XR ASSOCIATION

December 22, 2020

Dr. Leith States, Chief Medical Officer
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Document # 2020-25328; Document Citation 85 FR 73280

Dear Dr. States:

The XR Association (XRA) is pleased to submit comments in response to the Request for Information regarding the Department of Health and Human Services Landscape Analysis To Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations.

The XR Association represents headset and technology manufacturers across the XR industry, including Oculus from Facebook, Google, HTC VIVE, Microsoft, and Sony Interactive Entertainment. XRA is leading the way for the responsible development and adoption of XR by convening stakeholders, developing research and best practices, and advocating on behalf of our members and the broader XR industry. Our mission is to champion the thoughtful advancement of XR solutions that foster positive societal outcomes.

XR technology (virtual, augmented, and mixed reality), while still emerging, is already adding value to healthcare in ways unmatched by other technologies. Specifically, with respect to the theme of this Request for Information (RFI), XR is able to deliver its benefits to those who have limited access to healthcare infrastructure such as hospitals and doctors' offices because it is virtual. With XR, patients across the country can take advantage of treatments previously unavailable outside of a physical medical space. Indeed, this care can be given in the patient's own home.

As you will learn from the discussion below, virtual, augmented, and mixed reality solutions serve to prevent increases in morbidity and mortality due to deferred care by allowing healthcare practitioners to diagnose, treat, and monitor a patient's condition in real time without seeing that patient in person. XR is also playing an increasingly important role in patient therapy and rehabilitation, providing alternatives to prescribing drugs like opioids and to costly, infeasible hospital visits. What's more, researchers are looking to XR as a potential solution to the impending surge of demand for Post-Intensive Care Syndrome therapy for COVID-19 patients because it provides the means to administer fast, temporary, and tailor-made rehabilitation services at a distance.

We believe virtual medicine is the future and that it answers the concerns articulated in this RFI, as well as many others. We welcome the opportunity to explore ways in which the government and the private sector can work together to enhance healthcare and improve people's lives with XR.

1. Virtual Medicine and the Future of Healthcare

Over the past decade, XR technology has shown great potential to enhance healthcare both in theory and in practice. XR's use in healthcare is now on the rise, from the operating room to the medical classroom, from pain management and rehabilitation to mental health. Experts estimate the market for XR in healthcare could reach $7B by 2026.[1] What's more, 75% of business leaders in decision-making roles in the healthcare industry report that they are optimistic about the use of XR technology and believe healthcare will be at the forefront of adopting enterprise XR solutions. Healthcare leaders are looking to XR technology to help solve some of today's and tomorrow's most pressing challenges.[2]

The COVID-19 pandemic has shifted healthcare practice towards telehealth. Yet while telehealth as it exists now is limited to patient-provider engagement via video chat, XR will allow the practitioner to see through the end-user's eyes in a form of embodiment. Eye-tracking within XR devices will provide an intimate view of a patient's interaction with their world and with other people, giving the health practitioner a glimpse into the patient's daily behaviors, perceptions, and even build empathy. XR will project the sensation of touch through hand-controllers, giving providers the haptics necessary to consider diagnoses. Indeed, studies demonstrate the value that XR experiences can bring to an abundance of healthcare scenarios, as illustrated below. As Americans have decreased the frequency of health system interaction during the pandemic, XR, which is virtual and immersive in nature, can significantly impact the health and wellness of underserved populations, including the aged and those living in rural areas.

2. Health Promotion Using XR-Driven Solutions

Pain Management, Chronic Pain, and the Opioid Crisis: Physicians are exploring virtual reality (VR) technologies as an alternative to pain relieving prescriptions, including opioids.[3] VR is a mind-body treatment that does more than just distract the mind from pain - it also helps to block pain signals from reaching the brain, offering a drug-free supplement to traditional pain management.

