Alliance for Regenerative Medicine

July 23, 2019

Chairperson James Falahee
c/o Michigan Department of Community Health Certificate of Need (CON) Program
Policy Section
South Grand Building
333 S. Grand Ave.
Lansing, MI 48933
MDHHS-ConWebTeam@michigan.gov

Re: Proposed New Standard for Immune Effector Cell Therapy (IECT) Services

Dear Chairman Falahee and the CON Commission,

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to comment on the creation of a new standard for Immune Effector Cell Therapy (IECT) Services, which includes the administration of CAR T therapies. If implemented, this new standard would require any facility to receive both the Commission's approval and a third-party accreditation from the Foundation for the Accreditation of Cellular Therapy (FACT) in order to deliver these transformative therapies to patients in Michigan. Each facility has three years to receive both the Commission's approval and FACT accreditation.

ARM understands that this new process was developed to ensure quality of care and promote the safe administration of this new and innovative class of therapies. ARM, however, respectfully disagrees with the premise behind this new accreditation program because the manufacturing process for CAR T therapies and the current manufacturer site accreditation process already ensures safe administration and does not require a significant capital investment. As such, a new standard is not necessary. Specifically, the specialized re-engineering of a patient's T cells are manufactured off-site by the manufacturer of the CAR T and each manufacturer already accredits each facility via a FDA REMS requirement.

Therefore, ARM asks that you rescind the recommendation to create a new standard for IECT that will be an onerous barrier to access, create an unnecessary financial burden on health care facilities across the state, and limit the sites of care from offering cellular therapies to patients.

ARM is an international multi-stakeholder advocacy organization that promotes legislative, regulatory, and reimbursement initiatives necessary to facilitate access to life-giving advances in regenerative medicine worldwide. ARM comprises more than 300 leading life sciences companies, research institutions, investors, and patient groups

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that represent the regenerative medicine and advanced therapies community. ARM takes the lead on the sector's most pressing and significant issues, fostering research, development, investment, and commercialization of transformational treatments and cures for patients worldwide. As of year-end 2018, ARM estimates there are 906 regenerative medicine and advanced therapies developers worldwide sponsoring 1,028 clinical trials across dozens of indications, including oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.[1]

A subset of these clinical trials focuses on the power of chimeric antigen receptor (CAR T) therapies. These therapies are the first in a wave of new and exciting advanced therapies and technologies that are the next frontier in the fight against some of humankind's most devastating diseases and disorders. CAR T therapy is a type of treatment in which a patient's T cells (a type of immune system cell) are changed in the laboratory so they will attack cancer cells. T cells are taken from a patient's blood, as it flows through a tube to an apheresis machine, which removes the white blood cells, including the T cells, and sends the rest of the blood back to the patient. Then, the gene for a special receptor called a chimeric antigen receptor (CAR) is inserted into the T cells in the laboratory. Millions of the CAR T cells are grown in the laboratory and then given to the patient by infusion. The CAR T cells are able to bind to an antigen on the cancer cells and kill them.[2] ARM is currently tracking the outcomes of the approximately 158 ongoing clinical trials using the CAR T technology in a variety of stages of cancer and cancer types. ARM believes that this new and promising technology provides the possibility that most future treatments for many types of cancer at its many stages will focus on using the power of the patient's immune system to fight their particular disease.

What's critical about all the technologies represented by ARM, including CAR T, immunotherapy, and cell and gene therapy, is that many of the products are transformative – they provide a durable therapeutic benefit or even a cure with a single administration of the therapy. For patients suffering from a diverse array of serious and costly conditions, many without current therapeutic option, this field represents enormous potential and hope.

1. **Creating a New Standard for IECT is Outside the Scope and Jurisdiction of the Michigan Certificate of Need (CON) Program**

ARM believes that the jurisdiction to create a new standard to regulate CAR T cell therapy is outside the intent and scope of the Michigan CON Commission because the CON program is intended to control health care costs while ensuring safety and access by restricting health care facilities from unnecessary and expensive capital investments to serve their patient populations. These factors do not exist for a CAR T administration.

[1] https://alliancerm.org/publication/2018-annual-report/
[2] https://www.cancer.gov/publications/dictionaries/cancer-terms/def/CAR T-cell-therapy

Given current federal regulatory oversight of the manufacturing process, the new standard is unnecessary. Cell therapy products, such as those identified in the proposed language, can only be marketed if they receive FDA approval. By definition, that ensures that the products have undergone the scientifically rigorous FDA review process and have demonstrated safety. In addition, under current FDA rules, the agency has the authority to use Risk Evaluation and Mitigation Strategies (REMS) and other required programs to limit where patients can receive therapies – particularly new cell therapies. In other words, the safety of CAR T therapies is determined by the FDA and the FDA can regulate the site of care for administration. Finally, the significant capital investment required to create a CAR T therapy is absorbed by the manufacturer at a manufacturer's FDA regulated facility. The provider is not manufacturing the CAR T therapy such that neither objective of the CON program applies to CAR T therapies.

ARM urges the Commission to reject the new proposed standard because the scope of the CON program does not apply to CAR T therapies. Rather, ARM believes the FDA is best suited to regulate and determine the safety conditions for administering this new classes of therapies.

2. **Proposal to Require Third Party Accreditation Will Limit Access to CAR T cell therapy for Michiganders**

As stated above, the safety criteria are an important component of what a facility must demonstrate to deliver CAR T cell therapy and manage the associated adverse events. In their review and approval, the FDA requires comprehensive safety criteria and standards for any facilities to provide CAR T cell therapy through REMS. Additionally, the federal government is currently reviewing coverage and access for CAR T cell therapy, which may include additional provider site requirements. While we are encouraged by the discussion and interest of the Michigan CON Commission to provide CAR T therapy to patients, we believe it is premature for the Commission to approve any recommendation that could limit patient access by requiring additional onerous and costly approvals and third-party accreditation on sites of care that go beyond what the federal government requires, which may discourage or prevent sites of care from providing CAR T therapy to patients.

ARM believes that the proposed changes will negatively impact patient access to current and potentially new therapies. Based upon this new proposed standard, it seems that all of these facilities would now need to apply for a CON, which will likely disrupt access to current and future marketed therapies.

For example, based on current regulatory requirements and the burdensome process of obtaining a CON, many facilities will not be certified and their patients will have to seek care elsewhere. This will create a significant disruption in care, deterioration of treatment, and is likely to limit patient access to treatments that patients are currently receiving.

In addition, by restricting the number of facilities that a patient could receive a cell therapy treatment, the proposal specifically limits patient access to new transformative cell therapies. We have heard from many patients suffering from cancer about how these products represent their last and best chance for survival. To deliberately limit access to care for these patients would be, at best, unjust.

For a patient who receives CAR T therapy, the medically appropriate selection of administration as an inpatient or outpatient, in a transplant or non-transplant center, will depend on their treating provider's clinical judgment of the patient's clinical circumstances and the safety-related labeling provisions for the relevant CAR T therapy. With over 80 percent of cancer patients currently being treated in the community setting, it is imperative to ensure patient access to these new and transformative therapies, a provider's medical judgment and the patient's individual medical needs should determine the appropriate site of care. A new standard for IECT will prematurely limit the sites of care that can and will provide CAR T cell therapy services.

3. **The Proposed Changes are Likely to Increase Medical Costs**

By limiting the sites that can provide these potential lifesaving therapies, the sites gain significant leverage against payers for network participation. The CON sites will likely be able to dictate payment rates to Michigan health plans because they will be the only providers of these lifesaving therapies. These increased costs to the health plans could result in higher premiums for all patients. ARM believes that the new proposed standard will harm actual patient access to currently available and new and innovative therapies while also harming access due to the likely increased financial burden.

Conclusion

ARM believes it is unnecessary to require additional onerous and costly approvals and accreditations on any facilities that go beyond what the federal government requires, which may discourage or prevent sites from providing CAR-T cell therapy to patients.

ARM therefore urges the Michigan Certificate of Need Commission to take into consideration our comments and reject the proposed new standard for IECT. ARM looks forward to working with you to create policies that afford appropriate and equal access to innovative therapies. If you have any questions or need any additional information, please do not hesitate to contact me at rfalb@alliancerm.org

Sincerely,

Robert Falb
Director, U.S. Policy and Advocacy

Beaumont

July 11, 2019

Certificate of Need Commission
c/o Policy, Planning and Legislative Services
Michigan Department of Health and Human Services
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need Commission:

On behalf of Beaumont Health, I would like to express our support for the newly developed CON Review Standards for Immune Effector Cell Therapy (IECT) that the Commission took proposed action to approve on June 13, 2019.

