# Urinary Extracorporeal Shock Wave Lithotripsy (UESWL)



October 15, 2024

James "Chip" 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 this opportunity to provide written testimony regarding the CON Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

Corewell Health supports continued regulation of UESWL Services and does not recommend any changes to the standards.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for UESWL Services. Corewell Health appreciates the Commission's ongoing support for the safety and quality of care for Michigan's residents.

Sincerely,

Darryl A. Elmouchi, M.D. Chief Operating Officer Corewell Health



October 10, 2024

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 (HFH) would like to offer comments on Certificate of Need review standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services:

HF Health supports the continued regulation of NICU/SCN services and does not recommend any changes to the standards currently.

Respectfully,

Deur Brokas William

Denise Brooks-Williams, FACHE Executive Vice President & Chief Operating Officer Henry Ford Health

henryford.com

#### **Trinity Health Michigan**



October 10, 2024

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

# RE: Public Comment for Urinary Extracorporeal Shock Wave Lithotripsy 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 what, if any, changes need to be made to the Certificate of Need Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services in 2025.

Trinity Health Michigan believes the current Certificate of Need Standard ensures that Michigan's citizens have appropriate access to affordable, high-quality Lithotripsy services and that Lithotripsy is being appropriately regulated. For these reasons, Trinity Health Michigan supports the continued regulation of Lithotripsy Services without any further modification to the existing CON Standards.

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

Sincerely,

Shannon D. Stuebert

Shannon D. Striebich President and CEO Trinity Health Michigan Market



T. Anthony Denton, JD, MHSA Senior Vice-President & Chief Environmental, Social and Governance Officer

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October 18, 2024

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

### RE: Urinary Extracorporeal Shock Wave Lithotripsy - Certificate of Need Standards Review

Dear Chairperson Falahee:

This letter is written as formal testimony pertaining to the Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy Services. University of Michigan Health supports the continued regulation of this covered service and does not believe any specific revisions to these standards are currently necessary.

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

Respectfully submitted,

J. Arry Hanks

T. Anthony Denton, JD, MHSA Senior Vice-President & Chief ESG Officer University of Michigan Health Michigan Medicine

# Neonatal Intensive Care Services/ Beds (NICU) and Special Newborn Nursing Services



October 10, 2024

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 (HFH) would like to offer comments on Certificate of Need review standards for Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing (SCN) Services:

HFH appreciates the work completed by the Workgroup in 2022. HF Health supports the continued regulation of NICU/SCN services and does not recommend any changes to the standards currently.

Respectfully,

Deur Brokas William

Denise Brooks-Williams, FACHE Executive Vice President & Chief Operating Officer Henry Ford Health



October 10, 2024

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

#### RE: Public Comment for Neonatal Intensive Care Services/Beds (NICU) And Special Newborn Nursing 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 what, if any, changes need to be made to the Certificate of Need Standards for Neonatal Intensive Care Services/Beds and Special Newborn Nursing (NICU/SCN) Services in 2025. Trinity Health Michigan supports the continued regulation of NICU/SCN Scanner Services. Trinity Health Michigan believes the current Certificate of Need Standard ensures that Michigan's citizens have appropriate access to affordable, high-quality NICU/SCN services.

We are recommending the Commission review the requirements in Section 12 (c) related to outreach programs. As hospitals have aligned into larger systems, most neonate transfers are completed within systems; few neonates are transferred between health systems. As this consolidation has occurred, the role and function of outreach programs has become less formal. The current language does not reflect that change.

Additionally, we recommend the CON standards be reviewed to ensure alignment with The Joint Commission Maternal Levels of Care (MLC) Verification program. This important program benefits hospitals, clinicians, and patients, and ensures pregnant and postpartum individuals receive risk-appropriate maternal care. We believe the CON Standard should align with the MLC benchmarks.

We believe an informal workgroup would be appropriate to review these issues. We appreciate the CON Commission's consideration of our comments.

Sincerely,

Shanna D. Strebat

Shannon D. Striebich President and CEO Trinity Health Michigan Market



MyMichigan Health 4000 Wellness Drive Midland, Michigan 48670 Phone (989) 839-3000 www.mymichigan.org/midland

October 18, 2024

Mr. James Falahee, JD Chairperson, Certificate of Need Commission Michigan Department of Health and Human Services South Grand Building, 4<sup>th</sup> Floor P.O. Box 30195 Lansing, Michigan 48909

Re: Certificate of Need Review Standards for NICU Beds and Services

Chairperson Falahee,

Thank you for this opportunity to provide public comments regarding the CON Review Standards for NICU Beds and Services. MyMichigan Health supports the continued regulation of NICU beds and services under Michigan's CON program. However, we believe the bed need methodology in these standards is long overdue for a review.

According to the report presented to the Commission at the September meeting, the bed need methodology in the standards, utilizing the 2022 live births data from Vital Records, indicates NICU bed need has dropped over the past year. However, there are some planning areas in the state experiencing 90%+ average occupancy rates with more beds than what the methodology says are currently needed and yet the updated numbers indicate it should be even lower. For example, Health Service Area 6 has one NICU with 40 beds. According to the most recent CON annual survey, that NICU had an average occupancy rate of 90.9% in 2023. The current bed need for that HSA is 25 beds – the HSA has 160% more beds than the methodology says it should. And when the Department gives an effective date to the updated bed need numbers shared last month that number of beds needed in the HSA will drop to 23 beds. If the existing NICU only had 23 beds rather than 40, they would have had a 158% occupancy rate last year. Clearly an impossible feat which means babies would have been turned away at an alarming rate. Even at 90.9% average occupancy our system has experienced frequent denials of requests to transfer babies to the NICU due to capacity and staffing issues.

When looking at the bed need methodology in the current standards it seems clear that we need to look at ways to make it more accurate for predicting future need. The entire methodology is focused on low birth weight rates. It completely ignores the many other reasons why babies may need a NICU bed such as respiratory distress, hypoglycemia, jaundice, retinopathy, or intraventricular hemorrhage to name a few. It also does not take into consideration utilization rates at existing NICUs. We cannot continue to support a methodology that grossly underestimates the need for NICU services. We appreciate your time in considering our requests. We would be happy to discuss this further as well as participate in a SAC or workgroup addressing this issue in the coming year.

Respectfully,

Muniter

Sunita B. Vadakath, M.D. Senior Vice President and Chief Strategy Officer MyMichigan Health



October 15, 2024

James "Chip" 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 this opportunity to provide written testimony regarding the CON Review Standards for Neonatal Intensive Care (NICU) Services/Beds.

Corewell Health supports the continued regulation of NICU services, as we believe the current standards are effective and beneficial for the citizens of Michigan. We do not believe that any changes are necessary to the current standards.

We appreciate the Commission's consideration of our comments.

Sincerely,

Darryl A. Elmouchi, M.D. Chief Operating Officer Corewell Health

# Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds



October 15, 2024

James "Chip" 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 this opportunity to provide written testimony regarding the CON Review Standards for Nursing Home (NH)/Hospital Long-term Care Unit (HLTCU) Beds.

Corewell Health supports the continued regulation of NH/HLTCU beds. However, we ask the Commission to form a workgroup or Specialist Advisory Committee (SAC) to address items identified from the last review of the standards.

During the 2022/2023 review of the NH/HLTCU standards, a workgroup was tasked with considering language that addresses the impact of a public health epidemic on the CON process and reviewing the process of temporary closure to replace aging structures. At that time, the workgroup could not reach a consensus on these matters.

Corewell Health believes that additional conversation on these topics would be beneficial and ask that the Commission reopens these items. For additional context, please find enclosed a letter dated June 15, 2023, from the Health Care Association of Michigan.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for Nursing Home/Hospital Long-term Care Unit Beds. Corewell Health appreciates the Commission's consideration of our comments.

Sincerely,

Darryl A. Elmouchi, M.D. Chief Operating Officer Corewell Health



June 15, 2023

HCAM Comments: Nursing Home and Long-Term-Care Unit (NH-HLTCU) Informal Workgroup - Final Report & Draft Language

Chair Falahee and Commissioners,

Thank you for the opportunity to provide public comment regarding the final report and draft language for the nursing home and long-term-care unit informal workgroup.

I also pass my thanks to Commissioner Haney for his leadership as chair of the informal workgroup, and the multiple department staff who were so responsive during and between the workgroup meetings.

Through collaborative efforts and discussions, workgroup participants and department staff were able to find consensus language for charges 1 through 7, and charge 10. Several charges were technical in nature; however, several also include substantive changes to the standards that have material impacts on providers and the department staff who implement the CON process. HCAM greatly appreciates the collaborative effort and the department's willingness to receive and incorporate stakeholder feedback that led to consensus support for the draft language for each of these charges.

While HCAM is supportive of the department's recommended draft language before you today, we urge the Commission to consider proposed language to charges 8 and 9.

#### Charge 8

Charge 8 tasked the workgroup with considering language taking into account the impact of a public health epidemic on the CON process. It is well documented that the COVID-19 pandemic – and the ensuing economic climate that has followed – has had a significant impact on Michigan's economy and long-term care providers. Following the unprecedented clinical challenges experienced by providers in 2020 and early 2021, historic inflation, workforce shortages, and supply chain interruptions disrupted the entire economy for the last several years – many of these challenges continue to this day.

The clinical challenges diverted facility resources to focus solely on resident care, and the economic challenges led to delays entirely out of providers' control. While it is true that the department may extend timelines to a limited degree under the current standards and administrative rules, HCAM members noted the significant administrative burden currently required under the CON process. Additionally, due to the unforeseeable challenges of the pandemic, the extensions – if they were granted – often were not sufficient, resulting in expiration of some approved projects.

Stakeholders offered language that would allow the department to take into consideration the extenuating circumstances outside of the providers control when considering extensions to project delivery requirements contained in Section 11 of the NH-HLTCU standards. The department expressed



concerns with the initially proposed language, emphasizing that the standards should offer greater discretion to the department. HCAM worked with other stakeholders to review and update proposed language to ensure discretion to the department.

The language presented for charge 8 in the final report from workgroup Chair Haney maintains this discretion, and is flexible enough to apply to the varying experiences of providers and potential future public health emergencies. This language allows for extensions if the department determines the evidence of delays caused by the emergency presented by the provider are sufficient to warrant an extension.

HCAM requests the consideration of the Commission to adopt the proposed language for Charge 8.

#### Charge 9

Charge 9 tasked the workgroup with reviewing the process of temporary closure to replace aging structures.

Updated, state-of-the-art facilities are a critical component of delivering quality care to nursing facility residents. Michigan providers are committed to investing in capital infrastructure – leading the nation in new builds and renovations of existing facilities. As the demand for long-term care continues to rise as Michigan ages, it is imperative that the state implement policies that continue to incentivize these investments.

The Michigan Department of Licensing and Regulatory Affairs (LARA) recognizes the need to permit and incentivize investments in new buildings and renovations through building program agreements. Such agreements allow facilities to maintain licensed beds while temporarily closing operations while construction is underway. Unfortunately, department interpretations of the NH-HLTCU standards do not offer the same flexibility.

Stakeholders offered language to make clear in the standards that under CON providers have the ability to temporarily halt the operation of licensed beds for the duration of construction. The department and stakeholders emphasized the need to address the rights of the residents who would be displaced during construction – HCAM appreciates the consideration of the residents in this process.

Language included in Chair Haney's final report seeks to address this concern, and explicitly details the rights of temporarily displaced residents and the responsibility on the provider to ensure those residents' rights are protected.

HCAM agrees with Commissioner Haney's assessment that the workgroup was trending towards consensus, and given more time to meet, the language could have been developed to address the concerns of all stakeholders.

HCAM requests the Commission include the language from Commissioner Haney's final report. If language is ultimately not adopted into the standards today, we urge the Commission to make Charge 9 the top priority at the next standards review, before 2025 if there is opportunity to do so.



#### October 17, 2024

Re: Nursing Home and Long-Term-Care Unit (NH-HLTCU) Beds CON Review Standards

Chair Falahee and CON Commissioners,

Thank you for the opportunity to provide public comment regarding the Nursing Home and Hospital Long-Term-Care Unit Beds CON Review Standards that are scheduled for review in 2025.

HCAM respectfully requests inclusion of two issues on the charge for the review standards in 2025. First, the 2025 review should consider language that takes into account the impact of a public health epidemic on the CON process. Second, the review should review the process of temporary closure to replace aging structures.

Each of these issues was included as charges in the review process, which included an informal workgroup. Through collaborative efforts and discussions, workgroup participants and department staff were able to find consensus language for every other charge during the previous review process. HCAM greatly appreciates the collaborative effort and the department's willingness to receive and incorporate stakeholder feedback that led to consensus support for the draft language for each of these charges. At the June 2023 CON Commission meeting, HCAM supported the draft language while urging reconsideration of the two charges that remained unresolved. HCAM is hopeful that the productive conversations from the previous review can continue between stakeholders and the department during the 2025 review. The following offers a summary of each issue.

#### CON Extensions Due to Public Health Epidemic

It is well documented that the COVID-19 pandemic – and the ensuing economic climate that has followed – has had a significant impact on Michigan's economy and long-term care providers. Following the unprecedented clinical challenges experienced by providers in 2020 and early 2021, the economy was disrupted by historic inflation, workforce shortages, and supply chain interruptions that continue to this day.

The clinical challenges diverted facility resources to focus solely on resident care, and the economic challenges led to delays entirely out of providers' control. While it is true that the department may extend timelines to a limited degree under the current standards and administrative rules, HCAM members noted the significant administrative burden currently required under the CON process. Additionally, due to the unforeseeable challenges of the pandemic, the extensions – if they were granted – often were not sufficient, resulting in expiration of some approved projects.

