share best practices on how to address patient brokering and with the provider associations to approach this topic from an ethical standards perspective. Following the July meeting referenced above, the National Association of Addiction Treatment Providers (NAATP) launched an enhanced ethics initiative, which includes a process for monitoring their members’ adherence to the code of ethics.

a. Has HHS or any of its agencies taken any steps to combat patient brokers and the treatment centers that are utilizing patient brokers? If so, please describe this work.

Response:
HHS’ Office of Inspector General (OIG) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. OIG has both completed and ongoing investigations related to patient brokering and substance use disorder treatment. OIG is engaged in a proactive effort to coordinate nationwide with law enforcement partners and the private sector to hold parties within their jurisdiction responsible for the fraud and misconduct harming patients seeking addiction treatment. Through these partnerships and other means, OIG is aware of the increase in disturbing reports described in your letter and treats appropriately addressing such allegations as a top priority. Given the sensitive nature of law enforcement actions, OIG is available to provide the Committee with additional information on its activities via a follow-up briefing.

b. Similarly, has HHS or any of its agencies collaborated with other federal or state partners? If so, please elaborate.

Response:
The working group “The Ethical and Quality Issues in Residential Substance Use Disorder Treatment,” referenced above, provided a venue for SAMHSA to discuss the patient broker issue with stakeholders. Each participating member had follow up items. For example, the Association for Behavioral Health and Wellness was planning to reach out to the states where there were the most egregious issues and discuss what legal or other action would be available in that state. NAATP developed
a code of ethics and a process for monitoring their members’ adherence to the code of ethics. On June 26, Florida enacted a new law addressing a variety of issues around residential treatment.

SAMHSA has collaborated with individual state partners as well as stakeholder organizations representing states, accreditation bodies, and provider organizations, such as the National Association of State Alcohol and Drug Abuse Directors (NASADAD), The American Association of State Counseling Boards, The Joint Commission, Commission on Accreditation of Rehabilitation Facilities, and the National Association of Addiction Treatment Providers.

2. How do states regulate drug treatment centers and sober living homes? What licensure, standards, requirements and generally applicable? How often are they inspected?

Response:
There is wide variability among states in terms of how they regulate residential treatment and sober living homes. Enclosed is a document created by NASADAD in 2012 with information on state licensure bodies and practices at that time. SAMHSA has engaged NASADAD to update the document as quickly as possible. Regulation of sober homes is somewhat more complicated because they can be organized as group homes, in which case they are regulated by state laws that also regulate group homes for people with developmental disabilities and mental illness, but more frequently are organized in a manner that exempts them from regulation by simply having people pay rent and live as roommates who agree to certain standards of living together.

a. Has HHS or any of its agencies examined outcomes of drug treatment centers? Are there standards or metrics used to measure the effectiveness of drug treatment centers across the country? If so, please list them.

Response:
There is a large body of literature with multiple clinical trials on addiction treatment outcomes that show that treatment is effective. The duration of treatment has been shown to be more important than any other element, such as location or intensity of services. There are no universal standards of care to which programs are held accountable, however SAMHSA has published a series of treatment improvement protocols (TIPS), and the National Institute on Drug Abuse (NIDA) has published guidelines on effective treatment. The TIPS are widely used as the basis for standards of care that states and other entities have adopted. More than half of residential treatment programs are accredited by accrediting bodies similar to those that accredit hospitals. Eighty percent are licensed or certified by state bodies.

b. Further, are drug treatment centers required to report their compliance with these standards? Please list what they are required to report, who they report it to, and how frequently they report the information.
Response:
There are no national reporting requirements for substance use disorder treatment programs. Publicly funded programs do report admission and discharge data which includes information on reason for discharge and patient status at discharge. All states report admission data and most states aggregate and report discharge data to the SAMHSA Treatment Episode Data Set (TEDS) data collection system. However, there is no federal mechanism to address quality concerns at individual treatment programs that might be identified by this reporting system.

c. Are drug treatment centers required to report overdoses or overdose deaths of current or former patients or staff of their facilities? If so, who do they report this to?

Response:
Publicly funded treatment programs are generally required to report sentinel events, including overdose deaths, to the state.

3. What is the role of the federal government in oversight of drug treatment centers?

Response:
The federal government has oversight of opioid treatment programs (OTPs) but does not have oversight authority over other levels of care - states are responsible.

SAMHSA oversees accreditation standards and certification processes for OTPs through regulation at 42 CFR Part 8. OTPs must be accredited by a SAMHSA-approved accrediting body and certified by SAMHSA. Accreditation is a peer-review process that evaluates an OTP against SAMHSA’s opioid treatment standards and the accreditation standards of SAMHSA-approved accrediting bodies. The accreditation process includes site visits by specialists with experience in opioid treatment medications and related treatment activities. The purpose of site visits is to ensure that OTPs meet specific, nationally accepted standards for medication-assisted treatment. OTP accreditation:

- Enhances community confidence
- Improves medical staff recruitment
- Fulfills most state licensure requirements
- Meets certain Medicare certification requirements
- Influences liability insurance premiums

Federal law requires patients who receive treatment in an OTP to receive medical, counseling, vocational, educational, and other assessment and treatment services, in addition to prescribed FDA-approved medication. SAMHSA-approved OTPs are regulated by state opioid treatment authorities (SOTAs) based on their state’s regulations. SOTAs do an on-site inspection prior to the program opening and most states visit programs annually. The maximum accreditation cycle is 3-years. Within that timeframe, programs are assessed on the accrediting body’s standards. Each accrediting body has
individualized standards and they all align with 42 CFR Part 8.12. These reports are given to SAMHSA for review, and action is taken on unfavorable findings. Support services include identifying potential deficiencies and providing the resources to help make the necessary adjustments.