A 2019 study published in the Public Library of Science demonstrates the effectiveness of using virtual reality to combat pain in hospitalized patients. The 120 adults in the study were admitted to Cedars-Sinai Medical Center in Los Angeles for a variety of ailments including orthopedic problems, gastrointestinal diseases and cancer. All of the patients had an average pain score of at least three out of 10 during the 24 hours prior to participating in the study. Half of the patients were given VR goggles with a variety of relaxing and meditative experiences to choose from. They were advised to use the headsets three times a day for 10 minutes per session—and as needed for breakthrough pain—over three days. The other half of the patients were instructed to tune their in-room TVs to the health and wellness channel, which included guided-relaxation content such as yoga and meditation. They also were asked to view the channel three times a day for 10 minutes per session and as needed for breakthrough pain. Several times a day, nurses asked all the patients in the study to rate their pain using the standard zero to 10 scale. The study found the on demand use of VR resulted in statistically significant improvements in pain compared to the TV group, with patients in the VR group averaging

[1] *AR/VR in Healthcare Market to Reach USD 7.05 Billion By 2026*, GlobeNewswire, May 2019, available at https://www.globenewswire.com/news-release/2019/05/15/1825476/0/en/AR-VR-in-Healthcare-Market-To-Reach-USD-7-05-Billion-By-2026-Reports-And-Data.html

[2] *A New Reality in Immersive Technology (XR): Insights and Industry Trends,* September 2020, available at https://xra.org/a-new-reality-in-immersive-technology-2020/

[3] *Virtual Reality for Pain Management in New York: An Alternative to Opioids*, Miranda Felde, MHA, CPHRM, Vice President, Patient Safety and Risk Management, the Doctors Company, December 2018, available at https://www.thedoctors.com/articles/virtual-reality-for-pain-management-in-new-york-an-alternative-to-opioids/#7

1.7 points lower on the pain scale. When researchers analyzed findings from the subgroup of patients with the most severe baseline pain of seven or above, VR patients averaged three points lower than the TV group.[4] Another promising study of patients with neuropathic pain found that patients experienced a 69% reduction in pain during each VR session and a 53% pain reduction immediately after.[5] Many healthcare professionals believe that one day soon VR will be part of every doctor's tool kit for pain management.[6]

***Mental Health*:** Posttraumatic stress disorder (PTSD) develops as a result of directly experiencing, witnessing, or being repeatedly exposed to aversive details of a traumatic event such as death, combat, sexual assault or serious injury. A third of those confronted with a traumatic event subsequently develop clinically relevant PTSD symptoms such as re-experiencing, avoidance, hyperarousal and alterations in mood and cognition. Virtual reality is providing a viable approach to overcoming these intricate problems. VR offers multi-sensory cue representation in a highly interactive and emotionally engaging virtual environment. It carries the advantages of increased control over stimuli, unlimited repeat exposure, and the unique option to simulate environments that challenge the boundaries of everyday surroundings. Moreover, VR is shown to be effective in inducing stress and anxiety reactions which are comparable to those observed in analogous real-life situations.[7]

With respect to our nation's veterans, PTSD is one of the most debilitating psychological disorders affecting United States soldiers. Treatments for PTSD include psychological debriefing, which has been criticized for its questionable efficacy, and imaginal exposure therapy, which is problematic in that some PTSD sufferers are unable to engage well enough to elicit the necessary response. The weaknesses inherent in these treatments have created a pressing need for alternatives. Researchers cite virtual reality graded exposure therapy (VRGET) as a promising option. The Virtual Reality Medical Center (VRMC) conducted research, funded by the Office of Naval Research (ONR) and the Telemedicine and Advanced Technology Research Center (TATRC), studying virtual reality therapy as an early intervention tool for PTSD.[8] One study used VR therapy to treat PTSD in Vietnam veterans. In an initial case study, a VRGET patient experienced a 34% decrease in PTSD symptoms and a 45% decrease in self-ratings of symptoms. In a second study of 10 veterans with PTSD, the eight participants who were contacted at a 6-month follow-up reported a decrease in symptoms ranging from 15% to 67%. In the third project, a case study, the patient reported a dramatic drop in symptom levels, verified by standard PTSD measures, in both 3- and 6-month follow-up assessments.[9]