During the previous review process and informal workgroup, stakeholders offered language that would allow the department to take into consideration the extenuating circumstances outside of the provider's control when considering extensions to project delivery requirements contained in Section 11 of the NH-HLTCU standards. The department expressed concerns with the initially proposed language, emphasizing that the standards should offer greater discretion to the department. HCAM worked with other stakeholders to review and update proposed language to ensure discretion to the department. The language presented for charge 8 in the final report from workgroup Chair Haney maintains this discretion, and is flexible enough to apply to the varying experiences of providers and potential future public health emergencies. This language allows for extensions if the department determines the evidence of delays caused by the emergency presented by the provider are sufficient to warrant an extension.

HCAM requests the consideration of the Commission to include this issue as a charge during the 2025 review process to allow for continued review of previously proposed language updates.

#### Temporary Closure to Replace Aging Structures

Updated, state-of-the-art facilities are a critical component of delivering quality care to nursing facility residents. Michigan providers are committed to investing in capital infrastructure – leading the nation in new builds and renovations of existing facilities. As the demand for long-term care continues to rise as Michigan ages, it is imperative that the state implement policies that continue to incentivize these investments.

The Michigan Department of Licensing and Regulatory Affairs (LARA) recognizes the need to permit and incentivize investments in new buildings and renovations through building program agreements. Such agreements allow facilities to maintain licensed beds while temporarily closing operations while construction is underway. Unfortunately, department interpretations of the NH-HLTCU standards do not offer the same flexibility.

During the previous review process, stakeholders offered language to make clear in the standards that under CON providers have the ability to temporarily halt the operation of licensed beds for the duration of construction. The department and stakeholders emphasized the need to address the rights of the residents who would be displaced during construction – HCAM appreciates the consideration of the residents in this process.

Language included in the informal workgroup's final report sought to address this concern, as it explicitly detailed the rights of temporarily displaced residents and the responsibility on the provider to ensure those residents' rights are protected.

HCAM agrees with former-Commissioner Haney's assessment that the workgroup was trending towards consensus, and given more time to meet, the language could have been developed to address the concerns of all stakeholders.

HCAM requests the Commission include this issue as a top priority at the next standards review in 2025.

In addition to the issues previously considered, HCAM also requests the following be included during the next standards review.

#### Provider Tax Repayment Plans

Included in the updates of the standard during the previous review was language that allowed for facilities to be considered current on Quality Assurance Assessment Program (QAAP) payments in order to receive approval through CON for proposed projects. While this update certainly improves the CON process, the update was specific to just two sections of the standards. HCAM requests that the review of the standards in 2025 includes consideration of applying this update to all sections of the CON standards to make clear that providers on a payment plan are considered current on QAAP payments.

#### Bed Need Methodology Update

Recently, the CON Commission made the decision not to update the NH-HLTCU bed need due to the inaccuracy of the most recent utilization data, which was impacted by the pandemic and does not offer a useful prediction

of future bed need. HCAM requests consideration during the review standards for adding a provision that would adjust the methodology when the data contains anomalies due a public health epidemic.

#### Form CON-200-C Update

The form CON-200-C requires applicants to certify that the beds are available for the proposed project at the time of application according to the department's bed inventories. However, this creates delays in situations when a potential applicant may know of a closure that has not yet been reflected on the department's bed inventories. The current process may result in significant delays – up to five months – unnecessarily preventing availability of NH-HLTCU beds in the community. HCAM respectfully requests consideration of reverting to reviewing bed need at the time of decision rather than application.

HCAM greatly appreciates the time and consideration of these important issues by the CON Commission.

Respectfully,

Richie Farran, V.P. of Government Services Health Care Association of Michigan



October 17, 2024

Mr. James Falahee, JD Chairperson Michigan Certificate of Need Commission South Grand Building, 5<sup>th</sup> Floor 333 S. Grand Avenue Lansing, Michigan 48933

Re: CON Review Standards for Nursing Home & HLTCU Beds

Chairperson Falahee,

Thank you for this opportunity to provide comments regarding the CON Review Standards for Nursing Home & HLTCU Beds ahead of their regularly scheduled review in 2025. We support the continued regulation of these beds under Michigan's CON program. As a provider of long-term care services in Michigan, we see the tremendous value the program provides to both providers and residents, ensuring access to quality care at a lower cost by ensuring the right amount of beds are available in each county.

As you prepare to review these CON standards, we do have a few issues we would appreciate the Commission reviewing and considering updates to the standards to address. The current standards require a facility to be current on their Quality Assurance Assessment Program (QAAP) payments in order to obtain CON approval for almost any proposed type of project. However, during the last review of these standards, the Commission approved language in Sections 9 and 11 that allowed for facilities to be considered current on QAAP payments if they had entered into a payment plan and were current on those payments. We would like the Commission to consider expanding the payment plan provision to all sections of the CON standards where QAAP payments are referenced.

In addition, during the last review in 2023, the Commission included a charge to review whether any provisions should be added to address issues related to the pandemic. The workgroup had a great deal of support for a provision that would address implementation deadlines impacted by a pandemic but the Department was not supportive. We would like to see the Commission continue to support consideration of provisions to help alleviate issues from repeating if another pandemic were to occur. We continue to support provisions to change implementation deadlines in the case of a future pandemic. In addition, based on the challenges we are currently facing with utilizing the current methodology to update the bed need across the State, we would also support adding a provision to the bed need methodology that would modify the methodology when utilization data is impacted by a public health epidemic. We would be happy to work with Dr. Paul Delamater to develop an appropriate and effective provision to do this.



4000 Town Center Suite 2000 Southfield, MI 48075 P 248.386.0300 F 248.386.0314 cienahealthcare.com Another issue that received a lot of support at the last workgroup was adding clarity in the standards surrounding the need for facilities to temporarily shut down during a bed replacement project. The recommendations developed by the workgroup did not make it to the CON Commission due to a lack of full consensus, but with more time and all of the work accomplished previously, we believe consensus could be reached around a solution that works for everyone.

Finally, although it does not relate to a specific provision in the standards, we would also ask the Commission to review a change in Department policy that was implemented several years ago and directly impacts the availability of nursing home beds. Although the nursing home bed standards specify that an application shall be decided based on beds available at the time of decision, not the time of submission, the Department created a new application form, CON-200-C which requires all applicants applying for beds to certify that the published inventory at the time of submission shows at least the number of beds available that are being requested in the application. Although we appreciate the intent behind this change, the unintended consequences are a significant delay in getting beds back out and available in the community. The bed inventories are only published every other month so the impact of this policy can result in a delay of as much as 5 months.

For example, the bed inventory was just updated on September 1<sup>st</sup>. If a facility closes on September 2<sup>nd</sup>, those beds won't show up in the inventory as available until November 1<sup>st</sup>. An applicant aware of the closure previously could have applied for those beds on October 1<sup>st</sup>. However, under this new policy, the next opportunity to apply would be February 1st, 4 months later, or 5 months since the closure of the facility. When you add on the 6 month review time for a potential comparative review application, you are looking at almost a year from closure until the beds could be approved for a project to get them back online in the community. Cutting 5 months out of that timeline seems like an important improvement the Commission should consider advocating in support of.

We thank you again for your time and consideration of these requests. We look forward to participating in a SAC or workgroup to review these and any other issues that are brought forward.

Respectfully,

**CIENA HEALTHCARE** 

Anis Khan, Chief Executive Officer



4000 Town Center, Suite 2000 Southfield, MI 48075 P 248.386.0300 F 248.386.0314 cienahealthcare.com

#### From: To: Cc: Subject: Date:

Deanna Mitchell MDHHS-ConWebTeam David Herbel; Dalton R. Herbel Certificate of Need Standards Friday, October 18, 2024 5:39:06 PM

### CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

LeadingAge Michigan is committed to policies that promote and ensure quality of care and quality of life for Michigan seniors. We represent not-for-profit providers of post-acute and long term services and supports here in Michigan and believe that policies that will work to support high performance in service delivery are critical to safeguard the interests of Michigan frail seniors.

For the upcoming Nursing Home Standards Review, we suggest looking at the quality standards required for facilities applying to start a nursing home or increase beds. We believe that a ceiling of 14% to a maximum of five facilities (see the Quality Requirements Guide) who demonstrate any of the listed conditions is far too many. A corporation with 22 facilities should not be able to expand their business models when they have not managed to ensure that three of their facilities are adequately performing. All of the Quality Requirements listed in the standards clearly identify poor performers.

We look forward to a discussion about quality in nursing home care in Michigan with review of Section 6 .

Thanks

Deanna Ludlow Mitchell

Deanna Ludlow Mitchell RN, BSN, MSBA Vice President for Health Policy and Integrated Systems LeadingAge Michigan | 201 N. Washington Square, Suite 920 | Lansing, MI 48933

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## C: (734) 679-8708 (Preferred)





# Computed Tomography (CT) Scanner Services



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October 18, 2024

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

### **RE:** Computed Tomography - Certificate of Need Standards Review

Dear Chairperson Falahee:

This letter is written as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Computed Tomography (CT) Services. University of Michigan Health (UMH) supports the continued regulation of this covered service; however, UMH would like the CON Commission to consider making a revision to Section 14(e) of the Project Delivery Requirements.

The section currently reads as follows:

The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate emergency interventions, and a physician on site in or immediately available to the CT scanner at all times when patients are undergoing scans.

The following is the proposed revision to Section 14(e):

The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate emergency interventions. <u>A physician, nurse practitioner, physician assistant, or RN trained in the management of hypersensitivity and physiologic drug reactions to CT contrast materials shall be on-site when patients are receiving intravenous contrast.</u>

The same revision is being recommended by the Magnetic Resonance Imaging (MRI) Informal Workgroup that is currently reviewing the CON Review Standards for MRI Services.

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

Respectfully submitted,

J. Array Dants

T. Anthony Denton, JD, MHSA Senior Vice-President & Chief ESG Officer University of Michigan Health Michigan Medicine

Vikas Gulani, MD Fred Jenner Hodges Professor of Radiology Chair, Department of Radiology University of Michigan Health Michigan Medicine

#### **Trinity Health Michigan**



October 10, 2024

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

#### RE: Public Comment for Computed Tomography (CT) Scanner 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 what, if any, changes need to be made to the Certificate of Need Standards for Computed Tomography (CT) Scanner Services in 2025.

Trinity Health Michigan supports the continued regulation of CT Scanner Services. Based on the recent MRI Workgroup discussions, Trinity Health Michigan recommends review of the CT Standards Section 14(e) to ensure the language related to physician oversight is aligned with the current American College of Radiology guidelines. We believe this review could be addressed by an informal workgroup.

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

Sincerely,

Shannon D. Strebat

Shannon D. Striebich President and CEO Trinity Health Michigan Market



October 10, 2024

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 (HFH) would like to offer comments on Certificate of Need review standards for Computed Tomography (CT) Services:

HFH appreciates the work completed by the Workgroup in 2022 through 2023. HF Health supports the continued regulation of CT services and does not recommend any changes to the standards currently.

Respectfully,

Deure Books William

Denise Brooks-Williams, FACHE Executive Vice President & Chief Operating Officer Henry Ford Health



October 15, 2024

James "Chip" 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 this opportunity to provide written testimony regarding the CON Review Standards for CT Scanner Services.

Corewell Health supports continued regulation of CT services and believes there is no need to reopen and make any changes to the standards at this time.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for CT Scanner Services. Corewell Health appreciates the Commission's ongoing support for the safety and quality of care for Michigan's residents.

Sincerely,

Darryl A. Elmouchi, M.D. Chief Operating Officer Corewell Health



#### **MICHAEL WEBBER**

9TH DISTRICT P.O., BOX 30036 LANSING, MI 48909-7536 PHONE: (517) 373-0994 FAX: (517) 373-5981 senmwebber@senate.michigan.gov

October 16, 2024

Chairperson James Falahee 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

#### RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

I would like to thank the Certificate of Need (CON) Commission for the opportunity to comment on potential changes to the Standards for Computed Tomography Scanner Services. I hope that the Commission will consider the elimination of certificate of need regulation of cone beam CT (CBCT) scanners, or, in the alternative, provide an exemption for the chiropractic profession, as was done by the Commission for Michigan dentists in 2016.

Michigan is one of only two states that currently requires a CON for a licensed health care professional to purchase a CBCT scanner. I believe these important diagnostic tools should be treated the same as other low-cost, in-office medical equipment, such as digital x-ray, ultrasound, etc., which do not require a CON in our state.

As I understand it, by allowing treating physicians to see in three-dimensional images, the benefits of CBCT are many, including better image quality, a lower radiation does to the patient, more accurate diagnoses, and more precise treatment plans, leading to better patient outcomes and patient satisfaction.

But most patients in Michigan do not have access to this technology, because of the regulatory hurdles that must be cleared in obtaining a CBCT scanner, combined with the high costs associated with the process, including fees and the costs associated with hiring an attorney experienced in the process. As chiropractic practices, like dental offices, are typically owned and operated by small business owners, increased practice costs threaten the bottom line and discourage many providers who might be interested in a CBCT scanner for their office from investing in one.

Additionally, the operating level required under the current CT Standards to obtain a CON shut out many practitioners from meeting the requirement. It also does nothing to further the Commission's goals of preventing unnecessary services and minimizing healthcare costs.

These factors result in a virtual prohibition on the use of this important technology among health care providers outside of the dental profession in Michigan. Deregulating CBCT scanners (or providing an exemption for chiropractors) would allow more small practices to access the most up-to-date tools to treat their patients. This change would not only benefit chiropractic physicians and the patients they serve, but also those cared for by otolaryngologists (ENTs), who use CBCT systems to image the sinuses, often picking up changes in the soft tissues of the sinuses that aren't visible in x-rays.