In addition, prescribers who wish to prescribe buprenorphine for the treatment of opioid use disorder are overseen jointly by SAMHSA and by the Drug Enforcement Administration (DEA). Physicians and other prescribers must submit evidence of appropriate training to SAMHSA along with an application which is reviewed by SAMHSA and forwarded to DEA for certification. Physicians that wish to prescribe to more than 100 patients are required to submit data to SAMHSA annually on their patient populations.

a. Are there databases within HHS, HHS agencies, or other entities that would provide useful data about drug treatment centers?

Response:
The National Survey of Substance Abuse Treatment Services (N-SSATS)\(^1\) is an annual census conducted by SAMHSA of all substance abuse treatment facilities in the United States, both public and private. N-SSATS collects characteristics of substance abuse treatment facilities, such as services offered, who operates the facility (private for profit, private nonprofit, public), therapeutic approaches used and other characteristics.

The Treatment Episode Data Set (TEDS) contains the demographic characteristics and substance abuse problems of admissions to treatment facilities in the United States. TEDS has an admissions and a discharge data set.\(^2\)

4. Has HHS or any of its agencies had any communications with insurance carriers selling qualified health plans (QHPs) to identify outliers in claims with trends that reflect improper utilization of drug treatment centers and sober living homes?

a. Are insurance carriers required to report any suspicious trends or activity regarding drug treatment facilities or sober living homes? If yes, please provide a description of the process by which these reports are made, and the role HHS plays, if any, in investigating these reports.

Response to 4 and 4a:
The Centers for Medicare & Medicaid Services (CMS) reviews cases of suspected or potential fraud submitted by individual issuers in the individual market Federally-Facilitated Exchanges (FFEs) when they want to cancel a policy. CMS does not have direct visibility into patient claims but reviews rescission requests from FFEs pursuant to

\(^1\) https://www.samhsa.gov/data/substance-abuse-facilities-data-nssats/reports

\(^2\) https://www.samhsa.gov/data/client-level-data-teds
45 CFR § 155.430(b)(2)(iii) and 45 CFR § 147.128 related to intentional misrepresentations of material facts and fraud. Issuers on the FFEs report the rescission candidate to CMS and must demonstrate that rescission is appropriate to the reasonable satisfaction of the FFE before canceling the policy.

5. Is HHS or any of its agencies able to identify a trend in billing for drug treatment services based on geographical location?

   a. If so, please name the states with the highest spending when compared to prevalence of individuals with substance use disorder.

Response to 5 and 5a:
Because of a lack of Medicaid and commercial insurance data, CMS does not have information on usage trends of these treatment centers in those programs. CMS does not have Medicare data either.

6. Are there adequate anti-kickback protections that would make the aforementioned brokering a violation of federal law?

Response:
The federal anti-kickback statute, 42 U.S.C. 1320a-7b(b), makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. Per-patient, per-head, and similar payment arrangements (such as fees based on quotas) that directly take into account the volume or value of services ordered and provided are highly disfavored under the anti-kickback statute. To date, abusive payment arrangements involving opioid addiction treatment centers primarily have affected private health insurance plans. In the two news accounts that you enclosed, from the Orange County Register and from Stat, there is no indication that the specific incidents described involved Medicaid or any other federal health care plan. The anti-kickback statute applies only to federal health care programs; it does not apply to privately insured patients. To the extent federal health care programs, such as Medicaid and Medicare, are affected, the anti-kickback statute applies.

7. What steps can HHS or any of its agencies take to better protect individuals seeking treatment and eliminate the fraud and abuse that is occurring within the drug treatment industry?

Response:
A key pillar of HHS’ strategy for addressing the opioid epidemic is improving access to evidence-based treatment, including medication-assisted treatment, for opioid use
disorder. When an individual takes the courageous step of seeking treatment, we want to ensure the health system is able to respond, and that patients are not victims of greed, fraud, or abuse.

Fraud needs to be addressed by payers, including Medicaid. CMS maintains four program integrity field offices in high vulnerability areas of the country that provide an on-the-ground presence in known fraud “hot zones” and work closely with the joint HHS and Department of Justice Health Care Fraud Prevention and Enforcement Action Team known as “HEAT.” The field offices conduct data analysis to identify local vulnerabilities and coordinate special projects with Medicare contractors and state and local agencies on issues that have a national or regional impact. Law enforcement agencies with oversight authority, including the HHS OIG and state Medicaid Fraud Control Units, conduct investigations of fraud in the drug treatment industry.

As noted above, SAMHSA recently convened the “Ethical and Quality Issues in Residential Substance Use Disorder Treatment” working group to discuss issues regarding patient brokering and other ethical and quality issues in residential treatment. The report from that work group and recommendations for further action is being reviewed to plan next steps. SAMHSA also had a technical expert’s panel on sober housing in May with a similar report and recommendations that are under review to develop a proposed strategy. While the federal government does not have regulatory authority over either of these settings, it can develop and disseminate standards for states to adopt if they choose to do so, provide training and technical assistance to states where there are difficulties in managing these treatment settings, and work with national provider associations to disseminate standards and best practice guidance.

We appreciate your ongoing interest in this very important issue. We will continue to work with you and your staff to address the opioid crisis.

This response has been sent to the other signatories of your letter.

Sincerely,

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Enclosure