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ELECTRONIC DELIVERY: opioids@finance.senate.gov

The Honorable Orrin G. Hatch
Chairman, Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510-6200

The Honorable Ron Wyden
Ranking Member, Committee of Finance
221 Dirksen Senate Office Building
Washington, D.C. 20510-6200

Dear Chairman Hatch and Ranking Member Wyden:

Orexo appreciates the opportunity to submit its comments in response to the recent Committee on Finance (the Committee) request for policy recommendations addressing the opioid use disorder crisis. We appreciate the Committee's sense of urgency and commitment to leveraging the federal programs within its jurisdiction to effectuate policy changes toward changing the trajectory of this epidemic.

Orexo is a specialty pharmaceutical company focused on the research, development, and commercialization of patient-adapted formulations with the goal of offering superior medical benefit. Our Zubsolv® sublingual tablets (CIII) are an advanced formulation of buprenorphine and naloxone indicated for the treatment of opioid dependence as part of a comprehensive treatment plan. Medication assisted treatment (MAT) for opioid dependence with Zubsolv® can be initiated in an office-based setting by physicians trained and certified under the Drug Addiction Treatment Act of 2000 (DATA 2000). Zubsolv is dispensed in child-protective packaging, and, maybe most importantly, is available in the broadest range of dosages to facilitate induction, titration, maintenance and tapering toward a goal of abstinence from medication as appropriate.

As the Committee notes, the opioid epidemic afflicts individuals regardless of age, socioeconomic status, and geography. We need the full participation of our nation's health systems and providers if we are to have any hope of combatting this public health crisis. Orexo agrees with the Committee's conclusion that we must do more than invest in pain management innovation and addiction prevention. Policy changes must also leverage our reimbursement system to align incentives with our public health goals, including increasing access to treatment options such as Medication Assisited Treatment (MAT).

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Orexo's recommendations are grounded in the principle that access to OUD treatment, and the medications that are an essential part of evidence-based care, must be on par with access to opioid pain medications. Medicare and Medicaid can, through an appropriate incentive framework, play an important role in de-stigmatizing the OUD treatment "niche" so that mainstream providers are empowered to support OUD patients as we combat this crisis.

How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?

Orexo firmly believes that our healthcare system is equipped with the necessary tools to reduce overdose-related deaths, and to effectively treat opioid use disorder through evidence-based medication assisted treatment (MAT). Innovative, holistic approaches are, however, essential to drive those tools toward ensuring that individuals seeking recovery from opioid use disorder can access proven, life-saving treatments.

Unfortunately, our current payment structure is misaligned, and providers have disincentives to diagnose, refer, or appropriately treat Opioid Use Disorder. Similarly, the Quality Payment Program implemented to incentivize Medicare providers for high-quality care across their patient population creates disincentives for clinician activities aimed at reducing the opioid use disorder epidemic by putting a premium on other services and practice improvements.

Mainstream primary care doctors, family physicians and others treating OUD must be sufficiently reimbursed for the evidence-based care we want patients to receive:

- Diagnosis and/or confirmation of diagnosis
- Initial consultation w/ patient history, assessment of social supports, etc.
- Treatment plan development
- Care coordination w/ social support services
- Periodic drug screens
- MAT induction
- Periodic office visits of 15-30 minutes through induction, stabilization, and maintenance
- Assessing tapering feasibility and/or success
- Monitoring PDMP
- Confirming compliance with medication and counseling services
- Managing relapse through re-induction and treatment plan amendment, if necessary
- Additional fees for prior authorization burden that exceeds 5 min. of office time (PBMs charge add-on fees for the extra work required to process the PA requirements they choose to implement; clinicians should be compensated fairly)
- Maintaining diversion control protections
- DATA 2000 reporting requirements

Medicare and Medicaid must implement mechanisms (including appropriate procedure codes and adequate payment) for these services, and permit clinicians to submit claims for their additional

time and services when an office visit encounter reveals the need for more detailed inquiry into potential opioid use disorder treatment.

Similarly, the Medicare Quality Payment Program could have a transformative impact on clinician practice by driving incentives toward rational use of opioid pain relievers, screening and diagnosis of opioid us disorder, and high-quality SUD treatment services that effectively guide patients through induction and maintenance toward tapering of MAT and appropriate goals of abstinence from medication. This would permit clinicians to earn positive payment adjustments for incorporating opioid use disorder prevention, detection, and treatment strategies into their care for all patients, not just Medicare beneficiaries.