I believe the benefits associated with deregulating CBCT scanners from the CON process – or providing an exemption for the chiropractic profession – greatly outweigh any potential negatives, and I would urge the Commission to do so. Ending regulation of CBCT scanners would also bring Michigan into line with the rest of the nation, allowing Michigan health care providers to access up-to-date technology and provide the best possible care.

Again, thank you for the opportunity to submit these comments. Should you have any questions for me please feel free to contact my office at (517) 373-0994 or <u>SenMwebber@senate.Michigan.gov</u>.

Sincerely

Michael Webber State Senator 9<sup>th</sup> District

THE SENATE STATE OF MICHIGAN COMMITTEES: HEALTH POLICY, MINORITY VICE CHAIR ECONOMIC AND COMMUNITY DEVELOPMENT REGULATORY AFFAIRS



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October 18, 2024

Chairperson James Falahee Certificate of Need Commission c/o Michigan Department of Health and Human Services-Certificate of NeedPolicy MDHHS-ConWebTeam@michigan.gov Grand Building, 5th Floor 333 S. Grand Ave. Lansing, Michigan 48933

RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

I have been fortunate enough to be a practicing Chiropractor in this great state of Michigan for 25 years. Significantly contributing to the lives of thousands of Michiganders to date. As a student 25 years ago who had a choice as to what state to move, raise a family, and start a professional practice in, was partially based on the laws and regulations of Chiropractic in Michigan in 1999.

Moving to Michigan I used the telephone ads, typewriters, fax machines, and the old black and white 2D x-ray machine to start my career in Chiropractic. In today's world of 2024, we have 3D technology such as CBCT to analyze the head, neck, and spine. The imaging of today (CBCT) plugs into any 120v outlet. The unit can easily be placed anywhere in any room. All without lead walls or special electrical connections such as 240v. Complete opposite of installing and running an old dinosaur of a machine such as x-ray. CBCT images are instant and superior quality. Such as an ol black and white fax machine compared to today's cell phones to transfer data.

The citizens of Michigan can and will receive better analysis and treatment of the countless head and neck complaints that enter our offices daily with our use of CBCT. Not allowing me to use a CBCT is literally leaving our citizens in pain and with continuous suffering without this instant 3D imaging of CBCT. The outcomes of patients who have had a CBCT are far superior clinically than those without.

I also didn't realize the impact of Chiropractors not being able to use CBCT in Michigan had on the people outside of the state as well until recently. I'm now reaching the age of retirement and passing on the business of us taking care of people. So I've had prospective students, interns, and doctors visiting to start families and to possibly practice here in Michigan. Yet they all choose other states to start their lives in because of the CBCT issue. Michigan is literally one of a few states that do not allow our use of CBCT.

I am asking you Chairperson Falahee to please allow us to use this current technology in helping our citizens. I also appreciate the time and opportunity to express my professional opinion to the state. I hope you and the others voting allow us to use CBCT. As I continually look forward to serving the great people of Michigan with the best in today's Chiropractic.

IN Health,

Barry Hobbs, D.C.

Hobbs Specific Chiropractic 33664 five mile rd Livonia, MI 48154



October 11, 2024

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

### RE: Computed Tomography Scanner Services - Certificate of Need Standards Review

Dear Chairperson Falahee:

I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such a body includes consideration of the elimination of certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016.

Michigan is one of two states (the other is Connecticut) that require CON for a licensed health care professional to purchase a CBCT scanner. As of January 2024, 33 of the remaining 48 states have CON programs, yet chose not to require a CON for these important diagnostic tools. We believe this approach should be adopted in Michigan, which already does not regulate the other low-cost, in-office medical equipment such as digital x-ray, ultrasound, etc.

#### Use of CBCT in the Chiropractic Profession

Just as our founder, Dr. B.J. Palmer was a proponent of the use of imaging to improve evaluation and management services, ICA is encouraged by the advances in imaging technology that Cone Beam CT (CBCT) offers to chiropractic, particularly the Diplomates in Chiropractic Craniocervical Junction Procedures and others who focus on upper cervical care.

CBCT has been used in Chiropractic since 2011. CBCT has been shown so successful in the upper cervical region, that it is now within the teaching curriculum of chiropractic colleges and is becoming standard for new graduates. A continued virtual prohibition on the use of this technology in Michigan is affecting the limits chiropractors licensed in Miability of current license holders to attract new doctors of chiropractic to the state.



Page 2 - Michigan Certificate of Need Commission

#### Advantage of CBCT Over 2-Dimensional X-Ray

Three-dimensional CBCT is vastly superior to two-dimensional x-ray when it comes to imaging and analyzing the upper cervical spine. Some of the reasons for this include:

- Better Image Quality
- Lower Radiation Dose or Equivalent Dose
- 3D is the Medical Standard of Care for Management of the Head and Neck

#### **Proposed Exemption Language**

The Michigan Association of Chiropractors has offered the following exemption language to Section 2(k) of the CON documentation as a suggested option to consider (Additions in **bold**):

"CT scanner"... does not include... dental **OR CHIROPRACTIC** CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry **OR CHIROPRACTIC PROCEDURES BY A LICENSED CHIROPRACTOR UNDER THE PRACTICE OF CHIROPRACTIC** only. Any other use of CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer will require review and approval as a CT scanner service under applicable sections of these standards.

The International Chiropractors Association (ICA) supports the recommended exemption language offered by the Michigan Association of Chiropractors.

#### Conclusion

In conclusion, the chiropractic profession embraces CBCT, as it allows for better diagnosis and patient outcomes with lower or equivalent dose. Modifying the regulation of CBCT scanners by providing a chiropractic exemption would bring Michigan into line with the rest of the states and align with the evolving landscape of medical technology and patient-centered care.

The ICA greatly appreciates the opportunity to submit these comments and the Commission's consideration on this issue.

Yours in Health,

BAD Clay

Selina Sigafoose Jackson, DC, FICA President

Cc: Michigan Association of Chiropractors



### Sources Cited:

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- DeNunzio G, Evans T, Beebe ME, Browning J, Koivisto J. Craniocervical Junction Visualization and Radiation Dose Consideration Utilizing Cone Beam Computed Tomography for Upper Cervical Chiropractic Clinical Application a Literature Review. Dose Response. 2022 Jun
- Verderame, Jonathan & Dc, Jake. (2013). Cone-beam Computerized Tomography for the Bio-mechanical Assessment of the Occipito-atlanto-axial Articulation in a 75-year-old Woman with Migraines Undergoing Blair Technique.

#### Attachment

### Cone Beam CT Certificate of Need Exemption for the Chiropractic Field



### Cone Beam CT Certificate of Need Exemption for the Chiropractic Field

Over 20 years ago now Cone beam CT(CBCT) made its way into the dental field.[1] CBCT characteristics include a reduced imaging time, reduced dose to patients, sub-millimeter resolution for diagnostics of the Craniocervical Junction (CCJ)(C0-C1-C2), and three dimensional data acquisition in the CCJ with very little magnification compared to other imaging modalities.[2]

CBCT entered the chiropractic profession in 2011 and usage has been increasingly adopted.[3,4] CBCT produces 3D imaging at a lower or equivalent dose than a traditional 2D X-ray view series of the head and neck and 1/10th the dose of a traditional CT.[2,4] CBCT's three dimensional imaging technique acquires coronal, sagittal, and axial slices which form a 3D model. This 3D imaging acquisition is the standard of care for trauma imaging of the CCJ.[5]

What is the Difference between X-ray, CT, and CBCT?

Cone Beam CT is a 3D imaging system that produces a conical beam which travels around the patient once targeting a single detector. CBCT utilizes a kVp of 90-120 and an average mA of 8 and generates a peak power of 5 Kilowatts or less.[6] Whereas traditional Fan Beam CT acquires an image with multiple detectors that rotate around the patient 2-3 times. CT utilizes a kvp of 80-140 and an average mA of 220 and generates a peak power of 6-20 Kilowatts.[7] The Field of View (FOV) in diagnostic imaging, which is the size of the image acquired, is determined by the size of the detector. Most detectors in CBCT range from 8-30cm in width and height. This allows the unit to capture an image anywhere from 8x8cm (Occiput-Atlas-Axis) to 30x30cm (Cranium and Cervical spine).

The dose in a traditional CT scan is significantly higher around (600-1,200 micro-Sieverts) for the cranium or cervical spine versus (50-200 micro-Sieverts) in a Cone Beam CT scan of the same anatomy.[8,9] This CBCT dose is less than or equivalent to a traditional cervical x-ray series (2-3 views), which is 200 micro-Sieverts or higher.[2,4,10]

The gold standard in imaging of the head and neck especially after trauma is 3D. Providing imaging with axial, coronal, and sagittal plane analysis in a chiropractic setting is the ideal standard of care for patients that incur head and neck trauma. With CBCT, 3D imaging is more economical in terms of time, finances, and dose.[2,4,5]

Correcting spinal misalignment is the primary role of the chiropractic profession. X-rays were discovered by Wilhelm Roentgen in 1895. In 1910 the Chiropractic profession introduced X-ray for the purpose of measuring spinal misalignment. Since then, the profession has championed X-ray analysis of the spine and adopted new imaging modalities as they arise. When utilizing imaging to analyze the Craniocervical Junction (CCJ) for chiropractic misalignment, a 3D analysis is extremely valuable.[4,11,12] The CCJ is not only the most complex joint in the spine due to its biomechanical and neurological complexities, the CCJ is also highly prone to malformation, asymmetry, and micro and macro trauma.[4,12,13,14] These complex factors in correcting spinal misalignment in the cervical spine all lend weight to the clinical utility of CBCT.



The ability to discriminate 3D anatomy on CBCT over 2D X-ray is far superior.[2,4] The 3D spatial resolution to dose trade off with CBCT vs CT scanning is excellent for the cervical spine.[2,4] CBCT offers 3D imaging of the head and neck with little to no magnification, great detail, and few to no retakes when compared to 2D X-ray. CBCT mA is approximately 40 times less than CT mA, this produces a dramatically lower dose to the patient.[2]

Radiology courses on CT are already part of the curriculum in all chiropractic colleges across the country as well as in National Board exams. This exposure to CT in Chiropractic colleges covers axial, coronal, and sagittal plane analysis which translates directly to CBCT reading. Northwestern Chiropractic College as well as Sherman Chiropractic College already have CBCT on campus.[15] Diplomates in Chiropractic Radiology are reading for Chiropractors utilizing CBCT technology. Dental radiologists have partnered with our Chiropractic Colleges to teach courses and provide Chiropractic Continuing Education on CBCT. Training on Chiropractic use of CBCT is accessible to students and practitioners via the ICA's Council on Upper Cervical Care and Upper Cervical Chiropractic Affiliate organizations.

CBCT offers an array of clinical advantages. Requesting a specific Chiropractic exemption to the current CT Certificate of Need regulation for CBCT would ensure the Chiropractic profession stays current with the standard of care in spinal imaging. In 2006 CBCT or "Dental CT" as they called it was added to the CT CON documentation as an add on to CT CON. In 2016 the dental profession achieved an exemption. Initially the dental profession moved to remove CON entirely for CBCT but then found it easier to push for an exemption solely for their profession.[16,17]

"In June of 2016, Michigan's Certificate of Need Commission voted to remove dental cone-beam CT scanners (CBCT) from their list of regulated items in accordance with Michigan Senate bill 741."[17] "The removal of CBCT equipment from the list of items requiring a Certificate of Need (CON) in Michigan means that application fees (approximately \$3000), legal fees, and the extensive paperwork associated with certification will be eliminated."[17]

During the June 15, 2016, meeting, the CON commission approved to make an exception for Dental Cone Beam CT for dentistry only (pg. 32 - 79). The board voted 9-1 to approve the exemption. After reviewing the 2006 and 2016 meeting minutes the approach taken by the dentists i.e. adding an exemption for the chiropractic profession seems the most expedient. The Michigan Association of Chiropractors has offered language that will resolve this matter. The ICA Supports the language they have submitted to the CON.

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- 4.) DeNunzio G, Evans T, Beebe ME, Browning J, Koivisto J. Craniocervical Junction Visualization and Radiation Dose Consideration Utilizing Cone Beam Computed Tomography for Upper Cervical Chiropractic Clinical Application a Literature Review. Dose Response. 2022 Jun 13;20(2):15593258221107515. doi: 10.1177/15593258221107515. PMID: 35719850; PMCID: PMC9201332.
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- 10.) Oakley PA, Harrison DE. Radiophobia: 7 Reasons Why Radiography Used in Spine and Posture Rehabilitation Should Not Be Feared or Avoided. Dose Response. 2018 Jun 27;16(2):1559325818781445. doi: 10.1177/1559325818781445. PMID: 30013456; PMCID: PMC6043928.
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- 16.) Greene, Jay. February 21, 2016. Crain's Detroit Business; Dentists push to cut dental CT scanners from CON regulation. https://www.crainsdetroit.com/article/20160221/NEWS/302219993/dentists-push-to-eliminate-dental-ct-scanners-from-con-rules
- 17.) Greene, Jay. June 16, 2016. Crain's Detroit Business; CON Commission votes to deregulate dental CT scanners.



October 9, 2024

Chairperson James Falahee 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

### RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

On behalf of the Michigan Association of Chiropractors (MAC), I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such body includes consideration of the elimination of certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016.