We believe that the new standards will improve future access to IECT, including CAR-T Cell Therapy. We also believe it is appropriate to require FACT accreditation as a criterion for CON approval. Beaumont, Royal Oak's chairman of the Medical Hematology Oncology Department, Dr. Ishmael Jaiyesimi, participated on the BMT Standards Advisory Committee (SAC), which developed the new IECT CON standards, and is in support of the recommendations of this SAC. Beaumont is also in support of IECT becoming its own CON covered clinical service, as opposed to being incorporated into the BMT CON review standards.

We recommend that the Commission take final action to approve the proposed standards at the September 19 CON Commission Meeting. Thank you for the opportunity to provide comment.

Sincerely,

Nancy Susick

Nancy Susick, MSN, RN
President
Beaumont Hospital, Royal Oak

VIA ELECTRONIC DELIVERY

July 15, 2019

Michigan Certificate of Need Commission
c/o Michigan Department of Community Health Certificate of Need
Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

MDHHS-ConWebTeam@michigan.gov

Re: Proposed Standard for Immune Effector Cell Therapy (IECT) Services

Dear Chairman Falahee and the Certificate of Need (CON) Commission:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to include its voice in public comments on the Proposed Standard for Immune Effector Cell Therapy (IECT) Services.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Advances in cutting-edge medical science and technology are paving the way for the next generation of potential cancer treatments, such as CAR-T therapy. CAR-T therapies are made specifically for each patient isolating the patient's own T cells and re-engineering them to kill cancer cells and then returning the patients T cells back to the patient. This is a new and evolving technology as there are hundreds of active CAR-T clinical trials underway that are studying the therapy in both blood cancers and solid tumors.

In Michigan, the Certificate of Need program is considering a proposal to create a new standard for "Immune Effector Cell Therapy (IECT) Services," which would include CAR-T therapy. This new standard would require any site of care to receive CON committee approval and accreditation from the Foundation for the Accreditation of Cellular Therapy (FACT) within three years.

Our comments address the following topics:

- CAR T-cell therapies should not be subject to a state CON process;
- CAR-T is analogous to any other therapy which is administered via systemic routes of administration and additional approvals and accreditations that go beyond what the federal government requires are onerous and unnecessary; and

- Subjecting CAR T-cell therapies to CON processes raises patient access concerns.

I. It Is Inappropriate and Unnecessary to Subject CAR-T Therapy to a State CON Process

While BIO is encouraged by the discussion and interest by the Michigan's CON Commission to provide CAR-T therapy to patients, we believe it is inappropriate for the Commission to approve any recommendation that could limit patient access by creating a new standard for CAR-T therapy before the federal government releases a final decision on site criteria. Additionally, we believe requiring additional onerous and costly approvals and third-party accreditation to establish new sites of care that go beyond what the federal government requires, may discourage or prevent sites of care from providing CAR-T therapy to patients.

II. CAR-T Therapy Clinical and Access Standards Will Be Thoroughly and Adequately Administered at the Federal Level

Safety criteria are an important component of what a potential treatment facility must demonstrate to deliver CAR-T cell therapy and manage the associated adverse events. In their review and approval, the U.S. Food and Drug Administration (FDA) requires comprehensive safety criteria and standards for any facilities to provide CAR-T cell therapy through Risk Evaluation and Mitigation Strategies (REMS). Additionally, the federal government is currently reviewing coverage and access for CAR-T cell therapy, and the Centers for Medicare and Medicaid Services (CMS) has issued a Proposed Decision Memo which includes additional site requirements as conditions for continued coverage under the Medicare program. The CAR- T cell product is analogous to any other therapy which is administered via systemic routes of administration and should not be subject to additional requirements. For Michigan and other states to establish a patchwork of potentially varying or conflicting standards would sow confusion among patients, clinicians, and facility administrators, potentially delaying access to CAR-T therapy to patients who badly need it.

We therefore believe it is unnecessary to require additional onerous and costly approvals and accreditations on any facilities that go beyond what the federal government requires, which may discourage or prevent sites from providing CAR-T cell therapy to patients.

III. Subjecting CAR-T to CON Processes Raises Patient Access Concerns

According to the Commission's own bylaws, it must take special accounts of the health needs of its rural residents. The bylaws state specifically that the state must take "consideration of the health care needs of residents in rural counties in ways that do not compromise the quality and affordability of health care services for those residents…."[i] Patients in Michigan and elsewhere already face unacceptable barriers to accessing CAR-T therapy. Currently, residents in Copper Harbor in the Upper Peninsula face a drive of approximately nine hours to access CAR-T therapy in Grand Rapids, or approximately 10 hours to access it in Detroit or Ann Arbor.[ii] The CON Commission therefore need not erect any additional barriers to opening new therapy centers, nor maintain existing barriers, by piling on additional administrative requirements for establishing CAR-T therapy centers when the treatment protocols and coverage standards are already effectively promulgated

by the FDA and the medical community, and will soon be promulgated for the Medicare program by CMS.

For all these reasons, we ask that the Michigan CON Commission reject the proposed new standard for IECT.

Conclusion

BIO appreciates the opportunity to comment on this important issue. Should you have any questions, please do not hesitate to contact me at (202) 962-9200.

Sincerely,

/S/

Andy Cosgrove
Senior Director, Health Policy

Crystal Kuntz
Vice President, Healthcare Policy & Research
Biotechnology Innovation Organization

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[i] Michigan Certificate of Need Commission Bylaws, Article III, General Purpose. December 11, 2014. https://www.michigan.gov/documents/mdch/ByLaws_325718_7.pdf Accessed July 2, 2019.

[ii] According to its website, Yescarta is currently available in only three areas in Michigan, all in the southern half of the state. These are the Approximate driving times from Copper Harbor to Grand Rapids or Detroit using Google Maps. Accessed July 2, 2019.

CANCER & HEMATOLOGY
Centers of Western Michigan, P.C.
orchestrating results

July 30, 2019

Re: Proposed Standard for Immune Effector Cell Therapy (IECT) Services

Dear Chairman Falahee and the CON Commission,

Advances in cutting-edge medical science and technology are paving the way for the next generation of potential cancer treatments, such as CAR T therapy. All new and evolving technologies such as historic cytotoxic chemotherapy, immunotherapy (*i.e. Provenge*) or PDL-1 drugs at one point in history were new with immune-mediated side effects that were mastered in the community setting. There are hundreds of active CAR T clinical trials underway that are studying the therapy in both blood cancers and solid tumors and will undoubtable enter the everyday cancer therapy world.

With over 80 percent of cancer patients currently being treated in the community setting, it is imperative to ensure patient access to these new and transformative therapies across the state of Michigan fairly. Any new standard for IECT that prematurely limits the sites of care that can and will provide CAR T cell therapy services will do a disservice to our patients.

While we are encouraged by the discussion and interest by the Michigan's CON Commission to provide CAR T therapy to patients, we believe it is premature for the Commission to approve any recommendation that could limit patient access by:

- Creating a new standard for CAR T therapy before the federal government releases a final decision on site criteria.

- Requiring additional onerous and costly approvals and third-party accreditation on sites of care that go beyond what the federal government requires, which may discourage or prevent sites of care from providing CAR T therapy to all patients throughout Michigan.

We welcome any additional dialog you would like to have with our practice and how this impacts cancer care in West Michigan. Information regarding *Cancer & Hematology Centers of Western Michigan* can be found at www.chcwm.com and I can be directly reached at 616-724-7711.