Successful addiction recovery requires that healthcare providers be sufficiently trained to identify high-risk behaviors and drive timely interventions, and that jointly-developed care plans including patient education and inclusion of titration, maintenance, and tapering phases with the goal of abstinence from opioids. This means that the Medicare QPP incentives should align with our societal goals:

- opioid prescribers and waivered providers must be trained to recognize high-risk behavior indicative of medication abuse, misuse, dependence, or addiction;
- clinicians treating patients through evidence-based MAT incorporate discussions of titration and tapering into early care planning discussions and plan development, and work toward the patient's recovery goals;
- limits on patient and provider medication decisions should be based upon scientific evidence, designed to optimize successful tapering to medication abstinence, and/or respond to a safety, diversion, or abuse potential concern; and
- clinicians in specialties with a high reliance on opioids should be trained in detecting high-risk behaviors and/or patterns, and, ideally, qualified to utilize MAT.

Finally, clinicians detecting opioid use disorder and responding with either MAT or referral to a provider capable of prescribing an SUD program of care, should not face obstacles within Medicare and Medicaid related to the duration or sufficiency of the patient's condition. Lack of clarity on the definition of "addiction", whether it must persist for months or even years, and even whether the patient must have tried and failed to abstain from opioid medications, can significantly delay treatment and compromise patients' potential to stabilize, taper from MAT, and eventually abstain from medication, if possible, while maintaining optimal functioning in their family and community.

Congress and CMS know, from HIV to diabetes and oncology, that aligning reimbursement incentives leads to appropriate care. Long overdue is the need to apply those learnings to the opioid epidemic and tie financial incentives to the care we want Opioid Use Disorder patients to receive from the providers prescribing opioids.

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Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?

Recognizing the simple fact that adequate pain relief for individuals with severe, long-term pain can have an unintended consequence of dependence and even addiction could have a profound impact on diluting the stigma associated with opioid use disorder that has impeded incorporation of addiction-recognition and medication-assisted treatment into mainstream medical practice. Compromising pain relief at the patient level in response to a population-level public health crisis trades one problem for another. Ideally, opioid prescribers and patients would be empowered to manage this challenge, either through opioid tapering strategies with the introduction of alternative treatment regimens or the introduction of buprenorphine-based products, into a patient's evolving treatment plan to resolve physiological effects of opioid tolerance and dependence before behavioral manifestations of opioid use disorder and addiction emerge or proliferate.

Orexo believes that opioid-prescribing clinicians in the Medicare and Medicaid programs should be armed with knowledge on the inherent addiction potential of specific products and extended opioid pain medication use, and capable of recognizing and addressing both physiological dependence and high-risk patient behavior.

While most clinicians recognize the need to taper from high-dose or an extended duration of opioid use, it is not clear that reducing the patient's opioid prescription will always reduce the patient's opioid use. Opioid-prescribing clinicians have a moment of opportunity that is, unfortunately, frequently lost. For a patient who has been using escalating prescribed doses of opioid pain medication for a legitimate, but now-resolved pain condition, it may not be possible to stop opioid use without withdrawal symptoms. Clinicians treating pain must be empowered with the knowledge to recognize high-risk situations, and have a clear set of incentives to respond appropriately.

As more fully detailed in our recommendations on state Medicaid innovations, Orexo believes that in many, if not all, states, patients generally, and Medicaid patients in particular, can face significant barriers to effective treatment due to the lack of DATA 2000 waivered providers with capacity and a willingness to accept Medicaid patients. Similarly, clinicians are most motivated to detect a disorder when they are able to help respond to it. Mainstreaming MAT so that clinicians prescribing opioids to their patients for pain relief can prescribe MAT when they detect high-risk behavior and diagnose opioid use disorder, is a sensible approach in light of the magnitude of the opioid use disorder epidemic.

How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?

The current opioid use epidemic cannot be addressed without adequate resources to increase the number of addiction-trained psychiatrists, addictionologists and other physicians, nurses, psychologists, social workers, pharmacists, physician assistants, and community health workers and facilitate their deployment to regions and facilities with significant needs. As detailed above, Orexo believes that a rational first step is to encourage providers in all sub-specialties to be trained to

detect high risk behavior, utilize opioid use disorder detection tools, and discuss treatment options, including MAT, as part of the practice of medicine. Our societal response to this epidemic will remain inadequate until clinicians acknowledge the pervasiveness of opioid dependence and opioid use disorder, and recognize MAT as being as essential to the practice of medicine as pain relief and chronic pain management.

There are significant, structural disincentives for the clinicians prescribing opioids to incorporate MAT into their practice offerings. Clinicians utilizing MAT must complete training on appropriate buprenorphine prescribing practices, and are subject to oversight to ensure adherence to evidence-based care standards – this enhanced oversight confined MAT availability to "niche" practices. The number of qualified MAT providers is grossly insufficient to respond to the current treatment needs.

Orexo believes that clinicians prescribing opioid pain medications to Medicare and Medicaid patients should be required to receive training on recognizing when the nature of the patient or the dose and duration of treatment indicate a heightened risk for opioid dependence and opioid use disorder.