To the best of our knowledge, Michigan is one of only two states – the other being Connecticut – that requires a certificate of need for a licensed health care professional to purchase a CBCT scanner. As of January 2024, 33 of the remaining 48 states had certificate of need programs, yet chose not to require a certificate of need for these important diagnostic tools. We believe this approach should be adopted in Michigan, which already does not regulate other low-cost, in-office medical equipment such as digital x-ray, ultrasound, etc.

### Use of CBCT in the Chiropractic Profession

Cone Beam Computed Tomography has been used in chiropractic since 2011. CBCT technology is a standard tool used by Upper Cervical Chiropractic practitioners, whose focus is on the craniocervical junction and how the structural integrity of the neck influences the nervous system, vascular system, and cerebrospinal fluid flow in and out of the cranial vault.

The craniocervical junction is one of the most complex joints in the human body, given the region's bone morphology, biomechanics, neurology, ligamentous structures, and fluid dynamics. It plays a major role in cervical spine stability. By allowing the practitioner to see the craniocervical junction in three-dimensional images, CBCT has revolutionized the way upper cervical chiropractors examine and correct that region of the spine, providing the

exact location and degree of misalignment and allowing for the extremely gentle and precise corrections performed by upper cervical chiropractors.

While CBCT is extremely helpful in the upper cervical world of chiropractic, this modern 3D technology is being increasingly adopted throughout the profession. Any physician who wishes to properly analyze a patient with head and neck complaints benefits from this technology, which we expect will advance even further as it is further refined and expanded to analyze other areas of the spine and body.

CBCT is now within the teaching curriculum of chiropractic colleges and is becoming standard for new graduates in assisting them to be the best chiropractor they can be. However, the virtual prohibition on the use of this technology in Michigan chiropractic practice – due to the costly, time-consuming process of obtaining a certificate of need – is affecting the ability of current license holders to attract new chiropractic physicians to our state, and many new graduates are going to other states to practice and start their career and family, because of the lack of CBCT use in our state.

### Advantages of CBCT Over 2-Dimensional X-Ray

Three-dimensional Cone beam CT is vastly superior to two-dimensional X-ray when it comes to imaging and analyzing the upper cervical spine. Some of the reasons for this include:

- <u>Better Image Quality</u>. Because the image is three dimensional and covers 360° (unlike x-ray, which is 2D), there is no image distortion or overlap of structures. Also, cone beam CT can distinguish between many types of tissues (bone, nerves, soft tissues), unlike traditional x-ray.
- <u>Lower Radiation Dose</u>. It takes only one CBCT scan (as opposed to the typical threesix x-ray films needed) to gather the necessary information. A standard CBCT scan is 240 micro sieverts (equivalent to about 1/10 the radiation exposure of a standard 4view cervical spine X-Ray series). The amount of radiation emitted by CBCT technology does not even require lead lining in the walls, just six feet of distance.
- <u>More Accurate Diagnoses and Precise Treatment Planning</u>. Traditional twodimensional x-ray can sometimes result in misdiagnosis because of factors such as anatomical variations, asymmetry of structures, and positioning errors. CBCT allows for a wider variety of viewing angles and increased precision (more than 1,000 different angles of the spine vs. one view/angle per image), leading to better treatment outcomes. CBCT can also allow practitioners to visualize internal anatomy that cannot be diagnosed externally or by physical clinical examination.

For additional clarification that expands on these advantages and places them into context, please see the attached papers:

• "Cone Beam Computed Tomography: Technology Overview, Dose, and Utility Considerations for Chiropractors and Regulatory Bodies," from the *Journal of Contemporary Chiropractic*. From the conclusion: ""Utilizing CBCT in chiropractic practice is in the best interest of patients and clinicians from both an image quality and patient dose perspective and is an evolution to current technology as opposed to a new technology." • "Craniocervical Junction Visualization and Radiation Dose Consideration Utilizing Cone Beam Computed Tomography for Upper Cervical Chiropractic Clinical Application: A Literature Review," from *Dose-Response*. From the conclusion: "The use of CBCT for visualization of the craniocervical junction and cervical spine in the chiropractic clinical setting allows for adjunctive visualization of the osseous structures which is germane to clinical protocol. Further with CBCT the effective dose to the patient is equal or less than similar imaging protocols utilizing radiographs to evaluate the craniocervical junction."

### High Cost and Regulatory Hurdles of Obtaining a Certificate of Need

We believe that the cost impact on Michigan's health care system should the Commission deregulate CBCT (or provide an exemption for the chiropractic profession) would be nominal. In fact, requiring a certificate of need for CBCT scanners greatly increases chiropractic practice costs

– through fees, the hiring of an attorney experienced in the process, and navigating regulatory hurdles – for the chiropractic physicians who wish to optimize patient outcomes through the use of this technology.

Chiropractic practices are generally owned by small business owners, and this regulatory hurdle for technology increasingly being used throughout the nation adds costs to their bottom line. Deregulating CBCT (or providing an exemption for the chiropractic profession) would allow more practices to use the most modern tools, potentially reducing costs, improving the delivery of chiropractic care, and resulting in better patient outcomes.

Furthermore, as small business owners, the large majority of chiropractic physicians are shut out from receiving a certificate of need for a fixed CT scanner, as the current Standards require the applicant be able to demonstrate "an operating level of at least 7,500 CT equivalents per year for the second 12-month period after beginning operation of the CT scanner." This is the equivalent of more than 20 scans per day. This requirement exceeds the need in the offices of many chiropractic physicians and flies in the face of the goal of preventing overuse, limiting the number of unnecessary services, and minimizing costs.

#### **Proposed Exemption Language**

The Michigan Association of Chiropractors offers the following exemption language to Section 2(k) of the as a suggested option to consider (Additions in **bold**):

"CT scanner" ... does not include ... dental **OR CHIROPRACTIC** CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry **OR CHIROPRACTIC PROCEDURES BY A LICENSED CHIROPRACTOR UNDER THE PRACTICE OF CHIROPRACTIC** only. Any other use of CT scanners (such as but not limited to chiropractic utilization) that generate a peak power of 5 kilowatts or less as certified by the manufacturer will require review and approval as a CT scanner service under applicable sections of these standards.

#### Conclusion

In conclusion, the chiropractic profession embraces this emerging technology, as it allows chiropractic physicians to analyze images that generate 3D clarity and better detail and resolution than traditional 2D x-ray is unable to provide. X-ray remains an incredible tool, but cone beam CT is the imaging technology of the future. Its use and emergence make it a vital addition to chiropractic radiographic analysis, especially regarding the upper cervical region of the spine. The enhanced images of CBCT increase the accuracy of the patient's diagnosis, make treatment planning more precise, and will lead to superior outcomes, all while emitting a safer dose of radiation than other diagnostic imaging studies.

Ending regulation of CBCT scanners, or at least providing a chiropractic exemption, would bring Michigan into line with the rest of the nation and align with the evolving landscape of medical technology and patient-centered care, allowing chiropractic physicians to use the most modern tools, improving the delivery of chiropractic care and enhancing patient outcomes.

For these reasons, we believe that cone beam computed tomography is appropriate for use in chiropractic and across healthcare professions, not just dentistry.

We greatly appreciate the opportunity to submit these comments and the Commission's consideration of this issue. We look forward to continuing this dialogue and working with the Commission in the future. If you have any questions regarding these comments or if you would like any additional information, please contact MAC Assistant Director Tim Gaughan at tim@chiromi.com.

Yours in Health,

To Rotent O Marking DE

Robert Markle, DC President Michigan Association of Chiropractors

#### <u>Attachments</u>:

Scholten J, Kos A, Richardson M, Campion K. Cone Beam Computed Tomography: Technology Overview, Dose, and Utility Considerations for Chiropractors and Regulatory Bodies. JCC. 2023;6(1):92-99. DeNunzio G, Evans T, Beebe ME, Browning J, Koivisto J. Craniocervical Junction Visualization and Radiation Dose Consideration Utilizing Cone Beam Computed Tomography for Upper Cervical Chiropractic Clinical Application a Literature Review. Dose Response. 2022 Jun 13;20(2):15593258221107515. doi: 10.1177/15593258221107515. PMID: 35719850; PMCID: PMC9201332. Cone Beam Computed Tomography

JOURNAL OF Contemporary Chiropractic

# CONE BEAM COMPUTED TOMOGRAPHY: TECHNOLOGY OVERVIEW, DOSE, AND UTILITY CONSIDERATIONS FOR CHIROPRACTORS AND REGULATORY BODIES

Jeffrey Scholten, BSc, PgCPain, DC, DCCJP, FCCJP, FICA<sup>1</sup>; Arif Kos<sup>2</sup>; Matthew Richardson, DC, DACBR<sup>3</sup>; Karen Campion, DC, CCSP, FIAMA<sup>4</sup>

# ABSTRACT

**Introduction:** As computed tomography (CT) applications progress through advances in X-ray capture and computer capabilities, evolutions in this technology have created confusion in differentiating different CT technologies. This underscores the need to develop a common understanding of these ionizing radiationbased imaging modalities by regulators and educational institutions in the chiropractic profession. This narrative review seeks to provide clarification and provides technological context addressing the physics and the clinical applications of CT.

**Discussion:** Computed tomography (CT) has various applications of cone vs planar X-ray beam and flat vs curve receivers. The evolution of greater-sized capture devices for X-ray has allowed CT to evolve to use lower-dose cone beam applications, allowing for crosssectional CT imaging with lower dose and increased image clarity while reducing the imaging time required for patients.

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**Conclusion:** This review provides a synopsis of CT technologies and offers an opportunity to understand similarities and critical differences between cone beam CT and multidetector CT. The benefits of information gained from cross sectional CBCT studies that is unavailable with conventional X-ray examinations to patient management are summarised. Utilizing CBCT in chiropractic practice is in the best interest of patients and clinicians from both an image quality and patient dose perspective and is an evolution to current technology as opposed to a new technology. (*J Contemporary Chiropr 2023;6:92-99*)

**Key Indexing Terms:** Chiropractic; Radiographic Imaging; Computed Tomography; Cone Beam Computed Tomography; Patient Dose; Patient Safety

# **INTRODUCTION**

This narrative review, intended for chiropractors and their regulatory bodies, supplies a basic overview, comparison, and analysis of the technical workings of computed tomography (CT) (multidetector (MDCT) and cone beam (CBCT)) scanners. CBCT is an evolution in lower-dose computed tomographic imaging that is a variant of CT scanning rather than an entirely new technology.

# DISCUSSION

CBCT is a technological advancement in ionizing radiation-based studies that, like radiography and traditional CT, use X-ray radiation to produce diagnostic imaging studies for healthcare applications. The concept of use of the full cone beam was first introduced to the world of radiology soon after the development of the first CT scanners. (1,2) Its first utilization was mainly for angiography before being slowly introduced for other applications.

The most noticeable impact that cone beam scanners have had is their use in dentistry, which began in the 1990s. (2) Thanks to this evolution in CT scanners, the CBCT we see today has become ubiquitous in various dental applications such as orthodontics, implant planning, and endodontics. Slowly, more industries are beginning to see the usefulness of CBCT. In the last 3-5 years, CBCT use in chiropractic evaluation of the craniocervical junction has grown considerably and is providing chiropractors with high-quality 3D images of patient anatomy with lower effective dose of radiation than traditional CT. In most cases, the radiation dose absorbed by the patient is comparable to that of traditional chiropractic radiographic examinations of the head and neck. (1)

#### Review of Technology

X-ray tube: X-rays are generated in a tube containing an electrical circuit with 1 cathode and 1 anode separated by some distance in a vacuum. The cathode is generally made up of a tungsten filament which is heated when an electrical current is applied. (2) This in turn induces the release of electrons due to an effect commonly known as thermionic emission. Due to the high-voltage difference between the cathode and the anode, the electrons are then propelled towards the anode. These accelerated electrons collide with a focal spot made of high-density material [tungsten typically]. (2) As a result of these collisions, energy is created in the process and most is dissipated as heat. However, a small part of this energy is converted into X-rays via an effect known as Bremsstrahlung radiation. The X-rays form a beam as they exit the X-ray tube via a port, and the X-ray beam is controlled in size by collimation.

CT Scan: A difference between a conventional X-ray and a CT scan is that the X-ray tube and image receiver are fixed, whereas a CT scanner uses a motorized X-ray tube that circulates around the opening of a donut shaped ring, the gantry, which houses the radiation source. (3) During a CT study, the patient will lie on a flat bed that slowly moves through the gantry while the X-ray tube rotates around the patient. The X-ray tube in the CT unit produces a narrow stream of fan-shaped X-rays directed at the body of the patient. (3) Some of the X-ray photons are absorbed by the patient and some pass through the patient's body and are received by digital detectors which are positioned directly opposite to the X-ray source. In a CBCT unit, the x-ray tube is fixed opposite the digital plate on a C-arm, which rotates as a unit around the patient.

Another key difference between MDCT and CBCT is the shape and size of the scanner itself. In its current form, a CBCT scanner looks like a small and condensed version of a MDCT scanner. Patient conveyance is not required with CBCT, though this does limit the area available to be imaged in a scan. The gantry and the FPD rotate simultaneously around the patient while shooting pulsed X-rays at the area of interest. The resulting X-rays strike the FPD on the opposite side of the source. (1) The digital plate collects the 2D data set and the computer applies the FDK algorithm to the acquired data allowing for the reconstruction of a fully 3D image of the area of interest.

Data collected by these detectors is in the form of voxels. A voxel is a combination of both "volume" and "pixel," which is a value on a regular grid in 3-dimensional space. The image made by the CT scanner consists of a square matrix of elements (the pixels) which also incorporates a depth measurement to become a voxel, or a volume element of the tissue of the patient.