Sincerely,

Mark Campbell, MD, MHA, President: Mark Stroud Campbell

Copy Executive Committee
Thomas Gribbin, MD, Vice President
Timothy O'Rourke, MD, Treasurer
Amy VanderWoude, MD, Secretary
Brett Brinker, MD
Nehal Lakhani, MD
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Sent to: MDHHS-ConWebTeam@michigan.gov

Richard H. Bagger
EVP, Corporate Affairs &
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Celgene Corporation
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August 1, 2019

Michigan Certificate of Need Commission
c/o Michigan Department of Community Health Certificate of Need
Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

MDHHS-ConWebTeam@michigan.gov

Re: Proposed Standard for Immune Effector Cell Therapy (IECT) Services

Dear Chairman Falahee and the Certificate of Need (CON) Commission:

Celgene is a global biopharmaceutical company specializing in the discovery, development, and delivery of therapies designed to treat cancer, inflammatory, and immunological conditions. Celgene strongly believes that medical innovation can lead to better health, longer life, reduced disability, and greater prosperity for patients and our nation. To this end, we seek to deliver truly innovative and life-changing therapies for the patients we serve. Currently, there are more than 225 Celgene-sponsored clinical trials underway, examining at least 47 unique compounds for more than 60 indications.

Since its founding, Celgene has been committed to discovering and developing treatments in disease areas with unmet need. Notably, Celgene has played a central role in the significant improvement in outcomes for patients with serious and life-threatening hematological malignancies. We believe that genetic modification of T cells with chimeric antigen receptors (CARs) represents a potential new era for the effective treatment of these cancers.

Celgene is committed to the development of CAR T cell therapies across multiple cancers and indications. Presently, Celgene has two late stage CAR T cell therapies in development for difficult to treat cancers: ide-cel for the treatment of multiple myeloma and liso-cel for the treatment of lymphoma.

This commitment to cell therapy is evidenced by our significant investment in the research and specialized manufacturing required to effectively deliver CAR T cell therapies to patients. In 2018, we opened our second CAR T manufacturing site in Summit, NJ, in

addition to our existing manufacturing site in Bothell, WA. Celgene believes that CAR T cell therapy offers significant promise for patients with challenging cancer diagnoses, and we are proud of the work that we are doing to bring these innovations to patients.

Given the unique nature of CAR T cell therapy, and its potential to transform the treatment of cancer, we urge the CON Commission not to limit access to CAR T cell therapy to sites that have FACT accreditation and approval by the CON Commission for the following reasons:

- CAR T cell therapy studies are already underway in a variety of clinical settings, including in sites that have not obtained FACT accreditation.
- A requirement for both CON approval and FACT accreditation may inhibit access to this transformative technology based upon an individual patient's location.
- The federal government is currently considering standards for sites delivering CAR T cell therapy through a National Coverage Decision that is currently pending, and the FDA has clear Risk Mitigation and Evaluation Strategies (REMS) requirements for the currently marketed CAR T cell therapies.

CAR T cell therapy studies are already underway in a variety of clinical settings
Given the rapid advancement and evolution of CAR T cell therapy, there are currently more than 500 clinical trials underway to study the safety and efficacy of CAR T cell therapy across a variety of indications, patient populations and clinical settings that include both FACT accredited and non-FACT accredited sites.

Celgene is currently conducting multiple studies in outpatient sites of care, including sites that do not have FACT accreditation. The OUTREACH study[1] is designed to test the safety of liso-cel in outpatient sites of care that are non-hospital based specialty oncology sites in order to safely expand access of care to qualified oncology care sites that can support CAR T cell administration and management. PILOT[2] is a study in second-line, transplant non-eligible patients. This patient population is treated predominantly at non-academic centers that also have a predominantly outpatient site of care model.

Both trials will contribute significantly to our experience and data around administering CAR T cells safely in the outpatient setting, including in sites that may or may not be FACT accredited. However, these sites have several defining characteristics that represent relevant experience and capability to treat patients with CAR T cell therapy. First, they have demonstrated one of the following core capabilities: Transplant capability, phase 1 hematology/oncology trial experience, or CAR T experience with currently marketed CAR T cell therapies. Second, they work in a coordinated care model that includes cross functional CAR T cell therapy medical teams. Lastly, they are able to function seamlessly across the various disciplines and include oncologists, nurse coordinators, specialists such as neurologists and ICU physicians, apheresis centers, emergency room, infusion centers, and inpatient hospital staff to care for each patient. These are all sites that, whether FACT accredited or not, remain on the cutting edge of new therapies to treat cancer.

[1]Clinicaltrials.gov: A Safety Trial of Lisocabtagene Maraleucel (JCAR017) for Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL) in the Outpatient Setting, available at https://clinicaltrials.gov/ct2/results?cond=&term=NCT03744676&cntry=&state=&city=&dist=
[2] Clinicaltrials.gov: Lisocabtagene Maraleucel (JCAR017) as Second-Line Therapy (TRANSCEND-NHL-006), available at https://clinicaltrials.gov/ct2/show/NCT03483103?term=NCT03483103&rank=1

Like with many new medical advancements, CAR T cell therapy use began predominantly in academic medical centers. However, as the therapy evolves, including as new therapies with unique safety and efficacy profiles come to market, trials will have been conducted in a variety of clinical settings to demonstrate that safe delivery of CAR T does not need to be limited to FACT accredited centers. It is simply too early in the development and evolution of CAR T cell therapy for the CON to proactively decide to limit access to this transformative therapy.

A new standard that requires both CON approval and FACT accreditation may inhibit access to this transformative technology based upon an individual patient's geographic location.

The burden of travel from a patient's residence to healthcare centers is an important factor that influences access to treatment. Celgene recently conducted a study analyzing the geographic proximity of eligible lymphoma patients to sites delivering CAR T cell therapy to determine how proximity to care would change for eligible patients if CAR T cell therapy were offered only in academic settings, versus in a broader set of an additional 121 additional sites, including non-academic hospitals and specialty oncology network centers.[3] Among the findings:

- Each year, approximately 300 fewer third-line DLBCL patients would be within 50 miles to the nearest treatment center if sites are limited to academic hospitals compared to the scenario of all specialized sites. Of these, approximately 60 patients may not be willing to travel, even for improved survival benefits.[4]
- If CAR T therapies are only offered in academic hospitals, 40.5% of centers would be the sole providers with a 25-35 mile range, straining capacity, limiting referring physician choice and patient access to care, and imposing economic burdens on patients and payers.
- The median time a patient would need to travel to receive treatment would be 106 minutes if treatment is limited to academic sites, a 26.4% increase over broad availability of CAR T at all specialized oncology sites.

We believe these findings demonstrate the consequences that can be associated with limiting sites of care for CAR T cell therapy. While we understand that some non academic sites may be willing to undergo the time and expense necessary to achieve FACT accreditation, we do not believe that this is a prerequisite necessary to deliver safe and effective CAR T cell therapy treatment in light of standards in place by the FDA and individual biopharmaceutical companies. These site restrictions have real implications for patients living in rural areas.

The federal government is currently considering standards for sites delivering CAR T cell therapy through a National Coverage Decision that is currently pending

On May 17, 2018, the Centers for Medicare and Medicaid Services began a National Coverage Analysis for the Coverage of CAR T cell therapy for Medicare beneficiaries. The

[3] Data on file; July 2019

[4] Mitchell, Jean M., and Elizabeth A. Conklin. "Factors Affecting Receipt Of Expensive Cancer Treatments And Mortality: Evidence From Stem Cell Transplantation For Leukemia And Lymphoma." Health Services Research 50.1 (2014): 197-216.; Bristow, Robert E. et al. "Spatial Analysis Of Adherence To Treatment Guidelines For Advanced-Stage Ovarian Cancer And The Impact Of Race And Socioeconomic Status." Gynecologic Oncology 134.1 (2014): 60-67.; and Schwam, Zachary G., Zain Husain, and Benjamin L. Judson. "Refusal Of Postoperative Radiotherapy And Its Association With Survival In Head And Neck Cancer." Radiotherapy and Oncology 117.2 (2015): 343-350.

coverage decision, based on a review of the clinical evidence, will determine under what conditions CMS considers CAR T cell therapy "reasonable and necessary" for Medicare beneficiaries. Given the enormous consequence of this decision by CMS and the likelihood that it will be finalized in the very near term, it would be, at a minimum, premature for the CON commission to make decisions about site restrictions for CAR T cell therapy in Michigan that could be in conflict with the decision by the federal government and also limit patient access.

Conclusion

Celgene is committed to delivering truly innovative and life-changing therapies for patients and is excited about the promise and quickly evolving science of CAR T cell therapy. It is premature to regulate IECT under the CON program by creating a new standard which will require onerous and costly approvals and accreditations on sites of cares. We request that the CON commission reject the proposed new standard for IECT so that this innovation can reach more patients across the state.

Thank you for your consideration of our comments. If you have any questions or need additional information, please contact me or our State Government Relations Director, Helen Fitzpatrick at (312) 330-2884 or hfitzpatrick@celgene.com.