What's more, researchers are also utilizing VR as a PTSD prevention tool. One method being used in an attempt to prevent PTSD is Stress Inoculation Training (SIT). SIT is a technique to help "inoculate" individuals to future potentially traumatizing stressors. During preventative SIT, repeated exposure enables performers to gradually become desensitized to stimuli that may initially elicit such strong physiologic arousal that performance is impeded (i.e., "freezing in the line of fire") and psychological

[4] *New Study Shows Value of Virtual Reality for Pain Management*, Cedars Sinai, August 2019, available at https://www.cedars-sinai.org/newsroom/new-study-shows-value-of-virtual-reality-for-pain-management/
[5] *Virtual Reality for Pain Management in New York: An Alternative to Opioids*, Miranda Felde, MHA, CPHRM, Vice President, Patient Safety and Risk Management, the Doctors Company, December 2018
[6] *New Study Shows Value of Virtual Reality for Pain Management*, Cedars Sinai, August 2019
[7] *Virtual reality exposure therapy for posttraumatic stress disorder: a meta-analysis*, European Journal of Psychtraumatology, August 2019, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713125/
[8] *Virtual Reality as a Tool in Early Interventions*, Brenda K. Wiederhold, Ph.D., MBA, BCIA, and Mark D. Wiederhold, MD, Ph.D., FACP, the Virtual Reality Medical Center, Scripps Memorial Hospital, La Jolla, CA, April 2006, available at https://www.researchgate.net/publication/235210581_Virtual_Reality_as_a_Tool_in_Early_Interventions
[9] *Virtual Reality as a Tool in Early Interventions*, Brenda K. Wiederhold, Ph.D., MBA, BCIA, and Mark D. Wiederhold, MD, Ph.D., FACP, the Virtual Reality Medical Center, Scripps Memorial Hospital, La Jolla, CA, April 2006

trauma is likely. Phase I results indicated that those trained in a VR simulation while having stressors added (being shot at while tending to the wounded) were able to perform skills more effectively in the test phase of the study as compared to those trained in a "sterile" VR environment (no one shooting at them while tending to the wounded). Those receiving SIT were able to develop divided attention skills and learned to moderate physiological responses to stress while staying focused on the task at hand. Those not receiving SIT were pulled off task and experienced much more physiological arousal during the test phase (being shot at), which caused them to make mistakes (patients "died" or medics were "killed in action").[10]

***Alzheimer's and Dementia*:** Studies show that VR can effectively treat seniors living with advanced dementia like Alzheimer's disease and Huntington's disease by helping them to recall old memories that were otherwise unattainable due to illness or inaccessibility. Moreover, caregivers are able to learn more about patients' lives, helping to improve their social interaction. VR has been shown to improve mood, reducing levels of anxiety, depression, confusion and hostility, thus improving one's quality of life. As it becomes easier to produce virtual environments, creators will make VR settings that are custom to the patient, like a previous home or a favorite location.[11] A review published this April in the Journal of Alzheimer's Disease assessed existing studies on the benefits of VR for people living with Alzheimer's, especially when coupled with the use of contemporary neurodegeneration models and screening methods. The review found that VR is emerging as a viable method not only of therapy but also of diagnosis.[12] Given the prevailing emphasis on early diagnosis, cognitive-behavioral paradigms developed to target neuroanatomical sites compromised early in Alzheimer's disease are vital. Such assessments have been overlooked in the past, potentially owing to difficulty in application and replication. VR paradigms overcome these limitations.[13]

***Autism*:** The VR industry has an important role to play in shifting how we use technology to help support those on the autistic spectrum to connect, communicate and navigate.[14] Adults and children with autism have challenges in behavior, social skills, verbal and non-verbal communication, as well as sensory and attention issues that negatively impact their lives. Virtual reality is being embraced by therapists, counselors, teachers, parents, and their children to help the autistic better communicate and connect with the world around them. VR is also being used to help the non-autistic understand what living with the condition means. Many argue that there is no other medium that comes as close to putting you in someone else's shoes. What's more, people with autism are also using VR to convey their own experiences, both to raise awareness of the condition and to capture the cognitive and perceptual differences that characterize it.

