October 29, 2019
Submitted via email
The Honorable Michael Shirkey  
Senate Majority Leader  
Michigan Senate  
100 North Capitol Avenue  
Lansing, MI 48933

The Honorable Lee Chatfield  
Speaker of the House  
Michigan House of Representatives  
100 North Capitol Avenue  
Lansing, MI 48933

Dear Mr. Majority Leader and Mr. Speaker:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this letter to implore the Michigan State Legislature to stop the regulation of Immune Effector Cell Therapy (IECT) under the Michigan Certificate of Need (CON) program.

Not only will regulation under CON increase costs for Michigan, but it will also threaten patient access to important new therapies for cancer and other serious diseases. We note that no other state CON programs across the country regulate any drug or related therapies because it is widely recognized that the regulation of drug and related therapies is totally outside the scope of CON but instead is regulated by the FDA. The move to regulate drugs under CON is extremely alarming. As such, COA strongly recommends and requests that the Michigan State Legislature pass a concurrent resolution to reject the Michigan CON’s proposed new standard and regulation of IECT.

COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. For more than 16 years COA’s mission has been to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work.

CON programs are intended to control and lower health care costs while also ensuring patient safety and access by limiting unnecessary and expensive capital investments in technology by health care providers and facilities. The safe and effective administration of IECT, such as CAR-T, does not require any additional (and expensive) investment that is typically regulated by state CON programs.

Community oncology practices administer approximately 55% of cancer care in the United States. It is important to understand that there are state-of-the-art community oncology practices that have significant experience and capabilities in administering highly complex treatments in the outpatient setting. For example, stem cell transplants, which are similar in complexity to CAR-T therapy, are performed successfully in the community oncology practice setting. Such procedures often require the same infrastructure that CAR-T requires, with a designated care area that protects patients from transmission of infectious agents and allows for appropriate evaluation and treatment. In cases, community oncology practices conduct these complex procedures on their own. In other cases,
they do so in partnership with hospitals. For those practices that would need to partner with hospitals to administer CAR-T therapy, those relationships and capabilities are already in place.

Another example of community oncology practices’ experience with treatments similar in complexity to CAR-T is bispecific antibodies (BITEs), which have similar potential toxicity profiles as CAR-T. BITEs are typically administered in the outpatient setting and are already being administered in community, nonacademic settings of care in both hematologic malignancies and solid tumors. There are at least four studies in hematologic malignancies and five in solid tumors.

Basic requirements to administer CAR-T therapy, including apheresis, cell processing and infusion, and lymphodepleting chemotherapy, as well as toxicity management, are activities frequently performed in the outpatient setting. As for organizational capabilities to run such a program, community oncology practices have experience with requirements such as Risk Evaluation and Mitigation Strategies (REMS) programs, distance policies, CAR-T specific nursing support and patient education, registry reporting, and more.

It is extremely important to understand that some community oncology practices have already or are currently participating in studies on CAR-T, as well as T-cell receptor and antibody-coupled T-cell receptor, which are different technologies than CAR-T but that are also considered immune effector cell therapies. As an example, one of our member practices has already participated or is currently participating in 15 such trials for hematologic malignancies and eight for solid tumors. Practices’ direct experience conducting scientific research in CAR-T and related treatment areas demonstrates their ability, in many cases, to meet and exceed the research and evidence generation requirements outlined in the proposed NCD.

Regarding patient safety issues as raised by the Michigan State CON proposed regulation, we note that the FDA requires complete and comprehensive safety criteria and standards for any facilities to administer CAR-T under REMS. Whereas REMS is a drug-specific safety program, the Foundation for the Accreditation of Cellular Therapy (FACT Accreditation) is facility-specific. As such, the Centers for Medicare and Medicaid Services (CMS) issued a final National Coverage Decision (NCD) that provides coverage and to CAR-T in any independent practice or hospital enrolled in the FDA REMS program. Because of this, CMS decided against requiring FACT accreditation for CAR-T administration. As such, the Michigan State CON proposal is much more restrictive than requirements by both CMS and the FDA.

For all the reasons stated in this letter, COA strongly recommends and requests that the Michigan State Legislature pass a concurrent resolution to reject the Michigan CON’s proposed new standard and regulation of IECT.

Sincerely,

Ted Okon
Executive Director

CC: Members of the Michigan Senate
Members of the Michigan House of Representatives