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November 27, 2019

Submitted electronically to Rural_Urban@mail.house.gov.

The Honorable Danny Davis, Co-Chair
Rural and Underserved Communities Health Task Force

The Honorable Terri Sewell, Co-Chair
Rural and Underserved Communities Health Task Force

The Honorable Brad Wenstrup, Co-Chair
Rural and Underserved Communities Health Task Force

The Honorable Jodey Arrington, Co-Chair
Rural and Underserved Communities Health Task Force

RE: RURAL AND UNDERSERVED COMMUNITIES HEALTH TASK FORCE REQUEST FOR INFORMATION

Dear Representatives Davis, Sewell, Wenstrup and Arrington:

Masimo Corporation appreciates the opportunity to provide comments on the Request for Information of the Rural and Underserved Communities Health Task Force.

Masimo is a global medical technology company that develops and produces a wide array of industry-leading monitoring technologies, including innovative measurements, sensors, patient monitors, and automation and connectivity solutions. Our mission is to improve patient outcomes and reduce the cost of care. One of the ways we accomplish this mission is by the use of technology to monitor patients taking opioids to help identify patients with opioid-induced respiratory depression, which can cause devastating permanent injury or death. Unfortunately, with high risk medications such as opioids, the consequences of adverse events are often harmful or fatal. ***Individuals living in rural areas and those with a low income are particularly vulnerable to opioid overdose***.

Prescription opioids, while powerful painkillers, can also have dangerous side effects, even when taken exactly prescribed by a physician. People taking any form of opioids, including prescription or illicit, may respond to opioids in an unpredictable way, such as slow or stopped breathing. This is known as opioid-induced respiratory depression – where low oxygen levels are dangerous and may lead to brain damage and death. This can occur when people are resting or asleep--they may not even be aware of the risk. In addition, the majority of people suffering from an opioid overdose die alone. Today, more people die from breathing complications caused by opioid use than from automobile accidents.

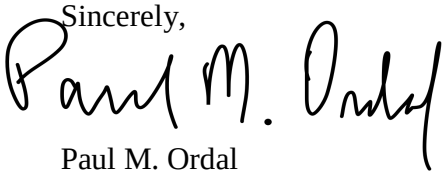
We recognize that clinicians face a difficult challenges in monitoring patients taking prescribed opioids, especially in rural areas. To address these challenges, we have developed a monitor specifically for opioid users. The monitor consists of a wearable adhesive sensor that measures oxygen saturation and pulse rate, a hub, and a smartphone application. The application allows the user to adjust alarm limits and define an alarm escalation procedure. The escalation procedure may include first alarming at the smartphone and hub and, if the alarm persists, notifying designated friends, family and emergency responders.

Masimo's opioid monitor was granted breakthrough device status by FDA after being selected among eight of more than 250 applications as part of FDA's Opioid Innovation Challenge. The Innovation Challenge was intended to spur the development of medical devices that could provide new solutions to detecting, treating and preventing opioid addiction, addressing diversion and treating pain. Masimo is currently working closely with FDA to obtain clearance of the opioid monitor. FDA has already cleared a general use version of the product, called Radius PPG™, which includes the same wearable sensor but without the opioid-specific smartphone app and hub that Masimo is currently selling in hospitals and can sell at home too.

However, in order to provide these safety measures in all care settings, Medicare must provide reimbursement for this life-saving pulse oximetry monitoring technology.

We appreciated your desire and effort to make our healthcare system work better and look forward to working with the Rural and Underserved Communities Health Task Force to address the opioid crisis, keep patients in rural settings safe, and reduce healthcare costs. Masimo appreciates the opportunity to share this feedback. If you have any questions, please feel free to contact Kaye Meier at 202-440-3691or by email at Kaye.Meier@Masimo.com.

Sincerely,



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

Rural and Underserved Communities Health Task Force
Request for Information

Task Force Question: What are the main health care-related factors that influence patient outcomes in rural and/or urban underserved areas?

*Masimo Response**: The ability of physicians to electronically monitor patients taking opioids in real time is essential in rural settings to keep patients safe.** Opioids are powerful painkillers, but are also powerful respiratory depressants. Opioids can cause slow or shallow breathing, which lowers blood oxygen to dangerous levels, leading to brain injury and death. Therefore, it is imperative that opioid users be monitored for respiratory depression – even at home.*

Opioid use, whether prescription or illicit, is dangerous. A comprehensive solution needs to address not just patients in hospitals, but the millions of patients at home using prescription opioid therapy as well as those using opioids for non-medical purposes. Opioid overdose monitors could save tens if not hundreds of thousands of users' lives and provide peace of mind for their families and friends.

Patients and physicians face a difficult challenges in remote monitoring of patients taking prescribed opioids. Fortunately, FDA-approved technology exists today that can meet those challenges by enabling physicians to prescribe the pain medications that they deem appropriate to manage pain and keep their patients safe from opioid induced respiratory depression, catastrophic permanent injury, and death.

***Recommendation**: Technology should be used to continuously monitor patients' oxygen saturation, pulse rate, respiration rate, and can notify clinicians and caregivers if a patient's condition deteriorates in time to intervene. In order to provide these safety measures in the outpatient setting, Medicare must provide reimbursement for pulse oximetry monitoring technology.*

Task Force Question: What successful models show a demonstrable, positive impact on health outcomes within rural or underserved communities, for example initiatives that address the use of telehealth/telemedicine/telemonitoring?

Masimo Response: Continuous electronic physiologic monitoring improves patient outcomes and research has shown that it lowers healthcare costs. One in-patient study by Dartmouth Hitchcock[1] found that annual cost savings due to decreased transfers of patients to the intensive care unit and decreased rescue events resulting from continuous electronic monitoring was $1,479,012. The potential annual cost savings to Medicare (assuming 50% Medicare Coverage) has been estimated at over $3 billion per year.