Each time the X-ray source makes one full rotation, the CT's computer will create these voxels using mathematical techniques and construct a 1-dimensional



Figure 1. Depiction of the difference between a pixel and a voxel in a data acquisition sense (Used by permission of Johan Moed, PlanMed)



Figure 2. Principle of how a CBCT scanner works. (6)

X-ray image slice of the patient. (3) This process is then repeated to produce another image slice and continues until the desired number of slices is collected. These image slices are then either viewed singularly (2D) or stacked to form a 3D image of the patient that shows the skeleton, organs, and tissues as well as any abnormalities that the practitioner is trying to identify. (3) Helical CT accomplishes this data collection in a single spiralized collection as opposed to aggregate single slices.

(Figure 1)

#### Technology Advancement

X-ray imaging devices (traditional radiography, MDCT, CBCT, fluoroscopy, etc.) use a common X-ray tube configuration to produce the beam. An X-ray tube used in CT scanners produces X-rays, which are then projected in a fan-shaped beam due to collimators in the machine. In MDCT, these fan-shaped beams strike a 1D detector, which interprets the values received and sends them to the computer to be interpreted, by which an image is then formed. Conversely, as the name suggests, CBCT scans use a cone shaped beam in which the X-rays come from the common X-ray tube configuration, only this time they strike a 2D flat-panel detector (FPD). (4) (Figure 2) These FPDs allow the CBCT to take multiple 2-dimensional X-ray images (basis projections) as opposed to the 1-dimensional X-ray images created by an MDCT scan. (5) For the 2D data from the FPD to be utilized properly by the CBCT,





it is able to use the same mathematical techniques and computer programs as a MDCT. However, these algorithms must be updated and transformed slightly to allow for the interpretation of the newly created 2D data. For the computer to properly portray the new type of data, the algorithm may be transformed using a Feldkamp-type reconstruction algorithm [FDK]. (2) The FDK algorithm is a mathematical transformation of the original algorithm used to construct MDCT images, only it now considers 2D data rather than 1D data and is what ultimately allows the CBCT to create its 3D image. This shift in data acquisition allows for reduced dose to the patient. The MDCT X-ray beam is lower in energy to allow for more differential absorption; in contrast, the CBCT study uses a high-energy X-ray beam which decreases the number of photons absorbed by the patient.

It should be noted that with increasing numbers of rows in MDCT detector arrays, the acquisition geometry approximates a cone beam system because the incident X-ray photons fall on a 2D area of detectors just as they do with FPD. (4) (Figure 3)

#### CBCT – image quality and patient dose

When it comes to radiology and the ability of a chiropractor to diagnose a patient, a critically important factor is the quality of the image. Image quality is what allows the doctor to observe the study and make a diagnosis, whether that is looking for bone malalignment, broken bones, or foreign objects in the body. In many areas of healthcare today, diagnostic imaging is the gold standard in terms of diagnosis and assists in development of the treatment plan; this is precisely why the quality of the image makes all the difference in not only the doctor's role, but also in the quality of care received by the patient.



Figure 4. Lateral Cervical Radiographs (SS)

Pictured above is a neutral lateral radiograph (Figure 4) and sagittal slice of a CBCT image of the same patient (Figure 5)

It is important to keep in mind that chiropractors take multiple images of the same anatomic region when using traditional radiographs to obtain the necessary detail needed for proper treatment. As we begin to consider patient dose, the effective patient dose to obtain an image similar to that of Figure 4 (lateral cervical radiograph) is 0.02 mSv (20 µSv) and for an AP cervical spine radiograph is 0.12 mSv. (7).

The description above quoted effective dose. Due to the individual sensitivities that different tissues have to radiation, it is important to be clear about the kind of dose being described: absorbed, equivalent, or effective.

Absorbed dose "is the energy deposited in a small volume of matter (tissue) by the radiation beam passing through the matter divided by the mass of the matter". (8) This is measured in Gray (Gy) and "is equal to a joule of energy deposited in a kilogram of substance." (9)

Equivalent dose is a variation on absorbed dose that is focused on radiation-type based on its interaction with tissue. A change to units from Gray (Gy) to Seiverts (Sv) occurs after the absorbed dose is multiplied by a



Figure 5. Midline sagittal reconstruction image -CBCT (SS)

radiation weighting factor. (8) This weighting factor is intended to allow for understanding of the amount of harm that is created by the various types of radiation (alpha, beta, gamma). (9) In X-ray, the radiation weighting factor is 1.0, so in effect the absorbed dose of 1 Gray (Gy) is equal to the equivalent dose in Seiverts (Sv). (8)

Effective dose multiplies the equivalent dose by a tissue weighting factor and is used to describe the effect of the radiation on the specific tissue that was exposed; effective dose is also described in Seiverts (Sv).

Understanding effective dose is necessary to evaluate the patient risk of having a diagnostic imaging study.

The effective dose obtained from Planmeca CBCT imaging supplies an effective dose range between 0.091 – 0.273 millisieverts (mSv)(91-273 microsieverts ( $\mu$ Sv)) depending on patient size using standard settings at 30cm x 30 cm field of view, with effective dose reduced to .023-.068 mSv (23-68  $\mu$ Sv) with an ultra-low dose protocol. (Table 1) In contrast, the dose of a cervical spine x-ray examination has a total average effective dose of 0.2 mSv (200  $\mu$ Sv), and an MDCT has a total average effective dose of 3 mSv (3000  $\mu$ Sv) for the neck and 2 mSv (2000  $\mu$ Sv) for the head. (10)

As a result of this comparison between CBCT and X-ray imaging dose, CBCT supports doses being as low as reasonably achievable (ALARA) when considered against traditional X-ray examination, especially in cases in which extra views are recommended as in cases of trauma, radiculopathy, anatomic anomalies, and most chiropractic upper cervical techniques (UCTs). (11) **Table 1.** Comparing patient size to voxel with exposure considerations.

|       |    | xs  |     |    | S    |     |     | м   |     |     | L   |     |     | XL  |     |
|-------|----|-----|-----|----|------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| VOXEL | kV | mAs | μSv | kV | mAs  | μSv | kV  | mAs | μSv | kV  | mAs | μSv | kV  | mAs | μSv |
| 600   | 90 | 28  | 91  | 90 | 32   | 104 | 100 | 25  | 120 | 110 | 22  | 144 | 120 | 20  | 171 |
| 450   | 90 | 36  | 117 | 90 | 40   | 130 | 100 | 32  | 153 | 110 | 28  | 183 | 120 | 25  | 214 |
| 300   | 90 | 45  | 146 | 90 | 50   | 162 | 100 | 40  | 191 | 110 | 36  | 236 | 120 | 32  | 273 |
| ULD   |    |     |     |    |      |     |     |     |     |     |     |     |     |     |     |
| 600   | 90 | 7,1 | 23  | 90 | 8,0  | 26  | 100 | 6,3 | 30  | 110 | 6,3 | 41  | 120 | 6,3 | 54  |
| 450   | 90 | 9,0 | 29  | 90 | 10   | 32  | 100 | 8,0 | 38  | 110 | 7,1 | 46  | 120 | 6,3 | 54  |
| 300   | 90 | 11  | 36  | 90 | 12,5 | 40  | 100 | 10  | 48  | 110 | 9,0 | 59  | 120 | 8,0 | 68  |

(Planmeca VisoG7 Effective Dose Chart, D0011748, J Koivisoto, University of Helsinki, Dept of Physics)

To understand health risks, it is helpful to understand what is allowed for people who work in occupations with regular radiation exposure. "The effective dose limits for a nuclear energy worker is set at 50 mSv in any one year and 100 mSv in five consecutive years. The dose limit for pregnant workers is 4 mSv from the time the pregnancy is declared to the end of the term." (9) For a frame of reference, the typical radiation an average individual in the USA can expect to encounter is 6.2 mSv (6200  $\mu$ Sv) (12,13) or from background radiation alone is 3 mSv (3000  $\mu$ Sv) annually. (10)



**Figure 6.** 3D reconstruction with threshold set to image bone surface using CBCT(SS)

Figure 6 depicts a 3D surface rendered reconstruction.

Figure 7 depicts a typical 3 view X-ray series; Figure 8 depicts multiplanar reconstruction (MPR) view using a single CBCT scan on the same patient.

#### Benefits of CBCT and 3D imaging

When considering chiropractic use of CBCT 3D imaging, there are several benefits available to the clinician, radiologist, and patient. These include less or equivalent radiation, better spatial resolution quality, wider variety of viewing angles, less time spent with image acquisition, easier patient positioning and improved patient experience, more precise treatment planning and protocol, reduction in electrical requirements, and reduced need for lead lined imaging suites.



Figure 7. X-ray 3 view series (SS)



Figure 8. CBCT multiplanar image reconstructions

In general, CBCT imaging lasts around 40 seconds and may be taken while the patient is either seated or standing; this provides both versatility and accessibility given that standing is not always a viable option for many patients.

Use of CBCT instead of traditional x-ray also negates the UCT specialty images that might be required in the thorough evaluation of the spine by chiropractors, especially those of the craniocervical junction and cervical spine. The ability to manipulate the image angles and perspectives replaces the need for multiple X-ray views to assess vertebrae and joints from different vantage points; this eliminates the need for retake imaging as well as multiple exposures to adequately assess an area.

Image resolution and the ability to create multiplanar reconstructions, combined with the lack of magnification and distortion in the image, provides for a diagnostic imaging study free of technical limitations inherent to traditional X-ray. With the use of CBCT we see a clear reduction in the time required for image acquisition while simultaneously improving image quality.

CBCT provides the ability to visualize and accurately discern complicated segmentation anomalies of the craniocervical spine and enhances the ability to identify pathogenic proximity to other anatomy as compared to X-ray. Assessing severity of joint disease and other disease that is not able to be well studied with radiographs, is also enhanced with CBCT applications [i.e. fusions not evident on traditional X-ray, calcium pyrophosphate deposition disease (CPPD)/ pyrophosphate arthropathy involving the cruciate ligament complex and other paraodontoid structures, Schmorl's nodes, and styloid process elongation (sometimes associated with Eagle Syndrome)]. The addition of CBCT in a chiropractic office not only improves the chiropractor's ability to provide care to their patients but does so while supporting ALARA guidelines.

#### Future Applications

After reviewing both MDCT scans and CBCT scans, CBCT is an evolution in existing computed tomography technology rather than a new technology. In both cases, X-rays are still produced in a similar fashion, with the only real changes occurring with image detection and computer programming. This progress is like the development of new imaging sequences, receptor development, or enhancing magnet strength in MR.

Although the data requisition in CBCT technology is 2D rather than 1D in MDCT, multiple detector arrays on regular MDCT scanners approximates the data collection of the CBCT's 2D surface. Essentially, this means that the special detectors used in MDCT are trying to recreate what the CBCT flat-panel detector already does during a scan. This mimicking of data acquisition is exactly what allows CBCT to essentially use the same algorithm that the MDCT scanner would use.

CBCT is seeing increased use in many different fields and is already used widely in dental imaging regarding the investigation of exact jaw pathologies such as tumours, inflammatory lesions, or for maxillofacial surgery. (14) The 3D cone beam also aims to address the limitations present in 2D imaging on mammography with high contrast between pathological and normal breast tissue. (15) CBCT is seeing advancements in both liver and lung imaging. (16,17) CBCT machines are being developed to evaluate the entire spine; the technology is advancing quickly, and in the coming decades it may replace conventional radiography in evaluating for many diseases of the spine. High-quality CBCT studies will provide chiropractors with improved detail resulting in more accurate identification of pathology and therefore improved quality of care for the patient.

CBCT and MDCT are both forms of CT with CBCT having significantly reduced effective radiation dose. The reduced dose provided by CBCT will allow it in many cases to replace traditional X-ray examinations. There is clear evidence to support the fact that CBCT is not something new entirely but rather an evolution of an existing technology that may be beneficial for both patients and chiropractors alike.

# CONCLUSION

Although CBCT has been used extensively in the dental industry for more than 2 decades, the ability for a single CBCT scan to replace a full cervical X-ray series is a recent development due to increases in capture device size. Technological advancement will likely soon allow all skeletal regions to be imaged by CBCT. MDCT and CBCT machines share similarities in X-ray generation and data processing, and as a result CBCT is an evolution of established CT and X-ray technology. With no increase in effective dose rates, and improvement in crosssectional imaging capability, CBCT should be available as chiropractors seek to follow informed patient care with mind to ALARA principles and is best regarded as inside the scope of chiropractic practice in which radiation-based diagnostic imaging is currently allowed. It is our opinion that CBCT is a valuable and safe dose radiation-based diagnostic imaging study appropriate for access and use across the healthcare professions.

# **AUTHOR CONTRIBUTIONS**

The need for this paper was conceptualized by JS and designed by JS and AK. The manuscript was drafted by AK and JS and edited with contributions by MR and KC. Radiographic and CBCT imaging provided by JS with patient consent. All authors read and approved the final manuscript.

# **CONFLICT OF INTEREST**

The authors declare no conflict of interest with this article.

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# Craniocervical Junction Visualization and Radiation Dose Consideration Utilizing Cone Beam Computed Tomography for Upper Cervical Chiropractic Clinical Application a Literature Review

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#### Abstract

**Objectives:** To highlight the detail obtained on a Cone Beam Computed Tomography (CBCT) scan of the craniocervical junction and its usefulness to Chiropractors who specialize in the upper cervical spine. A review of the dose considerations to patients vs radiography in a chiropractic clinical setting and to review the effective radiation dose to the patient.