Autism therapists and researchers started to use VR in the mid-1990s, often deploying the technology to create virtual environments to help autistic people prepare for encounters or situations that could be stressful. For example, the Center for BrainHealth and the Child Study Center at Yale University's School of Medicine collaborated to help young adults with autism achieve economic and social

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[10] *Virtual Reality as a Tool in Early Interventions*, Brenda K. Wiederhold, Ph.D., MBA, BCIA, and Mark D. Wiederhold, MD, Ph.D., FACP, the Virtual Reality Medical Center, Scripps Memorial Hospital, La Jolla, CA, April 2006
[11] *How Virtual Reality Can Help Seniors with Dementia*, Healthline, May 2019, available at https://www.healthline.com/health-news/heres-how-vr-can-help-people-with-dementia#Utilizing-VR
[12] *Use of Immersive Virtual Reality in the Assessment and Treatment of Alzheimer's Disease: A Systematic Review*, Journal of Alzheimer's Disease, April 2020, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7306888/
[13] *Use of Immersive Virtual Reality in the Assessment and Treatment of Alzheimer's Disease: A Systematic Review*, Journal of Alzheimer's Disease, April 2020
[14] *How Virtual Reality Can Help Those with Autism*, Sol Rogers, Forbes, April 2019, available at https://www.forbes.com/sites/solrogers/2019/04/03/how-virtual-reality-can-help-those-with-autism/?sh=4672f524198e

independence with the help of VR. In addition, phobias that often impact autistic people – fear of social situations, fear of public spaces, and fear of animals, for example - have been tackled with VR.[15]

Stroke Rehabilitation: Virtual reality-based rehabilitation programs are becoming an important complement to conventional motor therapy for stroke patients and individuals with neurodegenerative diseases. Immersion in virtual environments stimulates several sensory systems, especially sight and hearing, and intensifies central nervous system information input and output. The Brazilian Research Institute for Neuroscience and Neurotechnology (BRAINN) recently published a paper, "Biomechanics Sensor Node for Virtual Reality: A Wearable Device Applied to Gait Recovery for Neurofunctional Rehabilitation," that earned a Best Paper award in the Virtual Reality category at the 20th International Conference on Computational Science and its Applications (ICCSA 2020). The study described in the paper resulted in the development of a wearable device called Biomechanics Sensor Node (BSN) that captures user data and controls virtual environments, as well as a new software solution integrating the BSN with Unity Editor, one of the most widely used game engines and virtual world-building programs. Integration of the wearable with the Unity software means patients undergoing motor rehabilitation can interact with VR environments while the therapist views data for the movements performed during the session. The paper's author notes, "the technology is expected to increase brain connectivity by stimulating the new neural connections needed to repair the losses caused by injury or by the patient's clinical condition."[16] Another study highlighted improved walking and increased activation in cortical regions of stroke survivors after virtual reality-enhanced treadmill training and found that cortical recruitment was associated with better walking function. This study suggests that VR can improve training-induced recovery of gait function in stroke survivors.[17]

COVID-19, Telehealth, and Remote Practitioner Training: As the COVID-19 pandemic strains global healthcare resources and personnel, VR is helping to fill training and experience gaps. More than 300 doctors at Los Angeles' Cedars-Sinai hospital have learned new skills, such as how to assess a patient's symptoms or perform CPR while wearing protective gear, through VR. Early clinical research suggests that VR training reduces performance errors and increases accuracy relative to conventional training approaches.[18]