Sincerely,

Richard H. Bagger
Executive Vice President
Corporate Affairs and Market Access

Henry Ford Health System
One Ford Place
Detroit, MI 48202

July 19, 2019

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) strongly supports the new set of standards for Immune Effector Cell Therapy (IECT) Services.

The newly proposed standards respond to the goals of Certificate of Need in Michigan by ensuring access to high quality care while avoiding unnecessary costs and recognizing the difference between IECT and Bone Marrow Transplantation, and the need for a separate set of standards.

- **Cost-** Treatment cost approximately $800,000 (including the IECT treatment and associated inpatient care). Ensuring all treatments are provided at facilities with FACT (Foundation for the Accreditation for Cellular Therapies) accreditation will help consolidate this service at facilities that can provide all types of IECT rather than splitting these treatments across a mix of facilities that can only perform some and not all of the treatments that are required. This will save costs related to duplicative equipment and services at sites that do not have the proper staffing, policies and procedures, and facilities to meet FACT accreditation.

- **Quality-** By requiring FACT accreditation for all facilities providing IECT services we are ensuring the highest quality of care for patients in the state of Michigan. FACT is the global standard for high quality patient care in cellular therapies. Nearly 90 percent of transplant programs nationally are FACT accredited. FACT accreditation ensures that these providers have all of the necessary facilities, equipment, staffing, policies and procedures in place to provide IECT services in the safest manner possible. The IEC therapies available today are very high risk and often result in very dangerous and expensive complications. The two manufacturers selling these therapies today are requiring FACT accreditation currently, but there is no guarantee this will continue to be a requirement of current, or new to come, manufacturers. Given the complexity and risks with this treatment, we support FACT as the only requirement for delivery of IECT.

- **Access-** While limited in scope of treatment to certain types of Non-Hodgkins Lymphoma and Acute Lymphoblastic Leukemia, it is likely that Car-T is the first of many complex cellular therapies for the treatment of malignant diseases. It's difficult to project demand for immune effector cell therapy given how quickly this technology is evolving. We support the new standard not including any type of volume projection requirement or cap on the number of providers and services in the market at this time.

The complexity of the treatment and care, coupled with the unknown application, demand and reimbursement, makes IECT an appropriate service for a separate and new standard. HFHS believes the

recommended new IECT standards are essential to ensure delivery of high-quality immune effector cell therapy to our patients, to ensure access and to minimize cost to our patients and payers. Thank you for the opportunity to share our input.

Respectfully,

Dr. Steven Kalkanis
Medical Director Henry Ford Cancer Institute
Henry Ford Hospital
2799 W. Grand Blvd
Detroit, MI 48202

Robert G. Riney
President, Healthcare Operations and Chief Operating Officer
Henry Ford Health System
1 Ford Place
Detroit, MI 48202

August 1, 2019

Michigan Certificate of Need Commission (CON)
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933
Submitted electronically: MDHHS-ConWebTeam@michigan.gov

Subject: Proposed Standard for Immune Effector Cell Therapy Services

Dear Chairman Falahee and CON Commission Members:

The undersigned organizations represent and are committed to hundreds of thousands of U.S. cancer patients and survivors, including the more than 58,000 Michigan residents who will be diagnosed with cancer this year alone. It is this commitment to patients that prompts us to voice reservations about the CON-proposed creation of a new standard for Immune Effector Cell Therapy (IECT) Services. The proposal could compromise patient access to a number of promising anti-cancer therapies including but not limited to Chimeric Antigen Receptor (CAR) T-cell therapy.

Presently, two CAR T-cell therapies have been approved by the U.S. Food and Drug Administration (FDA) to treat some children and adults with advanced leukemia, and adults with large-B-cell lymphomas whose cancer has progressed after receiving at least two prior treatment regimens. The FDA noted upon the approval for the first CAR T-cell therapy that this treatment marks a milestone in the development of a whole new scientific paradigm for the treatment of serious diseases and that, "gene therapy has gone from being a promising concept to a practical solution to deadly and largely untreatable forms of cancer."

The impacted patient populations experience poor outcomes and have limited treatment options; in some cases, no other treatment option exists. These patients are seriously ill and cannot afford the time delay which may accompany any restrictions which will result from fewer sites offering the therapy.

While we appreciate the Commission's mission to ensure safe access to treatment, we are concerned that this proposal creates new and redundant requirements for providers that could at some point restrict access beyond the limitations already in place to fulfill FDA and federal standards. Facing such a situation, patients may not be offered CAR T-cell treatment or new cellular therapies in the future, or may experience significant health decline or death before they could identify a facility and gain access. Such a situation would needlessly place patients in danger.

Blood cancer patients currently treated with CAR T-cell therapy and cancer patients who may be dependent on cellular or gene therapies in the future cannot afford the interruption which may accompany a protracted delay in access to this treatment. Patients suffering from life-threatening

cancers require access to this and all treatment as recommended by their physicians without delay. We ask that you keep this in mind as you consider the proposed standard.

We appreciate this opportunity to provide these comments and are eager to work together to ensure that patient access to this innovative and potentially life-saving therapy is not compromised.

Sincerely,

American Cancer Society Cancer Action Network
Blood & Marrow Transplant Information Network
Cutaneous Lymphoma Foundation
International Myeloma Foundation
Lymphoma Research Foundation

August 1, 2019

Michigan Certificate of Need Commission
c/o Michigan Department of Community Health Certificate of Need
Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Proposed Standard for Immune Effector Cell Therapy (IECT) Services

Dear Chairman Falahee and the Certificate of Need (CON) Commission:

The Michigan Biosciences Industry Association (MichBio) appreciates the opportunity to comment on the Michigan Department of Health Certificate of Need (CON) Commission's consideration of the Proposed Standard for Immune Effector Cell Therapy (IECT) Services.

In Michigan, the Certificate of Need program is considering a proposal to create a new standard for "Immune Effector Cell Therapy (IECT) Services," which would include CAR-T therapy. This new standard would require any site of care to receive CON committee approval and accreditation from the Foundation for the Accreditation of Cellular Therapy (FACT) within three years.

MichBio has several concerns about the proposed standard, as follows.

First, we question whether the CON Commission is the right organization to assess which hospitals are prepared to safely and effectively provide CAR-T cell therapy to patients. These treatments are innovative and lifesaving, and there is no indication the Commission has fully evaluated what is needed to provide these services or that all Michigan citizens who could benefit will have access.

Additionally, we believe it is inappropriate for the Commission to approve any recommendation that could limit patient access by creating a new standard for CAR-T therapy before the federal government releases a final decision on site criteria. Furthermore, requiring additional onerous and costly approvals and third-party accreditation to establish new sites of care that go beyond what the federal government requires, may discourage or prevent sites of care from providing CAR-T therapy to patients.

Secondly, CAR- T cell product is analogous to any other therapy which is administered via systemic routes of administration and should not be subject to additional requirements. Establishment of a patchwork of potentially varying or conflicting standards by states will confuse patients, clinicians, and facility administrators, and potentially delay access to CAR-T therapy to patients who badly need it.

The U.S. Food and Drug Administration (FDA) already requires comprehensive safety criteria and standards for any facilities to provide CAR-T cell therapy through Risk Evaluation and Mitigation Strategies (REMS). Additionally, the federal government is currently reviewing coverage and access for CAR-T cell therapy, and the Centers for Medicare and Medicaid Services (CMS) has issued a Proposed Decision Memo which includes additional site requirements as conditions for continued coverage under the Medicare program.

Thus, there's no logical reason for Michigan through the CON process to impose an additional layer of regulatory burden for CAR-T therapy service.

Lastly, according to the National Conference of State Legislators, "(t)he basic assumption underlying CON regulation is that excess capacity stemming from overbuilding of health care facilities results in health care price inflation" (http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx). This assumption does not apply in the case of CAR-T treatments. These are individualized treatments where the patients' cells are withdrawn for treatment, and then replaced to combat the disease. Furthermore, the serious conditions of the patients and the clinical management challenges of the treatment guard against any excess utilization.

Again, we reiterate our concern around the precedent set by including an already heavily regulated, FDA-approved therapy into the CON process, as we believe this does not represent an improvement in patient safety and could ultimately have the effect of impacting timely patient access to cellular treatment.