**Methods:** A review of studies discussing cervical biomechanics, neurovascular structures, and abnormal radiographic findings, was discussed in relation to chiropractic clinical relevance. Further studies were evaluated demonstrating radiation dose to the patient from radiographs compared to CBCT.

**Results:** Incidental and abnormal findings of the craniocervical junction were shown to have superior visualization with CBCT compared to radiography. The radiation dose to the patient for similar imaging protocols to the craniocervical junction and cervical spine was equal or less utilizing CBCT when compared to radiographs.

**Conclusions:** The use of CBCT for visualization of the craniocervical junction and cervical spine in the chiropractic clinical setting allows for adjunctive visualization of the osseous structures which is germane to clinical protocol. Further with CBCT the effective dose to the patient is equal or less than similar imaging protocols utilizing radiographs to evaluate the craniocervical junction.

#### **Keywords**

cone beam computed tomography, craniocervical junction, upper cervical chiropractic, chiropractic radiography

#### Introduction and History of Cone Beam Computed Tomography

Visualization of the spine has helped chiropractors assess contraindications to care and differentially diagnose patient with

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The clinical use of Cone Beam Computed Tomography (CBCT) in healthcare has grown steadily since the first commercial CBCT system was offered in the US in the 2001 timeframe. Initially, CBCT was utilized by dental specialists for acute conditions typically related to surgical procedures. The use of CBCT for routine diagnostic imaging is being explored within other healthcare specialities, such as chiropractic.<sup>1</sup>

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upper cervical conditions. Imaging has also been used to determine spinal positioning, which allows for the measurement of force vectors for the upper cervical specific chiropractic adjustment procedures. There are techniques within the profession in which imaging of the craniocervical junction (CCJ) heavily influences treatment protocols.

Chiropractic providers, utilizing various techniques, are now among the healthcare specialties utilizing CBCT. Within the chiropractic profession there exists a sub-specialty, called Upper Cervical Chiropractic (UCC) which concentrates on the craniocervical junction and how the structural integrity of the neck influences the nervous system, vascular system and cerebrospinal fluid flow in and out of the cranial vault.<sup>2,3</sup> CBCT imaging offers a high quality imaging technique that minimizes radiation exposure to patients, and this type of imaging is of particular interest to UCC practitioners. Figure 1 demonstrates neutral lateral radiograph typical in an upper cervical chiropractic clinical setting. Figure 2 is the same person as Figure 1 with the 3-D rendering available with CBCT, allowing for appreciation of detail.

# Understanding the Biomechanics and Structure of the Craniocervical Junction (CCJ)

The craniovertebral junction (CVJ) or craniocervical junction (CCJ) are interchangeable and both terms refer to the Occiput (C0), Atlas (C1), and Axis (C2), and the supporting ligaments (Reddy et al, 2015). For the purpose of this paper, we will refer to the area as the craniocervical junction (CCJ). The Atlanto-occipital Joint (C0 on C1) and the Atlanto-axial joint (C1 on C2) are unique because they are diarthrodial, synovial pivot joints, with motion around hyaline cartilage surfaces. All vertebrae inferior to these 2 joints are fibrocartilaginous symphysis joints, classified as amphiarthroses and separated by discs.

The joints of the CCJ work together to allow for dynamic head and neck motion, while at the same time allowing the CNS to maintain its complex functions throughout the body (Reddy et al, 2015). The CCJ plays an important role in the overall motion of the cervical spine, accounting for 25% of the flexion and extension, and up to 50% of the axial rotation of the neck.<sup>4</sup> Although the CCJ consists of two distinct joints (atlanto-occipital and atlanto-axial), it functions as a single mobile unit, with the atlas acting like a washer between the cervical spine and the occiput. Each of these joints, however, has unique kinematic properties that contribute to the complex motion of the CCJ.<sup>5</sup>

The CCJ is the most complex joint in the spine.<sup>6</sup> The complex nature of the structure and function of the craniocervical junction makes it particularly vulnerable to injury and deformation, as forces acting upon the head and cervical spine may occur in complex patterns.<sup>3</sup>

The cervical spine exhibits complicated 3-dimensional movements according to Ref. [7], which could be adequately described using the 3-dimensional CT reconstruction



Figure 1. Lateral cervical radiograph.



Figure 2. Same person as Figure 1 showing increased visualization and large field-of-view.

method. Analysis of the reliability of 3-D CT reconstruction method showed very high inter-rater and intra-rater reliability, suggesting very good consistency.<sup>7</sup> Rotation at the upper cervical spine, specifically the occiput through C2, encompassed at least 60% of the total cervical rotation. Rotation at different parts of the cervical spine in the control group measured 69.7±5.5 for the total rotation of the cervical spine. The upper cervical spine contributes up to 63.13% of total rotation. The C1–C2 segment makes up 86.14% of the rotation of upper cervical spine and 54.40% of the total rotation of the cervical spine.<sup>7</sup> The CCJ protects the soft tissue contents within and around the upper cervical spine, including neurological and vascular tissue, while also allowing for significant mobility of the head and neck.<sup>8</sup> It is vital for UCC providers to consider how boney anatomy may influence structures in and around the CCJ. These structures, which may affect the nervous system can be influenced by abnormal biomechanics and fixations of the CCJ.<sup>6,9</sup> A distorted axis of motion may create pathologic neurophysiologic changes to the specialized and sensitive neurology located at the skull base, such as changes to the suboccipital muscles. The suboccipital muscles have the highest density of proprioceptors per gram of muscle tissue compared to the rest of the body,<sup>10</sup> and therefore are important pain generators among patients with neck pain and headache.

Osseous malformations, misalignment, and traumas which contribute to aberrant CCJ biomechanics may alter cerebrospinal fluid and blood flow, thus resulting in altered hydrodynamics between the cranium and spinal cord. Misalignments, malformation, and anomalies of the CCJ have been shown to obstruct flow through the vertebral arteries.<sup>3,6,9</sup> According to Ref. [9], the hydrodynamics of arteries, veins, and cerebrospinal fluid influence the pressure gradients that occur within an essentially closed cranial vault that has little room for expansion. This potential "choke point" at the CCJ for fluid flow may play a role in neurodegenerative disorders and conditions affecting brain health.<sup>3,6,9</sup>

Given the significance of the CCJ area, it has been notably absent from textbooks because the area is "in between" standard skull imaging and cervical spine imaging.<sup>11</sup> This area of the spine is poorly understood and is open to a potential of a multitude of misdiagnoses. For the most complete assessment, the CCJ should be visualized separately from the cranium and the cervical spine (Offiah and Day, 2017).

#### Difference in the Detail: CBCT versus Conventional Radiographic Imaging

According to Ref. [12], one third of reported traumas in the cervical spine occur at the CCJ. The CCJ may be closely correlated to brain health with consideration to concussion and post-concussion syndrome. Linear acceleration measurements causing concussive forces have been measured with head impact telemetry systems in high school and college football players, with the highest predictive value at 96.1 g (gravity).<sup>13</sup> Biomechanical studies for whiplash associated disorders reveal as little as 4.5 g of neck accelerate can cause mild strain injury to the soft tissue of the cervical spine.<sup>13,14</sup> The prevalence of injury to the CCJ area can affect the osseous alignment resulting in neurologic and vascular implications that warrant increased clinical consideration, including detailed imaging.

The detail of boney anatomy provided by a CBCT image of the CCJ is useful to appreciate the components of the CCJ and its role in cervical spine stability and clinical implications.<sup>12</sup> The craniocervical junction is an area of unique consideration given bone morphology, biomechanics, ligamentous structures, fluid dynamics, neurology, and neurophysiologic effects attributed to that area.

The use of CBCT for chiropractic clinical imaging of the cervical spine and craniocervical junction has shown to provide a more diagnostic image as related to structure, due to its detailed capture characteristics as compared to traditional 2-D radiography.<sup>15</sup> CBCT allows for a 3-dimensional visualization leading to the identification of structural anomalies, vertebral misalignments, and often times results in a lower patient absorbed dose when compared to traditional 2-D radiography.<sup>15,16</sup> Therefore, utilizing CBCT in an upper cervical chiropractic clinical setting would follow the principle of ALARA "as low as reasonably acceptable" that guides radiographic procedures for patients.

Identifying normal, abnormal, incidental, and anomalous findings on diagnostic imaging is paramount for specific manual therapy techniques, like UCC. Additionally, CBCT may be indicated to evaluate for traumatic fractures and hairline fractures within the cervical spine. It may also be used to evaluate cervical spine spondylosis, intervertebral foraminal stenosis, and facet joint arthrosis. These abnormal findings are regularly evaluated for in chiropractic offices that specialize in the craniocervical junction. One study reported that out of 427 CBCT scans performed for orthodontic evaluations, 356 of those scans had 842 separate findings that were not relevant to orthodontic work in the boney anatomy visualized.<sup>17</sup> While these finding were not relevant to orthodontic work, they may be relevant to chiropractic or medical treatment of the CCJ.

A retrospective study of CBCT scans by Ref. [18] found that 47.8% of all incidental findings pertained to the cervical vertebrae. This highlights the significant presence of anatomical variation in the CCJ. Incidental findings of the craniocervical junction that may influence both clinical diagnosis and application of treatment include fusions, flattening of joint surfaces, osteoarthritis, rotation, bony ossicles, single and bilateral posterior ponticus, non-union of posterior arch, elongated styloid processes, and asymmetrical mastoid processes.<sup>18</sup>

Posterior ponticuli are the most commonly noted on CBCT scans within 26.2% of the population,<sup>19</sup> and has been associated with symptoms such as neck pain, headaches, shoulder and arm pain, that are otherwise unexplainable.<sup>20</sup> Future investigation is needed to clarify the clinical impact for the patient of posterior ponticuli; however, noting calcification of the posterior atlanto-occipital ligament in the upper cervical spine informs the clinical picture for the provider and may influence the force vectors or contact point chosen for treatment by the UCC chiropractor with each patient.

The goal of the study by Ref. [21] was to define the presence and prevalence of incidental findings in and around the base of skull from large field-of-view CBCT of the

maxillofacial region and to determine their clinical importance. In this retrospective study, 400 large fields of view CBCT scans from January 1, 2007, to January 1, 2014, were reviewed with findings categorized into cervical vertebrae, intracranial, soft tissue, airway, carotid artery, lymph node, and skull base findings.<sup>21</sup> A total of 653 incidental findings were identified in 309 of the 400 CBCT scans.<sup>21</sup> Incidental findings of the cervical vertebrae made up 20.06% of the findings. Skull base incidental findings made up .15% of the findings. 31.24% of the findings required referral, and 17.76% required monitoring. If the provider determines that imaging is necessary, Ref. [21] concluded that a review of CBCT images surrounding the region of interest, specifically the base of skull, cervical vertebrae, pharyngeal airway, and soft tissue, would be warranted.

Ref. [22] found that a review of 7689 CBCT reports revealed 732 incidental findings, of which 9.5% occurred in the cervical spine or the clivus. Cervical spine findings made up 92.3% of those findings, and 78.7% were degenerative in nature, primarily occurring in females over 60 years of age. A more comprehensive analysis of the data showed that the odds of presenting with a degenerative incidental finding in the cervical spine or the clivus was 5.5 times higher in patients 50 years of age or older.<sup>22</sup>

It is important to note that the incidental findings vary in significance. Given the large range of incidental findings in the cervical spine as well as the complex boney and soft tissue considerations, it is ideal that upper cervical chiropractors, who are applying directed forces into the CCJ, have the most detailed visualization with the lowest risk to patients possible. Figure 3 and 4 demonstrate the difference in appreciating incidental findings with 2-D compared to a 3-D rendering of the same patient.

#### Radiation Dose Rate: Planmeca CBCT versus Conventional Radiographic Imaging

Various studies, as discussed below indicate that craniocervical junction imaging utilizing Cone Beam Computed Tomography has less reported effective dose radiation than plain film radiography/imaging. For comparison in this paper, Planmeca CBCT ultra low effective dose for large skull size imaging is 41  $\mu$ Sv or .041 mSv. (Table 1.)

Ref. [23] document the effective doses for AP and lateral cervical radiographs to be 120  $\mu$ Sv (.12 mSv). Ref. [24] found the effective dose for AP and lateral cervical spine films at 50  $\mu$ Sv and 30  $\mu$ Sv (.05 mSv, .03 mSv), respectively. It is important to note that UCC practitioners take multiple images when utilizing plain film radiographs, both as follow up and to obtain the necessary detail needed for treatment. A common five image series taken in the Upper Cervical Chiropractic protocol would have a total dose of 200  $\mu$ Sv or .20 mSv.<sup>2</sup> This is in comparison to the 41  $\mu$ Sv dose from Planmeca CBCT imaging. The views needed for "legal" set of films include two views, at right angles to each other. Ofori's study did not include imaging of the skull (2014). CBCT effective dose for the head and cervical spine was 50-250  $\mu$ Sv (.05–.25 mSv). As a point of reference, annual background radiation dose for the



Figure 3. Radiograph view showing malformation of the CCJ: Agenesis of the posterior arch of C1, Right accessory articulation of C1 transverse process and skull, Left posterior ponticus.