[1] Taenzer, Andreas H., and George T. Blike: Postoperative Monitoring—The Dartmouth Experience; APSF Newsletter; Volume 27, No. 1, 1-28 Circulation 94,429 Spring-Summer 2012.

<u>Task Force Question</u>: Access to providers that address oral, behavioral, and <u>substance use needs</u> in rural and underserved communities can be particularly limited. What approaches have communities or states taken to address such gaps in care delivery?

<u>Masimo Response</u>: Opioid use, whether prescription or illicit, is dangerous. A comprehensive solution needs to address not just patients in hospitals, but the millions of patients at home using prescription opioid therapy as well as those using opioids for non-medical purposes. Opioid overdose monitors could save tens if not hundreds of thousands of users' lives and provide peace of mind for their families and friends.

The benefits of naloxone are well known, but naloxone can only be successful if clinicians, first responders, family members etc. are notified that the individual is in respiratory depression.

Emergency medical personnel, health care professionals, and others who may witness an overdose are being trained in the use of the opioid antagonist medication naloxone, which can reverse the potentially fatal ***respiratory depression*** *caused by opioid overdose."*[2]

That is where continuous physiological electronic monitoring can save lives. Technology available today enables patients to wear a device to monitor oxygen saturation, pulse rate, and respiratory rate, transmit that data to a smart phone or remote view station, send alerts based on device alarms through an escalation protocol, and provide healthcare providers real-time patient monitoring, which is especially valuable in rural areas.

<u>Recommendation</u>**: Research and investment should be afforded to the technologies that enable the early identification of physiologic changes in patient conditions, which will enable clinicians, caregivers and emergency responders to use them.* ***The earlier the identification of deteriorating patient condition, the better the chance of a positive outcome.

<u>Task Force Question</u>: The availability of <u>post-acute care and long-term services and supports</u> is limited across the nation, but can be particularly challenging in rural and underserved areas facing disproportionately large burdens of chronic and disabling conditions. What approaches have communities taken to address these gaps in care delivery and the associated challenges of social isolation?

<u>Masimo Response</u>: There is growing concern that physicians are under-prescribing pain medications in certain populations, such as the elderly and those with chronic pain, due to the increased risk of opioid-induced respiratory depression.[3] *Research has shown that under-prescribing pain medications can actually harm these patients.*[4]

Although these patients are categorically at a high risk for opioid-induced respiratory depression, numerous tragic deaths have occurred in patients with no apparent risk factors. Therefore, we

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[2] Opioid Use Disorder Facts - Five Essential Steps for First Responders - Information for Prescribers Safety Advice for Patients & Family Members - Recovering From Opioid Overdose; Substance Abuse and Mental Health Services Administration (SAMHSA); HHS Publication No. (SMA) 18 4742. First printed 2013. Revised 2014, 2016, 2018. Pg. 5.

[3] Fitzpatrick, Margaret, AGING IN PLACE, "*Preventing Delirium by Managing Pain*," HomeCare; September 9, 2019. https://www.homecaremag.com/september-2019/preventing-delirium-managing-pain?utm_source=Newsletter&utm_medium=Email&utm_campaign=HomeCare_Monday&oly_enc_id=2915B9533689J3W.

[4] Fitzpatrick, Margaret, AGING IN PLACE, "*Preventing Delirium by Managing Pain*," Homecare; September 9, 2019. https://www.homecaremag.com/september-2019/preventing-delirium-managing-pain?utm_source=Newsletter&utm_medium=Email&utm_campaign=HomeCare_Monday&oly_enc_id=2915B9533689J3W.

recommend continuous physiologic electronic surveillance with measure through motion pulse oximetry of all patients taking opioids in all care settings, including at home in rural settings.

While the law recognizes the need for remote patient monitoring by providing reimbursement for time spent by healthcare professionals under certain circumstances, the circumstances are limited, and reimbursement is not provided for the actual medical device that is used to save the patient's life.

***Recommendation**: In order to enhance access to life-saving remote monitoring technology, we recommend that Medicare provide reimbursement for pulse oximetry monitoring technology in the home.*

Task Force Question: Are there two or three institutional, policy, or programmatic efforts needed to further strengthen patient safety and care quality in health systems that provide care to rural and underserved populations?

Masimo Response: Seamless information technology in healthcare should enable physicians and caregivers to identify problems in real time and resolve them before they become deadly. Today, however, these technologies are not always able to communicate or interoperate. Technology solutions must be required to openly share information, particularly when their purchase is subsidized with taxpayer dollars and patients' lives are dependent on it.

*Further, **continuous electronic physiologic monitoring must be available so that caregivers, physicians and other healthcare providers can recognize patient deterioration in time to save that patient's life.***

Numerous patient safety organizations endorse continuous electronic monitoring of patients taking opioids:

PPAHS strongly recommends the use of continuous electronic monitoring for all patients receiving opioids.

- Physician-Patient Alliance for Health & Safety

APSF recommends that monitoring be continuous and not intermittent, and that continuous electronic monitoring with both pulse oximetry for oxygenation and capnography for the adequacy of ventilation be considered for all patients.

- Anesthesia Patient Safety Foundation

Hospital protocols should include continuous oxygenation and/or respiratory monitoring (not spot check monitoring) with pulse oximetry through an adhesive sensor. Ideally use pulse oximetry with measure through motion and low perfusion technology, such as with a Masimo SET.

-Patient Safety Movement Foundation

San Diego Patient Safety Council (SDPSC) endorses the APSF statement6 that urges health care professionals to consider the potential safety value of using available technology to continuously monitor both oxygenation and ventilation in patients at risk for respiratory depression.

-San Diego Patient Safety Council