What's more, a paper published this fall by researchers at Radboud University Medical Center in the Netherlands argues that virtual reality could be key to COVID-19 rehabilitation. As the authors explain, many COVID-19 patients who were critically ill continue to have Post-Intensive Care Syndrome (PICS-COV) even after the infection is gone, leaving a potential risk for physical, psychological and cognitive impairment. The resources needed to provide rehabilitation treatment are expected to be inadequate because healthcare systems faced a shortage of high-quality treatment of these symptoms even before the COVID-19 crisis emerged in patients with comparable needs. VR provides healthcare practitioners with the means to administer fast, temporary and tailor-made

[15] *How Virtual Reality Can Help Those with Autism*, Sol Rogers, Forbes, April 2019
[16] *Virtual reality-based rehabilitation for recovery of stroke and neurodegenerative disease patients*, reviewed by Emily Henderson, B.Sc., News Medical, December 2020, available at https://www.news-medical.net/news/20201214/Virtual-reality-based-rehabilitation-for-recovery-of-stroke-and-neurodegenerative-disease-patients.aspx
[17] *Cerebral Reorganization in Subacute Stroke Survivors after Virtual Reality-Based Training: A Preliminary Study*, Behavioral Neurology, June 2017, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5506482/
[18] *Doctors and nurses are using VR to learn skills to treat coronavirus patients*, Samantha Murphy Kelly, CNN Business, April 2020, available at https://www.cnn.com/2020/04/21/tech/vr-training-coronavirus/index.html

rehabilitation services at a distance, and offers a solution to address the impending surge of demand for PICS-COV therapy.[19]

Relatedly, the Day One Project[20] included among its recommendations for the incoming Biden Administration an initiative to train 50,000 new nurses in VR over the next four years. Nursing instruction is already applying simulation training and seeing positive results; but application of VR will take this training to the next level. There is evidence that VR works in this context. The Robert Morris University in Pennsylvania, for example, developed a VR game to allow nursing students to practice urinary catheter insertion. Research showed that students spent more time practicing, completed more procedures in a 60-minute period, and gave higher marks to the immersive experience.[21]

3. Barriers and Opportunities for XR-Driven Solutions

One significant barrier to broad adoption and use of XR is a lack of access to 5G networks. XR relies on high download and upload speeds as well as low latency to deliver the immersive experience to the end user. With respect to augmented reality (AR) specifically, the ability to use AR in live, outdoor environments, away from reliable wi-fi signals, influences the types of interactions and integrations that developers can build for this space. 5G spectrum access can also be expensive for the end user. Typical mobile contracts are not permissive for 5G's increased data consumption. Thus, VR and AR serve as a faster way to accumulate overage charges or max their data plans, which stymies wider adoption.

Also, with respect to cost, while optimism about XR technology is extraordinarily high among business leaders, real and perceived barriers to adoption remain. When asked to choose the top three barriers to XR technology expansion, 26 percent of business leaders placed potential cost first.[22] Cost-sharing programs between the private sector and the government could help. For example, cost-sharing with long-term care facilities and community health centers - particularly around the acquisition of hardware and the training of healthcare practitioners - would help eliminate a significant obstacle.

4. Public-Private Partnership

Notably, business leaders generally agree that the federal government has a role to play in the development and adoption of XR technologies.[23] Federal funding has been critical in developing VR technology thus far, enabling universities to create and maintain leading-edge VR research centers, which have in turn contributed to the information revolution. Industry sectors and companies that generate billions of dollars in annual revenue trace their roots to federally funded research. A primary benefit of federal funding, particularly of university research, has been the creation of human resources that have carried out, and driven advances in, VR research. A number of graduate students and academic researchers who received federal support have made significant contributions to the field and