Figure 4. Identical patient as Figure 3 demonstrating increased visualization of CCJ malformation utilizing CBCT.

|       | XS |     |     | S  |      |     | М   |     |     | L   |      |     | XL  |     |     |
|-------|----|-----|-----|----|------|-----|-----|-----|-----|-----|------|-----|-----|-----|-----|
| Voxel | KV | mAs | μSv | kV | mAs  | μSv | KV  | mAs | μSv | K٧  | mAs  | μSv | KV  | mAs | μSv |
| 600   | 90 | 28  | 91  | 90 | 32   | 104 | 100 | 25  | 120 | 110 | 22   | 144 | 120 | 20  | 171 |
| 450   | 90 | 36  | 117 | 90 | 40   | 130 | 100 | 32  | 153 | 110 | 28   | 183 | 120 | 25  | 214 |
| 300   | 90 | 45  | 146 | 90 | 50   | 162 | 100 | 40  | 191 | 110 | 36   | 236 | 120 | 32  | 273 |
| ULD   |    |     |     |    |      |     |     |     |     |     |      |     |     |     |     |
| 600   | 90 | 7,I | 23  | 90 | 8,0  | 26  | 100 | 6,3 | 30  | 110 | 6,3  | 41  | 120 | 6,3 | 54  |
| 450   | 90 | 9,0 | 29  | 90 | 10   | 32  | 100 | 8,0 | 38  | 110 | 4, I | 46  | 120 | 6,3 | 54  |
| 300   | 90 | П   | 36  | 90 | 12,5 | 40  | 100 | 10  | 48  | 110 | 9,0  | 59  | 120 | 8,0 | 68  |

**Table I.** Effective doses attained using Planmeca VISO CBCT scanner using (skull 30 × 30 cm FOV protocol) for different patient sizes (XS, S, M, L, XL), voxel sizes (300, 450, 600  $\mu$ m) and using ultra low dose (ULD) protocol.

average citizen of the U.S.A. is 3100  $\mu$ Sv (3.1 mSv) and average daily background radiation dose is 17.8  $\mu$ Sv (.0178 mSv)<sup>25</sup>; August 06). Retrieved from https://www.epa. gov/radiation/radiation-sources-and-doses).

According to Ref. [26], the typical radiation exposure of common x-rays consisting of AP and lateral views of the cervical spine is  $200 \ \mu$ Sv or .2 mSv.

In a study by Ref. [16], it was found that the dose distribution can be inconsistent for dental CBCT exposures of a homogeneous phantom. This can be attributed to asymmetrical positioning and/or partial rotation of the X-ray source. This study revealed that the scatter tail along the *z*-axis was found to have a defined shape, generally resulting in a 90% drop in absorbed dose outside the primary beam.<sup>16</sup>

The CBCT study by Ref. [15] measured dose-area product to calculate effective dose. Dose-area product values from 90 patient examinations allowed for estimation of effective dose, which was estimated for three diagnostic tasks. Tasks included examinations of impacted lower third molars and retained upper cuspids and implant planning of the posterior mandible. Results varied between 11 and 77  $\mu$ Sv.

The paper by Casselman states the following: "These nondental CBCT studies gradually replaced conventional X-rays and CT/MDCT studies because they allowed imaging with higher resolution, lower radiation dose and less metal artifacts. In this paper the most important non-dental CBCT indications will be discussed" (Casselman et al, 2013, pg. 333). Among the areas discussed were imaging of the temporal bone, skull base, and vertex. Casselman maintains that the images only need to show bone, which is why they can be taken utilizing CBCT with its low dose and high resolution.

To evaluate scoliosis, the standard radiographic examination as set forth by the CLEAR Board of Advisors consists of (in part) the following: Five Cervical Spine x-rays (Lateral Cervical Neutral, Lateral Cervical Flexion, Lateral Cervical Extension, A-P Open Mouth, and Base Posterior) are taken, totaling 90  $\mu$ Sv (.09 mSv). Two additional cervical spine x-rays (APOM and a stress x-ray) may need to be taken depending on the individual patient necessity and the clinical decision-making of the healthcare provider to evaluate the effect of the treatment, adding an additional 40  $\mu$ Sv (.04 mSv).<sup>27</sup> Therefore, cervical spine total dose is the initial 90  $\mu$ Sv in addition to 40  $\mu$ Sv for the additional views, totaling 130  $\mu$ Sv. Again, these values are compared to Planmeca's CBCT ultra low dose of a large skull of 41  $\mu$ Sv.

According to Ref. [28], cervical spine plain film radiography measurements of the effective dose for children less than 1 year of age through 15 years of age ranged from 20 to  $100 \ \mu$ Sv (.02–.10 mSv) and the effective dose for adults averaged 80  $\mu$ Sv (.08 mSv).

From Ref. [29], the dose rate to the skull from plain film radiography is shown to be  $30 \ \mu Sv (.03 \ m Sv)$  for the AP view and  $10 \ \mu Sv (.01 \ m SV)$  for the lateral view, for a total dose rate of 40  $\ \mu Sv$ . These dose rates are very similar to CBCT dose rates, but do not show the detail of CBCT.

In the upper cervical chiropractic clinical practice, imaging of the craniocervical junction, when indicated, is a vital aspect of the protocol. The above studies report a sampling of patient dose factors that highlight the overall reduced risk to the patient when CBCT is used to visualize the CCJ.

#### Discussion

Modern CBCT uses a conical beam of pulsed x-radiation that is directed 90° to a Flat Panel Detector (FPD). The beam and FPD move in tandem, spinning in varying degrees (180 to 540, depending on image requirements) around the region to be imaged. Great advancements have been made in recent years to both the reconstruction algorithms and the FPD to increase image detection while decreasing patient radiation exposure.<sup>30–32</sup>

Current literature on the effective dose utilizing CBCT to evaluate the craniocervical junction is limited. Extrapolations were made utilizing dental cranial scans as a close comparison. This is a unique publication in its mention of CBCT as a method for evaluation of the craniocervical junction for chiropractic clinical practice. Additional limitations include a lack of literature on the current trends of use of CBCT in chiropractic clinical settings. More research is needed to gain full understanding of the scope use for CBCT by chiropractors.<sup>33-36</sup>

The authors are not suggesting that traditional 2dimensional radiographs of the cervical spine are insufficient for evaluation of the cervical spine. Attention should be given to current technologies available with reported xradiation effective dose that approximates or is less than conventional methods of imaging, with additional benefit of three dimensional visualizations. These three dimensional images can deliver greater detail and may enhance diagnosis and treatment considerations in a chiropractic clinical setting.<sup>37-40</sup>

#### Conclusion

The craniocervical junction is a complex anatomical,<sup>41,42</sup> kinematic and neurophysiologic region of human anatomy which is often under-reported with current imaging modalities. Additionally, it is an area of increased osseous malformation and significant clinical consideration with respect to trauma of the head and neck. Visualization of the CCJ with Cone Beam Computed Tomography offers an option for detailed osseous assessment of this region readily accessible in a private chiropractic clinical setting, with equal to or lesser effective dose to the patient.<sup>43-47</sup>

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| From:        | Dr. Daniel Judge                                                     |
|--------------|----------------------------------------------------------------------|
| То:          | MDHHS-ConWebTeam                                                     |
| Subject:     | Request for CON review of CBCT utilization in a chiropractic setting |
| Date:        | Friday, October 11, 2024 7:55:19 PM                                  |
| Attachments: | CON request for CBCT utilization.pdf                                 |

# CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Dear Chairperson Falahee,

Thank you for taking the time to consider this important issue regarding use of Cone-beam Computed Tomography in a Chiropractic setting. Hopefully you are receiving several emails regarding this matter and I hope that this does not feel burdensome, but rather serve to indicate the value this technology can provide to our population.

I have been practicing chiropractic in Michigan since 2008, focusing mainly on complicated and difficult neck problems. Using detailed imaging, we are able to help patients with very gentle adjustments that are able to be done in a neutral position with very little force. Over my years of practice, I have found precise and accurate imaging of the neck to be invaluable in achieving better outcomes for our patients. Using CBCT would help improve my work even further.

Over the last decade I have become aware of more and more chiropractors first collaborating with dentists who utilize CBCT, followed by many chiropractors purchasing their own CBCT equipment around the country. The images and results are truly a large step up compared to digital x-ray, but being much less expensive than MRI and much less radiation than traditional CT scanning.

Allowing chiropractors in Michigan to use this technology will greatly enhance our ability to provide gentle, precise and cost-effective care for our patients and improve outcomes. Please consider allowing our profession the use of CBCT imaging. Please also see the attached letter that I have signed in agreement with. Thank you for your time.

Sincerely,

Daniel Judge, DC, DCCJP

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

#### RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

As a Chiropractor who utilizes imaging of the head and neck, I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such body includes consideration of the elimination or certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016.

Michigan is one of two states (the other is Connecticut) that require CON for a licensed health care professional to purchase a CBCT scanner. AS of January 2024, 33 of the remaining 48 states have CON programs, yet chose not to require a CON for these important diagnostic tools. We believe this approach should be adopted in Michigan, which already does not regulate the other low-cost, in-office medical equipment such as digital x-ray, ultrasound, etc.

#### Use of CBCT in the Chiropractic Profession

CBCT has been used in Chiropractic since 2011. CBCT is now within the teaching curriculum of chiropractic colleges and is becoming standard for new graduates. However, the virtual prohibition on the use of this technology in Michigan is affecting the ability of current license holders to attract new chiropractic physicians to the state.

#### Advantage of CBCT Over 2-Dimensional X-Ray

- Better Image Quality
- Lower Radiation Dose or Equivalent Dose
- More Accurate Diagnoses and Precise Treatment Planning
- 3D is the Medical Standard of Care for Management of the Head and Neck

#### Proposed Exemption Language

The Michigan Association of Chiropractors offers the following exemption language to Section 2(k) of the CON documentation as a suggested option to consider (Additions in **bold**):

"CT scanner"... does not include... dental **OR CHIROPRACTIC** CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry **OR CHIROPRACTIC PROCEDURES BY A LICENSED CHIROPRACTOR UNDER THE PRACTICE OF CHIROPRACTIC** only. Any other use of CT scanners (such as but not limited to chiropractic utilization) that generate a peak power of 5 kilowatts or less as certified by the manufacturer will require review and approval as a CT scanner service under applicable sections of these standards.

#### Conclusion

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| From:        | Dr. Daniel Judge                                                  |
|--------------|-------------------------------------------------------------------|
| То:          | MDHHS-ConWebTeam                                                  |
| Subject:     | Additional request for CBCT utilization in a chiropractic setting |
| Date:        | Saturday, October 12, 2024 2:17:10 PM                             |
| Attachments: | Signed Patient Letters CON MI.pdf                                 |

# CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Dear Chairperson Falahee,

I am attaching several letters signed by current patients who feel they would benefit from chiropractors in Michigan being able to utilize CBCT imaging in our offices. Thank you again for your kind attention and time for this matter.

Your work is much appreciated,

Daniel Judge, DC, DCCJP

Dynamic Life Chiropractic 3400 Rochester Rd Royal Oak, MI 48073

p: 248.593.0843 f: 248.593.3069 www.dynamiclifechiropractic.com

Confidentiality Notice:

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

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Chairperson James Falahee 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

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MDHHS - Con Web Team @ michigan . gov

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# Additional Comments

| From:        | Dr. Daniel Judge                           |
|--------------|--------------------------------------------|
| То:          | MDHHS-ConWebTeam                           |
| Subject:     | CBCT utilization in a chiropractic setting |
| Date:        | Thursday, October 17, 2024 5:51:37 PM      |
| Attachments: | Signed Patient Letters CON MI-2.pdf        |

## CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Dear Chairperson Falahee,

Thank you again for taking your time this week to consider the value of CBCT usage in chiropractic offices. I sincerely appreciate your time and consideration.

I have attached a number of additional signed letters by Michigan citizens who agree this would be a valuable service to them if it was offered in their chiropractor's office.

I hope that you will see the value in chiropractors being able to provide better imaging for their patients, with equivocal or less radiation. Not only will it help our treatment plans and recommendations, but around the country the enhanced imaging of the neck is leading to earlier diagnosis of medical issues that are found in the 3D CBCT imaging that would have been missed if those chiropractors only had digital x-ray.

Sincerely,



Signed Patient Letters CON MI-3.pdf

Daniel Judge, DC, DCCJP

Dynamic Life Chiropractic 3400 Rochester Rd Royal Oak, MI 48073

p: 248.593.0843 f: 248.593.3069 www.dynamiclifechiropractic.com

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Chairperson James Falahee 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

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Chairperson James Falahee 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

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- Better Image Quality
- Lower Radiation Dose or Equivalent Dose
- More Accurate Diagnoses and Precise Treatment Planning
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Sharn Height Strazon Heigel 10/15/2024

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| From:        | Sasha Taroma                                                                |
|--------------|-----------------------------------------------------------------------------|
| To:          | MDHHS-ConWebTeam                                                            |
| Subject:     | Computed Tomography Scanner Services – Certificate of Need Standards Review |
| Date:        | Monday, October 7, 2024 9:35:14 PM                                          |
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Chairperson James Falahee,

My name is Dr. Sasha Taroma, D.C and I am a Chiropractor from California. Attached are signatures from both myself and my husband who are chiropractors. We utilize CBCT on a daily basis for our patient care, attached are signatures from our patients from today who agree that the usage of CBCT is extremely vital to our care for them. As a collective, I hope that our efforts can show how important this imaging is for our profession and our patients.