For all these reasons, we urge the Commission to reconsider its position and reject the proposed new standard for IECT.

Sincerely,

Stephen Rapundalo, PhD
President and CEO
Michigan Biosciences Industry Association (MichBio)

SENATE MAJORITY LEADER
MIKE SHIRKEY
PHONE 517.373.5932

STATE SENATOR
CURTIS S. VanDERWALL
TOLL FREE 855.347.8035

STATE SENATOR
JOHN BIZON, M.D.
TOLL FREE 855.347.8019

July 31, 2019

Michigan Certificate of Need Commission
c/o Michigan Department of Community Health Certificate of Need
Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Proposed Standard for Immune Effector Cell Therapy (IECT) Services

Dear Chairman Falahee and the CON Commission,

As the Chair, Vice Chair of the Michigan Senate Health Policy committee and as the former Chair of Health Policy and the Senate Majority Leader, we appreciate the Commission's attention to cellular therapy, however we write in opposition to the creation of a new standard for Immune Effector Cell Therapy (IECT) Services that would require any provider to receive the Commission's approval and a third-party accreditation within three years of this approval in order to deliver this transformative therapy to patients in Michigan.

New advances in cellular therapy, including Chimeric Antigen Receptor T Cell (CAR T) therapies, are paving the way for the next generation of potential cancer treatments. There are currently two FDA-approved CAR T cell therapies and more than 500 active clinical trials studying this novel approach in both solid tumor and blood cancers. CAR T cell therapy has the potential to dramatically improve cancer patients' outcomes, both those with severe relapsed disease and in earlier lines of treatment.

We understand the Commission's work to ensure safe access of these novel therapies to Michiganders, however we ask that you rescind the recommendation. We believe the requirement to obtain a third-party accreditation will be an onerous barrier to access, create an unnecessary financial burden for providers, and limit the sites of care from offering cellular therapies to patients.

Creating a New Standard for IECT is Inconsistent with the Intent of the Michigan Certificate of Need (CON) Program

The CON program is intended to control health care costs while ensuring safety and access by restricting health care facilities from unnecessary and expensive capital investments to serve

their patient populations. However, CAR T cell therapy is a personalized treatment that does not require additional investment, but rather, specialized professionals who meet any and all criteria to administer the therapy set by CMS, the FDA, the biopharmaceutical manufacturer and the facility in which the service is performed.

The safe administration of CAR T cell therapies in a site of care does not require any additional or specialized capital investment as the specialized re-engineering of a patient's T cells are manufactured off-site by the biopharmaceutical company.

Proposal to Require Third Party Accreditation Will Limit Access to CAR T cell therapy for Michiganders

We are concerned that the MI CON Commission's proposal to require any facility to receive FACT accreditation will limit patient access by preventing sites from providing CAR T cell therapy.

Safety criteria are an important component of what a facility must demonstrate to deliver CAR T cell therapy and manage the associated adverse events. In their review and approval, the U.S. Food and Drug Administration (FDA) requires comprehensive safety criteria and standards for any facilities to provide CAR T cell therapy through Risk Evaluation and Mitigation Strategies (REMS). Additionally, the federal government is currently reviewing coverage and access for CAR T cell therapy, and the Centers for Medicare and Medicaid Services (CMS) has issued a Proposed Decision Memo which includes additional provider site requirements.

We believe it is unnecessary to require additional onerous and costly approvals and accreditations on any facilities that go beyond what the federal government requires, which may discourage or prevent sites from providing CAR-T cell therapy to patients.

Thank you for your consideration of our concerns. We ask that the Michigan Certificate of Need Commission reject the proposed new standard for IECT.

Sincerely,

Senate Majority Leader Mike Shirkey
District 16

Senator Curtis S. VanderWall
District 35
Chairman, Senate Health Policy and Human Services Committee

Senator John Bizon
District 19
Vice Chair, Senate Health Policy and Human Services Committee

SPECTRUM HEALTH
Spectrum Health Lemmen Holton
Cancer Pavilion | MC 120
145 Michigan St. NE Suite 5120
Grand Rapids, MI 49503

July 25, 2019

James Falahee, Chairperson
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Thank you for allowing us to submit written comments regarding the new CON Review Standards for Immune Effector Cell Therapy (IECT) Services.

We are pleased with the work of the recent BMT SAC and believe the committee was extremely thorough and, in our opinion, has produced an exceptional recommendation given the uncertainty surrounding immune effector cell therapy. By requiring facilities offering IECT to obtain FACT accreditation, the Commission is ensuring consistent safety practices for patients. We believe this is important for many reasons:

1. FACT is a non-profit organization, which has developed evidence-based standards based on the input of scientists and clinical experts and provides a rigorous accreditation process.
2. Although the two manufacturers of immune effector cell therapies currently on the market are requiring FACT accreditation, there is no regulatory requirement outside of these proposed standards that would require this to continue.
3. As more IECT products are developed, without these CON standards there is no other regulation requiring new manufacturers to require FACT accreditation.
4. We have heard that some companies currently developing IECT products are opposed to requiring FACT accreditation which would seem to be an indicator that they are not planning to require FACT accreditation themselves.
5. FACT accreditation ensures that the facilities providing these extremely complex and challenging treatments have all the appropriate facilities, staffing, policies, and procedures in place to ensure high quality treatment and the best outcomes for patients. If such a high cost treatment is going to be provided, we need to ensure every patient is getting what they pay for.

Thank you again for allowing us the opportunity to provide support for the new CON Review Standards for Immune Effector Cell Therapy (IECT) Services.

Sincerely,

Mary Kay VanDriel

Mary Kay VanDriel, FACHE

The US Oncology Network

July 25, 2019

VIA ELECTRONIC SUBMISSION

James Falahee
Chairman, Certificate of Need Commission
Department of Health and Human Services- Certificate of Need Policy Section
South Grand Building- 333 S. Grand Ave.
Lansing, MI 48933

RE: Proposed Recommendation from the SAC on CON Standards for BMT, including CAR T- Cell Therapy

Dear Chairman Falahee and the CON Commission,

On behalf of the physicians of The US Oncology Network (The Network), I thank you for the opportunity to comment on the proposed Certificate of Need (CON) Review Standards for Immune Effector Cell Therapy (IECT) Services. As I stated before in an earlier letter to the Standard Advisory Committee, community oncology clinics have considerable experience and capabilities in complex treatments and are highly capable of administering CAR T treatment. I encourage the CON commission to ensure consistent patient access to current and future innovative therapies, such as CAR T, across the State of Michigan in the community-based setting.

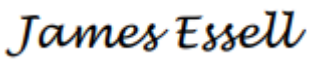
Immune Effector Cell (IEC) Therapy, including CAR T, research and development is rapidly evolving. There are numerous ongoing research studies looking at CAR T in other diseases such as myeloma, Hodgkin's Disease and solid tumors such as glioblastoma, prostate cancer, pancreatic cancer and breast cancer – many of which are frequently treated in the community setting today. Given the potential of this promising treatment, we encourage Michigan Certificate of Need Commission to protect and provide access to beneficiaries who are unable to travel or who prefer treatment closer to home.

We understand the BMT SAC has provided to the CON commission a recommendation to adopt the Foundation for the Accreditation of Cellular Therapy (FACT) as the standard requirement for the safe delivery of IEC/CAR T-therapies. During the deliberation process, we submitted a letter to the SAC to convey two things. First and most importantly, we wanted to encourage the SAC to consider patient access to care as a primary factor in its recommendation. Without community cancer clinics some patients will not have the resources to travel to a major academic medical center and thereby will be excluded from the potential benefits of this life saving therapy. Secondly, we acknowledged FACT accreditation would promote quality practice and patient safety.

On behalf of The US Oncology Network and our more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide our comments on the

recommendation by the SAC to the CON commission. We welcome the opportunity to discuss the issues outlined above and other critical issues impacting community cancer care with you.

Sincerely,



James Essell, MD
Chair Cellular Therapy
The US Oncology Network

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor MI 48109

July 26, 2019

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Immune Effector Cell Therapy

Dear Commissioner Falahee:

This letter is written as formal testimony in support of the proposed Certificate of Need (CoN) Review Standards for Immune Effector Cell Therapy (IECT) Services. Over the past two years the University of Michigan Health System (UMHS) has participated in the process of developing CoN Standards that will ensure that this therapy is accessible to the citizens of Michigan and is administered at facilities that will have the necessary infrastructure and knowledge base to safely achieve the highest possible outcomes.