[19] *Could Virtual Reality play a role in the rehabilitation after COVID-19 infection?*, BMJ Open Sport Exerc Med. 2020, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7642212/
[20] The Day One Project is an organization working with new and expert voices across the science and technology community, helping them develop actionable policies that can improve the lives of all Americans, and readying them for Day One of the next presidential term.
[21] *Using Game-Based Virtual Reality with Haptics for Skill Acquisition*, Clinical Simulation in Nursing, Volume 16, P25-32, March 1, 2018.
[22] *A New Reality in Immersive Technology (XR): Insights and Industry Trends,* September 2020
[23] *A New Reality in Immersive Technology (XR): Insights and Industry Trends,* September 2020

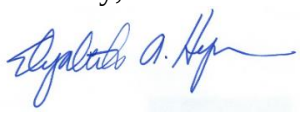
have established leading companies.[24] Moreover, federal research and development (R&D) funding has laid a foundational plank for the United States' ability to compete and lead internationally. It promotes finding and identifying new solutions to both existing problems as well as new challenges. Indeed, federal R&D spending has often yielded great returns on investment, seeding successes[25] such as the internet, the Google search engine, the MRI, and the Human Genome Project—ubiquitous advances that play critical roles in improving people's lives.[26]

The XR Association is committed to the development and adoption of XR to help individuals and enhance society as a whole. Our objective is to see Americans across the board – regardless of socioeconomic status, age, or location - benefit from XR. Public-private partnerships would help to advance the technology in this spirit. We believe there are opportunities for the XR industry to collaborate with a whole host of government entities with respect to XR and healthcare, including not only the Health and Human Services Department and its components like the Indian Health Service and the Administration for Community Living, but also the Veterans Administration; the Center for Medicare and Medicaid Services; and the White House Office of Science and Technology Policy. We are also actively engaging with Senators and Members of Congress, as well as experts in civil society, academia, and science to ensure XR technology respects the individual's right to privacy as we strive to establish best practices for data collection, storage, and processing that are consistent with societal and ethical norms around the world. In addition, XRA is working with industry partners, disability advocacy groups, and members of the disabled community to establish best practices for inclusive design that enable use of XR by everyone, regardless of physical ability.[27]

We hope the information above provides a good understanding of how the XR industry is approaching innovative efforts around healthcare, especially with respect to aging and underserved populations. We believe a public-private partnership would accelerate the realization of the full potential of this burgeoning technology and help to ensure its benefits can be successfully delivered to healthcare providers and patients alike. Each use case has tremendous independent growth potential, and over time, XR developers and healthcare consumers will need to learn how best to utilize and apply this tool. In the meantime, our hope is that developers, insurance companies, and healthcare providers, alongside vested policymakers, continue to make meaningful decisions to encourage innovation.

We are eager to further discuss the form and function of potential collaboration.

Sincerely,



Elizabeth Hyman, CEO
XR Association

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[24] *Funding a Revolution: Government Support for Computing Research*, *Chapter: 10 Virtual Reality Comes of Age*, The National Academies Press, 1999, available at https://www.nap.edu/read/6323/chapter/12#p200065669960231001

[25] *Federally Supported Innovation: 22 Examples of Major Technology Advances That Stem from Federal Research Support*, Information Technology and Innovation Foundation, 2014, available at http://www2.itif.org/2014-federally-supported-innovations.pdf

[26] *Redesigning Federal Funding of Research and Development*, The Center for American Progress, Christian E. Weller, Rhonda V. Sharpe, Danyelle Solomon, and Lisa D. Cook August 18, 2020 available at https://www.americanprogress.org/issues/race/reports/2020/08/18/489609/redesigning-federal-funding-research-development/

[27] *XRA'S DEVELOPERS GUIDE, CHAPTER THREE: Accessibility & Inclusive Design in Immersive Experiences*, October 2020, available at https://xra.org/wp-content/uploads/2020/10/XRA_Developers-Guide_Chapter-3_Web_v3.pdf