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Via Email Submission:
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The Honorable Ron Wyden
Chairman
U.S. Senate Committee on Finance
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
U.S. Senate Committee on Finance
Washington, DC 20510

RE: Inequities and Barriers to Mental Health and Substance Use Treatment

Dear Chairman Wyden and Ranking Member Crapo:

Masimo appreciates the opportunity to provide comments on the Request for Information, and appreciates your dedication to a comprehensive approach to advancing equity and access to mental health and substance use disorder treatment. We support your efforts and believe that innovative medical technology should play a significant role in any comprehensive strategy to provide increased access to safe and quality healthcare for underserved populations.

Medical technology can bring the care *to the patient*, which eliminates many of the barriers standing between individuals and quality healthcare, and can help keep individuals with substance use disorder safe. Medical technology can also alleviate withdrawal symptoms, providing a non-pharmacological transition to abstinence or medication assisted therapies (MAT).

While progress has been made to address the rising death toll caused by opioids, major gaps in protection against opioid risks remain, especially within vulnerable and underserved communities.

Background

The effects of opioids are unpredictable. While two people may receive the same dose, opioids can have dramatically varied effects on breathing—meaning opioid overdoses can occur even when someone is taking an opioid exactly as prescribed by their doctor.

During an opioid overdose, a person's breathing slows and can eventually stop, causing a drop in the oxygen that circulates in the bloodstream (oxygen saturation). Without intervention, a sustained lack of oxygen to the brain leads to impaired consciousness and, eventually, brain injury or death. It only takes three to five minutes of oxygen deprivation to cause permanent brain damage.

Methadone and Buprenorphine Are Opioids: Individuals using Medically Assisted Treatment (MAT) drugs should also be carefully monitored due to the known risk of respiratory depression associated with methadone and buprenorphine. One study revealed that methadone accounted for approximately 1% of all opioids prescribed for pain, but was responsible for approximately 23% of all prescription opioid deaths in 2014.

The Naloxone Gap: Almost 50% of overdoses occur when a patient is alone. The benefits of naloxone are well known, but this overdose reversal medicine can only be successfully administered if clinicians, first

responders, caregivers, or family members are notified that an individual who is using opioids is in distress and needs attention. Naloxone has been shown to decrease deaths by about 14% in states that have implemented co-prescribing. However, naloxone in a medicine cabinet or in the hands of someone miles away is useless to the person overdosing. Monitoring and notification aided by the use of technology can help close this gap in safety, preventing overdoses and providing a link between those at risk and those who can help.

The Role of Technology in Addressing the Opioid Crisis: The role that medical technology can play in our efforts to end the opioid crisis cannot be understated. Technology exists today that can monitor individuals taking opioids to detect when their oxygen saturation dips, so that organ failure, brain damage, and death due to overdose can be prevented. Further, technology can alleviate withdrawal symptoms that too often stand in the way of recovery.

The Benefits of Noninvasive Physiologic Remote Monitoring: During the COVID-19 pandemic, remote monitoring is being used to care for patients in their homes with hospital grade technology. Continuous physiologic data is sent to the patient's providers to identify when medical intervention may be required, providing critical advanced insight about a patient's condition. Early intervention and treatment may help patients from deteriorating to a point that requires assisted ventilation and/or intensive hospital care. ***This same vital sign technology can be used to monitor individuals taking opioids.***

The use of this technology is not only safe, but it is cost-effective. Researchers at Dartmouth-Hitchcock Medical Center, over a ten-year period, found improved outcomes following installation of continuous postoperative electronic monitoring. Specifically, researchers were able to eliminate preventable deaths and brain damage due to opioid overdose in post-surgical units as well as reduce rapid rescue events by 60%, ICU transfers by 50%, and costs by an estimated \$7 million annually.

The Dangers of Opioid Withdrawal: Opioids, including prescription opioid painkillers, can produce severe withdrawal symptoms that can last for a week or more. Research has found that unassisted withdrawal can be life-threatening, and the threat of relapse is as high as 91%. Opioid withdrawal syndrome can include nausea, vomiting, anxiety, insomnia, hot and cold flushes, perspiration, muscle cramps, diarrhea as well as other symptoms, all of which provide a disincentive to those addicted to opioids from attempting to withdraw. This fear can prevent those addicted from even attempting to seek treatment. Further, opioid agonists used for MAT, such as methadone or buprenorphine, can be associated with severe withdrawal symptoms on their own, because both of those drugs contain long-acting opioids.

The Benefits of Neuromodulation Technology: FDA-approved medical technology, such as neuromodulation, can assist with opioid withdrawal, helping individuals overcome painful symptoms and reducing barriers to successful opioid cessation and treatment. Neuromodulation provides non-surgical and non-pharmacological options for withdrawal management.