Background: On August 30th, 2017 the Food and Drug Administration (FDA) approved the use of Kymriah® (tisagenleuleucel) for the treatment of acute lymphoblastic leukemia (ALL) in children and young adults. The commercialization of Kymriah® in childhood ALL is the first of multiple cell therapy trials using IECT the FDA will be reviewing in the upcoming decade, for both pediatric and adult disorders.

Recommendation: The consensus of the CoN Standards Advisory Committee:

- An applicant proposing to initiate an IECT service shall agree to obtain Foundation for the Accreditation of Cellular Therapy (FACT) accreditation within three years of CoN approval.
- The applicant shall specify the site at which the service will be provided.
- An applicant shall certify that it will only offer IECT products that have FDA approval or are offered as part of a clinical or investigational trial.
- There will be no cap on the number of IECT providers in Michigan.

The proposed CoN Standards are specific to the use of IECT, and are not designed to impede the treatment for other medical conditions. The intent of the SAC was to recommend CoN Standards that ensure both adequate access for IECT and high quality care for the citizens of Michigan.

Why do we feel the proposed IECT CoN Standards are important? Given the complexity of "gene therapy" products like IECT, the following should be recognized.

- The Food and Drug Administration (FDA) provides stringent guidelines for the manufacture of IECT. The FDA does not provide guidelines regulating who can administer these products, once they have been commercialized.
- Opponents of the current CoN proposal will state that the FDA has established a Risk Evaluation and Mitigation Strategies (REMS) program for IECT, and this program alone will ensure high quality care. This is a fallacy. The IECT REMS program focuses on providing patient and provider education, and toxicity reporting. It does not focus on the quality of the blood bank handling IECT products, the quality of the clinical site delivering these products or the quality of the staff overseeing the patient care.
- On the other hand, FACT guidelines for IECT focus on quality at all levels (the Blood Bank, the clinical site, staff), and should be mandatory for delivering IECT products. Yet, the perception that FACT guidelines alone will self-regulate IECT providers is risky. The FDA does not require centers to have FACT accreditation to administer IECT products. FACT is a voluntary organization that commercial IECT suppliers (and health care insurers) may or may not require for centers. It is a voluntary oversight body, not a FDA or CMS mandate. We are asking the CoN to make FACT accreditation mandatory for centers providing IECT care in our state.

It is for these reasons that we hope the CoN Commission will support these Standards and move them forward to the State Legislature. Our goal is to provide unlimited access to quality care for IECT products. We believe the current CoN proposal will meet this goal.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

David Spahlinger, MD
President, University of Michigan Health System and
Executive Vice Dean for Clinical Affairs, University of Michigan Medical School

T. Anthony Denton, MHA, JD
Senior Vice-President and Chief Operating Officer, University of Michigan Health System

Gregory Yanik, MD
Leland and Elaine Blatt Family Professor of Pediatric Hematology/Oncology

SAINT JOSEPH MERCY HEALTH SYSTEM

MERCY HEALTH

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

July 31, 2019

RE: Public Comment for Proposed Changes: Immune Effector Cell Therapy (IECT), Psychiatric Beds and Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the proposed changes to the Certificate of Need Review Standards for Lithotripsy and Psychiatric Beds and Services, and the newly proposed Certificate of Need Standards for Immune Effector Cell Therapies. Trinity Health Michigan supports all of the proposed Standards as presented at the June 13, 2019, Commission meeting with the following comments.

Specifically, we would like to thank the CON Commission for addressing the need for expanded access to psychiatric beds in Michigan. While we do support the proposed changes in the CON standards, we also strongly agree with the CON workgroup's findings that the most pressing barriers to care are beyond the scope of the CON Commission: the shortage of qualified clinicians, inadequate reimbursement, and the need for the improved integration of behavioral health with primary care. We would be happy to partner with the Commission in any communications it has with the legislature regarding non-CON-related policies and initiatives that might address these other, more significant barriers to behavioral health care in Michigan.

We support the work and recommendations of the Standards Advisory Committee regarding Immune Effector Cell Therapy (IECT). We believe the IECT recommendation to require FACT accreditation is a well-reasoned and acceptable requirement that ensures the highest quality, safest cellular therapies in Michigan. The Standards Advisory Committee uniformly supported the proposed language; FACT has a long track record of promoting quality patient care and laboratory practices in cellular therapies. If you or others have any questions regarding the reasoning for the recommendations, Philip Stella, M.D., the co-chair of the IECT Standards Advisory Committee and Medical Director of St. Joseph Mercy Hospital's Oncology Program, noted he would be happy to engage in further conversation.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Rosalie Tocco-Bradley, MD, PhD
Chief Clinical Officer

Ascension

August 1, 2019

Chairman James Falahee
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee and CON Commission Members,

This letter is written as formal testimony pertaining to the CON Review Standards for Psychiatric Beds and Services review in 2019, and to the recommendations provided by the 2019 CON Psychiatric Bed Workgroup.

Ascension Michigan would like to ask the CON Commission to provide clarity on the creation of a new special pool subgroup for high acuity psychiatric beds language. Specifically, we ask the CON Commission to clarify in the standards language what the defined procedure is when a patient no longer meets the criteria set forth in the standards? Is the expectation that the patient would need to go to a General Psych area? Furthermore, we request clarity in the standards language as to what is the expected procedure if there is not a general psych unit available (i.e. transfer within 25 miles, a lateral transfer, etc.)?

Ascension Michigan is concerned with how this is to be determined and what are the are qualifications for discharge? In its current iteration, we are concerned, though well-intended, that this will lead to increased "boarding" times in the ED's with many patients ultimately being declined admission to general units refusing them based upon their presentation. In addition, we have concerns that many patients who have spent time on a "high acuity" unit will encounter problems with placement when they are ready for discharge.

Sincerely,

Jarrett M. Schroeder, MD
Chief of Behavioral Health Services
Ascension Michigan

Selena Schmidt, PMHNP-BC
Director, Behavioral Health Service Line
Ascension Michigan

Beaumont

July 11, 2019

Certificate of Need Commission
c/o Policy, Planning and Legislative Services
Michigan Department of Health and Human Services
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need Commission:

On behalf of Beaumont Health, I would like to express our support for the proposed modifications to the CON Review Standards for Psychiatric Services and Beds that the Commission took proposed action to approve on June 13, 2019.

We believe that the new standards will improve access to psychiatric beds for both adults and child/adolescents. We would also like to thank Laura Hirshbein, MD, PhD, who chaired the Psychiatric Beds and Service Workgroup. Beaumont participated in all of the Workgroup meetings and supports the Workgroup's recommendations.

We recommend that the Commission take final action to approve the proposed standards at the September 19 CON Commission Meeting. Thank you for the opportunity to provide comment.

Sincerely,

Lee Ann Odom

Lee Ann Odom
President, Shared Services

SEIU Healthcare Michigan | United for Quality Care

Good morning, My name is Geri Souve and I am a member of SEIU Healthcare Michigan, an affiliate of the largest union of healthcare workers in North America, and I work at Beaumont Hospital Trenton. Our experience as direct caregivers, healthcare consumers, as well as our longstanding dedication to healthcare advocacy puts us in a unique position to share facts in public forums to help stakeholders carefully evaluate proposals, such as the Certificate of Need (CON) psych standard revisions presented here today. I appreciate the opportunity to provide public comment today.

While we recognize that there are mental health challenges facing our state and we support efforts to improve Michigan's mental health care system, we believe that the psychiatric providers who will be entrusted to care for our state's most vulnerable populations should be held to the highest standards, and Michigan's CON standards are essential in ensuring this. However, we believe that the CON standard revisions as they currently stand, are lacking in one specific area.

We are concerned that there are no specific rules preventing providers who are under federal or state investigation for alleged fraudulent activities form obtaining CON approval. These investigations are rare and should cause other regulatory bodies to act with caution. We believe it is in the best interest of patients, workers, and taxpayers, to include an explicit provision within the CON psychiatric standards that prohibits providers currently under state or federal fraud investigation from expanding bed capacity or psychiatric services for any patient population.