What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?

Orexo agrees that collaboration among State prescription drug monitoring programs, and federal regulatory and law enforcement functions on interoperable prescription drug monitoring program databases that include information related to all opioid prescribing products, including those used as part of medication-assisted opioid use disorder treatment programs (including methadone) and overdose rescue treatments would serve to:

- Reduce the potential for diversion;
- Alert clinicians of a patient's opioid overdose experience so that further prescribing can be avoided in favor of referral to a treatment program;
- Ensure that providers have a simple mechanism for ascertaining whether a patient is in a recovery program for which prescription of opioids or benzodiazepines would be contraindicated.
- Enable physicians in an acute care situation to make informed decisions with patients taking all forms of medication assisted treatment for their opioid dependency.

It is essential that prescribers have full visibility over all opioid related prescribing (pain; medication assisted treatment and rescue based therapy), and are mandated to seek this information, to support appropriate clinical decisions and prescribing. Medicare and Medicaid coordination with their prescription drug programs should:

- Ensure that Naloxone administrations by first responders and providers are incorporated into the EHR and prescription drug monitoring database;
- Implement inter-state operability of both EHRs and PDMP databases;

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- Facilitate inclusion into the EHR of Naloxone rescue doses disseminated (whether or not administered) to individuals impacted by opioid use disorder and/or their families;
- Coordinate with SAMHSA to supplement the database of office-based MAT so that providers across settings can identify an office-based MAT provider for an opioid use disorder patient. This information would include the MAT provider's ability to take new patients, participation in the patient's third-party payer, and services provided; and
- Facilitate increased provider participation in DATA 2000 by enabling real-time coordination with ancillary providers, including nurse practitioners, available to augment MAT with patient-centered care management and psychosocial services.

What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?

Although the States have always controlled health professional licensing requirements, including training standards, qualifying clinicians to prescribe all other controlled substances regulated by the DEA, DATA 2000 sets nationwide limits on who can prescribe MAT and under what circumstances. States have to find ways to respond to the nature and magnitude of the opioid use disorder within their borders, yet when population treatment needs exceed provider capacity, the simplest, most effective solution, (i.e., to quickly expand the number of MAT providers) is largely outside State and local government authority. What was once a cautionary step in an effort to mainstream Opioid Use Disorder treatment from methadone clinics to physician offices has in fact displaced traditional state authority and hampered the Opioid Use Disorder treatment "mainstreaming" goals that drove enactment of DATA 2000. This is completely out of sync with the great deal of effort taking place across the nation to increase physician awareness of potential opioid use disorder in their patients.

Orexo urges the Committee to consider encouraging state Medicaid innovation models that respond to MAT provider supply/demand disparities and return power and responsibility to the states to set appropriate parameters and safeguards for primary care physicians and other "front line" providers to not only identify Opioid Use Disorder early but prescribe MAT to their patients. While this would require conforming amendments to DATA 2000 permitting such "waivers," it could significantly improve states' ability to appropriately address their population needs by, for example, allowing physicians who treat for pain and prescribe opioids, to prescribe MAT to their patients, and incentivizing these clinicians to identify and address the spectrum of their patients' needs.

Orexo further urges the Committee to require that state Medicaid innovation waiver requests and other models developed by the Center for Medicare and Medicaid Innovation (CMMI) include mechanisms that expand access to screening and diagnosis of SUD, enable evidence-based treatment with MAT, and utilize evaluation tools that include reporting on tapering and successful transition to abstinence from medications

For patients seeking recovery, MAT tapering can and should be part of the treatment plan and its implementation. For health systems, the key is to empower patients and providers with the tools

they need for successful tapering and, ideally, transition to abstinence from medication. This means that clinicians must be appropriately trained on how to incorporate tapering discussions into an initial treatment plan, encourage patients to begin a tapering schedule, and support the patient for successful dose reduction through an appropriate dose tapering schedules. Just as importantly, clinicians and patients must have access to products that facilitate the best chance for a safe, gradual and successful tapering schedule.

Outcome measures for opioid use disorder treatment through the Medicare QPP, or in any Medicaid innovation models will fail to capture value or care quality unless they include reporting and evaluation of this aspect of a successful care plan. CMMI-based initiatives could be helpful in facilitating promising models, as well as in applying these value-driven outcome measures to evaluating model success.

Conclusion

Once again, Orexo appreciates the opportunity to respond to the Committee's request for policy recommendations. We are eager to work with you as the Committee crafts innovative strategies for addressing the opioid use epidemic to ensure that individuals suffering from addiction or dependence have the best possible chance for recovery. If you have any questions or need additional information, please contact me or Saira Sultan at 202-360-9985.

Respectfully Submitted,

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