Increasing integration, coordination, and access to care

Technology needed to improve access to care across the continuum of behavioral health services:

The devastating impact of the opioid crisis has been well researched and documented. By 2019, one person was dying of an opioid overdose every 10.7 minutes, with an estimated 1.6 million individuals in the U.S. having active opioid use disorder (OUD). The annual cost of opioid abuse in America has been estimated at \$500 billion.

Not only are the most vulnerable individuals largely the ones impacted by the opioid epidemic, but they are also the most underserved populations with regard to resources and healthcare. Individuals using opioids receive

consistently lower quality of care across preventive and chronic illness care and care coordination.

Policies that can improve and ensure equitable access to and quality of care for minority populations and geographically underserved communities:

Opioid use disorder is common where access to healthcare and treatment are scarce, and populations are already vulnerable: in rural areas, pregnant women, the elderly, and incarcerated persons.

Many factors contribute to this correlation: the increased prevalence of chronic medical, psychiatric and substance use, exposure to stigma, housing instability, unemployment, and poor access to healthcare and treatment all exacerbate the challenges facing these communities.

Support for Medical Technology: In order to increase access to care, Congress must adopt policies that enable providers to bring the treatment *to the patient*. By supporting the development and implementation of innovative technology that can be brought into homes, jails, clinics, and communities, we can break down countless barriers to care and treatment.

Consumer and Provider Education: In addition to enabling access to remote patient monitoring for opioid-induced respiratory depression and medical technologies to assist individuals in withdrawing from opioids, agencies must develop and implement a robust and accessible education campaign on the dangers of opioid-induced respiratory depression.

Engagement with all stakeholders, including the private sector: In order to break down barriers and save lives, Congress and federal agencies must expand engagement and partner with state and local agencies, as well as the private sector. Such collaboration will enable us to reach our vulnerable and underserved communities. There are numerous federal agency programs relevant to the opioid crisis, but those same programs ignore or discourage private sector involvement that can not only provide expertise, but resources.

Further, federal agencies should assist in matching academic, community, federal, state and local resources with private industry experts and partners to promote education, demonstrations and pilot programs that bring the benefits of medical technology to vulnerable populations.

The Need for Adequate Medicare and Medicaid Coverage and Reimbursement for Medical Devices and Technology

Payment policies, such as the lack of adequate Medicare coverage and reimbursement, greatly contribute to the challenges in delivering quality and accessible mental health and substance abuse treatment. Congress should ensure that Medicare and Medicaid provide comprehensive, adequate coverage and reimbursement for medical devices and technology that are approved by the Food and Drug Administration for the diagnosis, treatment and/or recovery of opioid dependence and opioid use disorder or addiction, including detoxification and rehabilitation services and the treatment of withdrawal symptoms.

The Benefits of Telemedicine in Keeping Individuals with Substance Abuse Safe

The Impact of the COVID-19 Pandemic on the Opioid Crisis: The need to address the opioid crisis is even more urgent because the COVID-19 pandemic exacerbated the opioid crisis and overdose deaths have increased dramatically. From September 2019 through August 2020, there were over 88,000 overdose deaths, which made 2020 the deadliest year for overdoses on record.

The COVID-19 pandemic taught us that we need programs and policies that enable healthcare to reach individuals where they are. Congress should continue to support the expansion of telemedicine, including remote physiologic monitoring that is playing an extremely important role during the pandemic, and will continue to improve safety and access to individuals with substance use disorder.

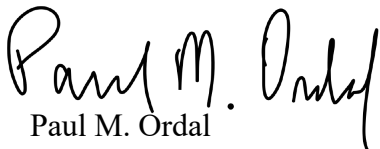
Medical innovation and technology enable people to live longer, with more independence, and with less pain and greater quality of life. Medical technologies also save patients, insurers, employers, governments and hospitals billions of dollars by keeping patients healthy and out of the hospital. In order to continue to enable innovators to create new medical solutions to save lives and improve the quality of life, we all need to work together.

We applaud your commitment to addressing the overdose and addiction epidemic and look forward to working with you on this critical issue and your willingness to engage and work with all stakeholders, including the private sector.

We welcome the opportunity to brief you and/or your staff on the value of medical technology and the ways that medical devices and technology can be used to break down barriers and provide increased access to safe and quality healthcare, including mental health and substance use treatment, to underserved populations in vulnerable communities.

If you have any questions or would like to address any aspects of our comments, please feel free to contact Kaye Meier at Kaye.Meier@Masimo.com.

Sincerely,



Paul M. Ordal
Vice President, Government Relations and Public Policy

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