This is a pressing matter because it is our understanding that Beaumont Health—where I and a thousand of my fellow union members are employed—has entered into a partnership with Universal Health Services (UHS), a publicly-traded company that operates more than 200 behavioral health facilities across the country,[1] to expand behavioral health services in the state with a brand new inpatient facility.[2] While UHS will tout their "long-standing commitment to quality care and expertise in the field of mental health,"[3] we're deeply troubled by the fact that the company is the subject of a multi-year, coordinated civil and criminal fraud investigation into the corporate parent and 34 of its behavioral health facilities in 13 states, including Forest View Hospital in Grand Rapids, Michigan.[4]

The company has disclosed in SEC filings that the investigation is being undertaken by several offices: the Office of Inspector General for U.S. Health and Human Services, the U.S. Department of Justice, and various U.S. Attorneys' and state Attorneys' General Offices. The company has also disclosed that the investigation pertains to potential criminal and civil liability related to *"medical necessity issues and billing for services not eligible for payment due to non-compliance with regulatory requirements relating to, among other things, admission eligibility, discharge decisions, length of stay and patient care issues.*[5]

It's clear that providing a therapeutic environment for patient populations with complex mental health needs can be difficult, but we believe that loosening the standards to add beds, while failing to have explicit safeguards in place to limit providers who are facing significant regulator investigations, is not the solution. It is not just about adding beds, but about the quality of care, staffing, and treatment patients will receive once they are in the beds. Therefore, we strongly urge the commission to add our recommendation to the CON psychiatric bed standards. Thank you for your consideration.

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[1] Universal Health Services, Inc. SEC 10Q Filing for the period ending March 31, 2019- https://www.sec.gov/Archives/edgar/data/352915/000156459019017239/uhs-10q_20190331.htm#ITEM_2_MANAGEMENTS_DISCUSSION_ANALYSIS_F, p27

[2] https://www.modernhealthcare.com/article/20181105/NEWS/181109958

[3] https://www.prnewswire.com/news-releases/beaumont-health-universal-health-services-partner-on-significant-comprehensive-new-project-to-enhance-mental-health-services-in-michigan-300743747.html

[4] Universal Health Services, Inc. SEC 10Q Filing for the period ending March 31, 2019- https://www.sec.gov/Archives/edgar/data/352915/000156459019017239/uhs-10q_20190331.htm#ITEM_1_LEGAL_PROCEEDINGS, p54-55

[5] Universal Health Services, Inc. SEC 10Q Filing for the period ending March 31, 2019- https://www.sec.gov/Archives/edgar/data/352915/000156459019017239/uhs-10q_20190331.htm#ITEM_1_LEGAL_PROCEEDINGS, p54-55

Universal Health Services, Inc.
UHS of Delaware, Inc.

Statement in response to SEIU public comment at MDHHS CON hearing
July 2019

CON Eligibility

We disagree with SEIU's suggestion that CON-eligibility be impacted in the event of a pending governmental investigation. Such an approach would penalize companies that are merely under inquiry but for which there are no formal findings. Further, and contrary to SEIU's factually incorrect assertion, civil false claims act investigations are not "rare" but are an unfortunate and common reality in the health care provider industry in light of the significant amount of government reimbursement all providers receive.

Summary of Investigation

UHS has publicly disclosed the existence of the DOJ investigation for many years in its regular public filings. **UHS has vehemently denied any wrongdoing or improper conduct** and continues to do so today.

SEIU references a criminal investigation. They fail to advise that DOJ announced a policy several years ago that all civil false claim act cases would be shared with the Criminal Division to determine if a parallel criminal investigation should be opened. Further, following a lengthy and comprehensive investigation by the Government, **the criminal investigation was closed with no charges filed** against UHS or any of its facilities.

About UHS' Clinical Quality Reputation, Accomplishments and Awards

UHS has a strong commitment to quality, operates a mature Compliance program, and is well regarded in the industry, with high quality scores as reported by independent accrediting authorities and multiple earned distinctions. The company has a longstanding, independently validated and evidence-based record of providing quality healthcare services to patients and their families:

- All UHS hospitals are fully accredited by independent organizations including The Joint Commission (TJC) and/or Commission on Accreditation of Rehabilitation Facilities (CARF), whose rigorous clinical assessment protocols are widely respected throughout the healthcare industry. Many facilities also hold advanced specialty accreditations.
- In the 40-year history of UHS, no facility has failed to be accredited or re-accredited by TJC or any other CMS-deemed organization.

Specific to the UHS Behavioral Health Division:

- In the past three years, UHS Behavioral Health (BH) facilities underwent 300+ Joint Commission (TJC) surveys with a 100% success rate for re-accreditation.
- Between 2012 and 2015, 83 UHS facilities (including 69 in the Behavioral Health Division) were publicly designated as Top Performers on Key Quality Measures® by TJC. In the BH Division, over half of UHS's eligible facilities received this quality recognition during the program's four-year existence. To be a Top Performer, a facility was required to achieve performance of 95% or above on HBIPS (Hospital Based Inpatient Psychiatric Services) accountability metrics for the prior calendar year.
- While TJC abated the Top Performer program in 2016, UHS BH facilities continue to routinely exceed the national average in HBIPS scores while also receiving other laudable distinctions. For example, Hartgrove Hospital was the first hospital in the nation to be awarded a rigorous Disease-Specific Certification for Trauma-Informed Care from TJC.
- All UHS BH hospitals participate in CMS' Inpatient Psychiatric Facility Quality Reporting Program (IPFQR) used by over 1,600 BH hospitals across the U.S. to measure a broad set of evidence-based clinical practices linked to positive patient outcomes and are published on CMS' Hospital Compare web site. UHS BH hospitals' aggregated results regularly exceed national and state averages and the scores of its major BH multi-facility competitors.
- Between January 2015 and June 2018, over one million UHS BH patients completed anonymous patient satisfaction surveys (with nearly 70% return rate). On a five-point scale (1 being low and 5 being very high), UHS patients rated their overall satisfaction during this period at 4.51, with 92% indicating that they felt better after care.2
- In 2017, 166 UHS BH facilities and RTCs representing 571 distinct treatment programs captured evidence based clinical outcomes measures for 137,240 patients. UHS continues to dramatically expand use of these tools to benchmark performance and enhance our patients' quality of life. In the past year approximately 75% of UHS BH patients exhibited statistically meaningful improvement.

Please see the **UHS Fact Sheet** for further information about the company.

Anne Mitchell
Private Citizen
Mitchell_anne@yahoo.com

July 22, 2019

MDHHS CON Commission and Department
C/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 South Grand Avenue
Lansing, MI 48933

RE: UESWL Standards Review **Public** Comment

Dear MDHHS CON Commission and Department:

Thank you for the opportunity to provide public comment for your 2019 Review of CON Standards for *Urinary Extracorporeal Shockwave Lithotripsy*. This public comment is intended for inclusion in your **Public Hearing for Immune Effector Cell Therapy (IECT) Services, Psychiatric Beds and Services and Urinary Extracorporeal Shock Wave Lithotripsy (UEWSL) Services/Units** to be held on July 25, 2019.

It is disingenuous, intellectually dishonest, and disgraceful to construe UESWL cost, quality, and access in simplistic terms of capital expense. By ignoring its true costs, your decisions about access to UESWL result in grave and deliberate harm to Michigan residents.

I have attached my public comment to you of June 3, 2019 as reference. Since 1989, UESWL has ***caused*** Chronic Kidney Disease (CKD) in more than 55,000 individuals in each year of these last thirty in the United States; 1,600 each year in Michigan. Notwithstanding the associated suffering, misery, and torment, this singular UESWL adverse effect has generated unnecessary healthcare costs nationwide topping $1.6 Trillion since then. In Michigan, this cost has neared $175 Billion. We are far smarter than this. We are far better than this. Now is the time for action; if not now, when?

It is relevant to discuss the dire importance of how these $175 Billion and $1.6 Trillion might otherwise have been spent. Rather than misusing these healthcare dollars to support dark, subversive, fraudulent and life-threatening business practices, you might otherwise have ***cured*** kidney disease. You might have ***prevented*** kidney disease with this money. Instead, the path

chosen was one to grant and protect the private rights of urologists to fraudulently cast UESWL as merely a "commonly used" "industry standard." The corruption of medical science was made possible through "Urological Interests'" conspiratorial concealment of the truth of serious harm caused by use of UESWL in order to protect kickbacks urologists and their "business partners" receive for performing the procedure.

Their carefully hatched and very secretive "non-provider-physician-owned" extortionist racketeering/patient referral schemes developed through substantial financial influence of government officials have polluted and effectively destroyed the intent of our clear anti-kickback laws against physician self-referral. These lucrative schemes have permitted urologists to create the completely false front of proper patient care while dissembling their true financial motives and destroying America's kidney function. Extreme and entirely unnecessary cost borne of this nauseating fraud should be a sobering wake-up call for all Americans. Its example illustrates how profoundly the scourge of deceit and duplicity on our badly broken U.S. healthcare system harms us.

There are factual clear-cut reasons why we do not dependably enjoy proper healthcare in the United States. One reason is that half-truths are lies. Lies of omission are lies. Another reason is that duplicitous fraud should never be deemed "industry standard." It is not rocket science; UESWL is obviously a public health disaster in both life and treasure. But the stakes are far too high now for offending urologists to honor the truth after all they've done to corrupt medicine and all they've neglected to do to protect their patients' welfare over the past thirty years.

I recommend you fully utilize this characteristic UESWL debacle as an opportunity to go back to the CON drawing board. You have a dutiful obligation to act. Correctly calculating access to high-cost/ low-value medical services like UESWL requires you see through the fresh eyes of objective scientific and financial experts. Use your MDHHS epidemiologists. Invite the FDA. You may even invite physicians from outside the United States. Formulate an objective SAC that excludes the compromised, untrustworthy, unethical, unscrupulous, extortionate profiteers from the mix. Nothing about this is simple or "easy," but it is absolutely necessary for a reliable and accountable standard to be reformulated. Please fix this. It will be well worth it.

Thank you for your consideration.

Sincerely,

Anne Mitchell

Anne Mitchell
Private Citizen
Mitchell_anne@yahoo.com

June 3, 2019

Michigan Certificate of Need Commission and Department
C/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 South Grand Avenue
Lansing, MI 48933

RE: UESWL Standards Review **Public** Comment

Dear Michigan Certificate of Need Commission and Department:

Thank you for the opportunity to provide public comment for your 2019 Review of CON Standards for *Urinary Extracorporeal Shockwave Lithotripsy*.

First, let's do a little arithmetic and extrapolation:

Based on today's published research and USRDS reporting, at your current reported performance rate, UESWL will conservatively *cause* Chronic Kidney Disease (CKD) needlessly in **1,600** Michigan patients per year. Because conspiring "non-provider-physician-owned" lithotripsy service providers' carefully engineered business plans are being shielded by slick lobbying organizations like the "*Council for Urological Interests* (CUI)" (https://urologicalinterests.org), kidney stone patients are neither clearly nor honestly made aware of medically obvious, outlandish, and deliberately concealed risks. Moreover, CKD is hardly the only known risk of UESWL – consider End Stage Renal Disease (ESRD), hemodialysis, or the exploding of a spleen, a pancreas, or renal artery. The average annual cost for treating CKD alone in an individual patient is **$23,000.00**.

Notwithstanding considerable suffering and premature death caused by these unchallenged UESWL "business" schemes, the cost is mind-blowing. In this light, please take stock of your own CON responsibilities to regulate quality- and cost-based access to UESWL services.

The following table represents aggregate direct costs should all patients survive and suffer for ten, twenty, and thirty years from the preconceived and otherwise needless CKD "collateral damage" in your Michigan population. No consideration is given below to those patients progressing to ESRD caused by CKD for whom cost would otherwise triple. No cost consideration is given in the following for cardiovascular damage and subsequent risks or death due to the unjustifiable CKD. Therefore, this is a very conservative estimate:

Surviving with CKD (1600 patients/year)	Cost
First 10 years	$8,022,400,000.00
At 20 years	$56,598,400,000.00
At 30 years	$174,432,000,000.00

This seems a bit predacious, don't you think? Can we really afford to bestow the urologists' "non-provider-physician-owned' businesses with such a lurid little luxury? Hmmm…at year thirty we might otherwise have spent these same Michigan healthcare dollars on 872,160,000 primary care visits with emphasis on preventive medicine. Just try to render these figures on a national scale: **Monstrous**. It can easily be proven that UESWL is an extremely high-cost and dangerously low-value therapy.

Spending these *hundreds of billions of dollars* on UESWL adverse effects is entirely indefensible, because alternative methods for kidney stone removal spare the kidney. Somehow we choose to tolerate this disgraceful scandal, which is irresponsible, uncaring, *and* completely unacceptable.

Via their cooperative moneyed interests, urologists conspire to duplicitously distort crucial facts from their patients' grasp. The half-truth whopper, the myth, that UESWL is advantageously "non-invasive" does not represent the whole truth that it is also precipitously harmful and manifestly lethal. Indispensable and highly consequential information is not indulged; deliberate neglect of their patients' essential humanity and rightful, reasonable decision-making capacity to choose treatment options by taking known life-threatening facts into consideration is "standardized." Were it not for decades-long performance of UESWL based on prioritizing personal financial interests

over patient care, these hundreds of billions of dollars would be nearly ZERO. Substantial indirect costs (work-related absence, time/travel-related costs, pain and suffering, etc.) in this population are also not represented in these figures.

Intentionally neglecting to provide the necessary clinical information to make patient informed consent even possible for mitigating life-threatening risks of UESWL allows urologists to capitalize on their "non-provider-physician-owned" businesses in the cleverest way. Their victims do not even rate as "guinea pigs" in the schemes; there are deliberately no reasonable efforts undertaken to document and relate the most relevant findings about them following treatment with UESWL. Contrived patient consent forms are the insidious and evasive means of concealing known risk from patients; the truth of what has actually been observed (and yet purposely entirely absent, or inaccurately represented in the medical literature) is not discussed openly, honestly, and responsibly.

Moral integrity requires standards of behavior to be upheld even when personal and financial ties are at stake. Urologists owe their patients a duty of care: Period. We license doctors to practice medicine based on this straightforward standard here in the USA. If it were as expected, it is required that physicians make <u>all diligent efforts</u> to uncover and communicate ***all aspects*** of any given therapy relevant to the welfare of their patients so as to develop free and trusted communications with all parties involved. In medicine, because we seek the truth, we are obliged to tell the truth. Decisions about life and death require these faithful and trusted efforts. Urologists' have subjugated the best medical interests of their patients now for decades in favor of their personal UESWL "business" goals. This is a consummate and sickening injustice, not borne of wasteful indulgence, but entirely of fraud and abuse.

Rather than being sold a bill-of-goods laundry list of disinformation, were all patients given crucial requisite statistical information in clear terms about the very serious risks posed them prior to deciding to undergo UESWL, they would likely think twice whether or not to choose suffering with CKD and its costly, deadly effects for the rest of their lives just so their urologist can cop an extra $1500.00 or so.

The question is this: How do you imagine that *reducing* by half the required number of UESWL procedures in CON provider standards from 1000 to 500/annum will affect cost, quality, and access? It would seem that access to such exorbitant danger should be more limited and surely not more widespread. How will it affect Michigan patients? Michigan employers? Michigan taxpayers? Does it even matter to MDHHS? Well, the facts do matter. It is time to go to your legislature with the facts.

I propose that your CON Standards take the distressing clinical UESWL facts into account by formulating a regulatory standard ***requiring*** explicit and extensive performance reporting related to harm and cost in a mandated registry. The cost of such a mandate in both life and treasure would be a miniscule pittance by comparison to what is now the unjustifiable standard. It is not remotely an unreasonable requirement. It would be even better if lithotripsy "business" providers were required to pay for the registry.

I also propose you create reasonable provisions that will by far more strictly limit access to UESWL in your CON Standards.

Something has got to be done, and soon. Because the FDA has abdicated reporting responsibilities for UESWL to "voluntary" status, the nauseating injustices and dangers of mendacious UESWL "business" schemes disguised as medical "standard-of-care" are far too easily swept under the rug. We simply cannot become so numb as to tolerate such an absurd paradox. It is most likely that many lives and great cost will be spared by enacting State-by-State programs where public employees and agencies of good conscience make clear and purposeful efforts to do what is right and just both clinically and financially to mitigate grave harm, injustice, and needless deadly outcomes for their residents. In the long term, this will certainly become a measure of best practice. This is one circumstance in which careful oversight is surely warranted. We are at a crossroads: I recommend you start now.

Thank you for your consideration.

Sincerely,

Anne Mitchell
Private Citizen