Yours in health,

Dr. Sasha Taroma, D.C



**Dr. Sasha Taroma D.C** Co-founder & Upper Cervical Chiropractor Infinite Life Chiropractic 1714 E. McFadden Ave. Suite M Santa Ana, CA 92705 P: (714) 406-0408 E: drstaroma@infinitelifeoc.com Web: www.infintelifeoc.com

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

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KRISTOPHER NAUYEN D.C. 10/7/24

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## Advantage of CBCT Over 2-Dimensional X-Ray

Three-dimensional CBCT is vastly superior to two-dimensional x-ray when it comes to imaging and analyzing the upper cervical spine. Some of the reasons for this include:

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Elizabeth Santos Elizabeth Santos

Chairperson James Falahee 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

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Rosaisela Rowan Rasaisela Rowan

Chairperson James Falahee 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

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10/07/24

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Scot Marche 10/7/24

# Additional Comments Submitted

# D. Campbell Upper Cervical Chiropractic Corporation.

October 7,2024

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

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620 E. St Wasco, Ca 93280 P: (661)758-5131 F: (661)758-5421 https://denniscampbelldc.com

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Dennis L Campbell DC Director of Certification and Instruction Blair Chiropractic Society Professor Life West University.

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#### October 9, 2024

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Eric T. DiMartino, DC

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Yours in Health, fronth Andria fronth Candice Smith

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## Blair Upper Cervical Chiropractic Society, Inc. 2149 West 1st Street #1661 Gulf Shores AL 36542-1661

October 7,2024

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Assinado por: 692EB29B9FA149E...

10/8/2024

Dr. Jake Hollowell - Board President

DocuSigned by:

10/8/2024

Traci Jones - Executive Director

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Tiffany Dauphinais, DC

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**Christine Sorice** 

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October 8,2024

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

### RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

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Three-dimensional CBCT is vastly superior to two-dimensional x-ray when it comes to imaging and analyzing the upper cervical spine. Some of the reasons for this include:

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California Chiropractic Association

Dr. Casey Tucker - Board President

Jausen

Dawn Benton - CEO

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# Blair Upper Cervical Chiropractic Society, Inc. 2149 West 1st Street #1661 Gulf Shores AL 36542-1661

October 8, 2024

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Dr. Jeffrey Hannah (DC, DCCJP Candidate) Blair Technique Instructor Clear Chiropractic Spokane

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| From:        | Jane Brewer                                                                     |
|--------------|---------------------------------------------------------------------------------|
| То:          | MDHHS-ConWebTeam                                                                |
| Subject:     | RE: Computed Tomography Scanner Services - Certificate of Need Standards Review |
| Date:        | Wednesday, October 9, 2024 11:57:44 AM                                          |
| Attachments: | Outlook-2k0r4ccq.png                                                            |

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Dr. Jane Brewer DC, DCCJP www.precisionchiroco.com 970•663•1617

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 From:
 Kyle Durieux

 To:
 MDHHS-ConWebTeam

 Subject:
 Computed Tomography Scanner Services – Certificate of Need Standards Review

 Date:
 Monday, October 7, 2024 1:08:23 PM

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October 7,2024

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With the use of CBCT in the office errors unknown to other health professionals, including other chiropractors not using CBCT, have been found, avoided, and corrected; thus, diminishing errors in treatment delivery and vastly improving patient treatment and outcomes.

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The Michigan Association of Chiropractors offers the following exemption language to Section 2(k) of the CON documentation as a suggested option to consider (Additions in **bold**):

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Dr. Kyle Durieux , D.C., B.Sc., PT Simply Health Chiropractic Center 1091 N Bluff Street, Suite 309 Saint George, Utah 84770

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

#### RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

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| From:    | Elizabeth Hoefer                                                                |
|----------|---------------------------------------------------------------------------------|
| То:      | MDHHS-ConWebTeam                                                                |
| Subject: | RE: Computed Tomography Scanner Services – Certificate of Need Standards Review |
| Date:    | Tuesday, October 8, 2024 1:07:14 AM                                             |

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October 7,2024

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

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Dear Chairperson Falahee:

As a Chiropractor who utilizes imaging of the head and neck, and Immediate Past President of the California Chiropractic Association, I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such body includes consideration of the elimination or certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016.

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Founder & CEO, Well Connected Chiropractic Immediate Past President, California Chiropractic Association



26302 LA PAZ ROAD SUITE 214 MISSION VIEJO, CA 92691 949-359-8385

www.wellconnectedchiro.com "May the God of hope fill you with all joy and peace as you trust in him, so that you may overflow with hope by the power of the Holy Spirit." Romans 15:13

#### October 10,2024

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Chairperson James Falahee 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

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From:Elizabeth BagleyTo:MDHHS-ConWebTeamSubject:Utilization of advanced imaging for chiropractors.Date:Monday, October 14, 2024 3:40:09 PM

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October 14, 2024

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

#### RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

As a Chiropractor who utilizes imaging of the head and neck, I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such body includes consideration of the elimination or certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016.

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CBCT has been used in Chiropractic since 2011. CBCT is now within the teaching curriculum of chiropractic colleges and is becoming standard for new graduates. However, the virtual prohibition on the use of this technology in Michigan is affecting the ability of current license holders to attract new chiropractic physicians to the state.

# Advantage of CBCT Over 2-Dimensional X-Ray

- Better Image Quality
- I Lower Radiation Dose or Equivalent Dose
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The Michigan Association of Chiropractors offers the following exemption language to Section 2(k) of the CON documentation as a suggested option to consider (Additions in **bold**):

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Matthew Sopha

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

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Sincerely, Dr.allin Bgn

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

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Nicole DiLorenzo

October 15, 2024

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

# RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

My name is Dr. Alex Wolfe and I am a licensed chiropractor in the State of Michigan. I frequently make use of x-ray, MRI, helical CT and CBCT images in my clinical decision-making process. The use of such imaging in the management of complex cases has allowed for improved patient outcomes, better interprofessional communication, heightened diagnostic capability, and elevated patient satisfaction.

I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such body includes consideration of the elimination or certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016.

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# Use of CBCT in the Chiropractic Profession

CBCT has been used in Chiropractic since 2011 and as you may suspect, the value of this imaging technology has become broadly recognized by many of our professional organizations, schools, and advanced educational programs. CBCT is now within the teaching curriculum of chiropractic colleges and is becoming standard for new graduates. However, the virtual prohibition on the use of this technology in Michigan is affecting the ability of current license holders to attract new chiropractic physicians to the state. I personally have travelled out of state to obtain a CBCT study of my own craniocervical region to guide care related to post-concussion symptoms. Additionally, I have several patients that have imaging

previously completed at dental offices which we have been able to review to better evaluate concerns related to anatomical asymmetries and pathologies.

# Advantage of CBCT Over 2-Dimensional X-Ray

Three-dimensional CBCT is vastly superior to two-dimensional x-ray when it comes to imaging and analyzing the upper cervical spine. This technology has allowed us to take what we have already been doing well and expand upon the efficacy of our treatment and management of complex cases. Some of the reasons for this include:

- Better image quality
- Lower radiation dose or equivalent dose
- More accurate diagnoses and precise treatment planning
- 3D is the medical standard of care for management of the head and neck

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Yours in Health,

Alexander Wolfe, DC, DCCJP

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| From:    | Lori Crowder                                                                |
|----------|-----------------------------------------------------------------------------|
| To:      | MDHHS-ConWebTeam                                                            |
| Cc:      | Chris Thornburgh; Tyler Evans                                               |
| Subject: | Computed Tomography Scanner Services – Certificate of Need Standards Review |
| Date:    | Tuesday, October 15, 2024 11:26:06 AM                                       |

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October 15,2024

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

# **RE:** Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

As a vendor, **CBST SYSTEMS**, **INC**., I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such body includes consideration of the elimination or certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016. Michigan is one of two states (the other is Connecticut) that require CON for a licensed healthcare professional to purchase a CBCT scanner. AS of January 2024, 33 of the remaining 48 states have CON programs, yet chose not to require a CON for these important diagnostic tools. We believe this approach should be adopted in Michigan, which already does not regulate the other low-cost, in-office medical equipment such as digital x-ray, ultrasound, etc.

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# Christopher Thornburgh Owner and CEO

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189 Fulton Court Peachtree City, GA 30269 Chris Cell: 770-316-0520

To learn more about the i-CAT® 3D Imaging System visit this website:

https://cbctsystems.com/

CBCT Systems helps match healthcare and manufacturing specialists with high-quality new or certified pre-owned X-ray equipment, saving them time and money.

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**Cliff Tao DC DACBR** *Chiropractic Radiologist, Inc* 

15642 Sand Canyon Ave #53093 Irvine CA 92619 714-876-1126 www.clifftaodcdacbr.com

October 16, 2024

Chairperson James Falahee CON Commission c/o Michigan DHHS – CON Policy Section South Grand Building, 5<sup>th</sup> Floor 333 S. Grand Ave. Lansing, Michigan 48933

# <u>RE: Computed Tomography (CT) Scanner Services – Certificate of Need (CON) Standards</u> <u>Review</u>

Dear Chairperson Falahee:

Thank you for the opportunity to comment on potential changes to be made to CON Standards for CT Scanner Services in 2025. I am a chiropractic radiologist, and our radiology group provides imaging interpretation, including of cone beam CT (CBCT) on a daily basis to chiropractors nationwide.

Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the change of such body includes consideration of the elimination of CON regulation for CBCT scanners, or, providing an exemption for the chiropractic profession, as was appropriately done for the dental profession in Michigan in 2016.

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"CT scanner"... does not include... dental **OR CHIROPRACTIC** CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry **OR CHIROPRACTIC PROCEDURES BY A LICENSED CHIROPRACTOR UNDER THE PRACTICE OF CHIROPRACTIC** only. Any other use of CT scanners (such as but not limited to chiropractic utilization) that generate a peak power of 5 kilowatts or less as certified by the manufacturer will require review and approval as a CT scanner service under applicable sections of these standards.

The chiropractic profession utilizes CBCT as it allows for a low radiation dose option of better diagnosis and patient outcomes. Ending regulation of CBCT scanners, or providing a chiropractic exemption, would bring Michigan into line with the rest of the nation and align with the evolving landscape of medical technology and patient-centered care.

I greatly appreciate the opportunity to submit these comments. Thank you for your consideration on this issue

Yours in Health. Cliff Tao DC DACBR

- 1. Scholten J, Kos A, Richardson M, Campion K. Cone beam computed tomography: technology overview, dose, and utility considerations for chiropractors and regulatory bodies. *J Contemporary Chiro* 6(1):92-99, 2023.
- DeNunzio G, Evans T, Beebe ME, Browning J, Koivisto J. Craniocervical junction visualization and radiation dose consideration utilizing cone beam computed tomography for upper cervical chiropractic clinical application a literature review. *Dose Response* 20(2):15593258221107515, 2022.
- 3. Verderame J, Hollowell J. Cone-beam computerized tomography for the bio-mechanical assessment of the occipito-atlanto-axial articulation in a 75-year-old woman with migraines undergoing Blair technique. *J Upper Cervical Chiro Research* July 2013: 60-4.

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

# RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

Dear Chairperson Falahee:

As a Chiropractor who utilizes imaging of the head and neck, I would like to thank the Certificate of Need Commission for the opportunity to comment on potential changes to be made to the Certificate of Need Standards for Computed Tomography Scanner Services in 2025. Should the Commission form a Standard Advisory Committee (SAC) or Informal Workgroup to review the CT Standards, we request that the charge of such body includes consideration of the elimination or certificate of need (CON) regulation for cone beam CT (CBCT) scanners, or, if the Commission will not deregulate cone beam CT scanners from the CON process, they will consider providing an exemption for the chiropractic profession, as was done for the dental profession in Michigan in 2016.

Michigan is one of two states (the other is Connecticut) that require CON for a licensed health care professional to purchase a CBCT scanner. AS of January 2024, 33 of the remaining 48 states have CON programs, yet chose not to require a CON for these important diagnostic tools. We believe this approach should be adopted in Michigan, which already does not regulate the other low-cost, in-office medical equipment such as digital x-ray, ultrasound, etc.

# Use of CBCT in the Chiropractic Profession

CBCT has been used in Chiropractic since 2011. CBCT is now within the teaching curriculum of chiropractic colleges and is becoming standard for new graduates. However, the virtual prohibition on the use of this technology in Michigan is affecting the ability of current license holders to attract new chiropractic physicians to the state.

#### Advantage of CBCT Over 2-Dimensional X-Ray

Three-dimensional CBCT is vastly superior to two-dimensional x-ray when it comes to imaging and analyzing the upper cervical spine. Some of the reasons for this include:

- Better Image Quality
- Lower Radiation Dose or Equivalent Dose
- More Accurate Diagnoses and Precise Treatment Planning
- 3D is the Medical Standard of Care for Management of the Head and Neck

# **Proposed Exemption Language**

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# Conclusion

In conclusion, the chiropractic profession embraces CBCT, as it allow for better diagnosis and patient outcomes with lower or equivalent dose. Ending regulation of CBCT scanners, or at least providing a chiropractic exemption, would bring Michigan into line with the rest of the nation and align with the evolving landscape of medical technology and patient-centered care.

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Yours in Health,

Dr. Zale Bonnett

- Scholten J, Kos A, Richardson M, Campion K. CONE BEAM COMPUTED TOMOGRAPHY: TECHNOLOGY OVERVIEW, DOSE, AND UTILITY CONSIDERATIONS FOR CHIROPRACTORS AND REGULATORY BODIES. JCC. 2023;6(1):92-99.
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- 3) Verderame, Jonathan & Dc, Jake. (2013). Cone-beam Computerized Tomography for the Biomechanical Assessment of the Occipito-atlanto-axial Articulation in a 75-year-old Woman with Migraines Undergoing Blair Technique.

# Planmed

October 18,2024

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

#### RE: Computed Tomography Scanner Services – Certificate of Need Standards Review

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Sincerely,

Johan Moed

#### Planmed, A Planmeca group Company

Director of Sales and Operations, North America phone: 630-235-4389 email: johan.moed@planmed.com web: www.planmed.com

PLANMED OY

Address Sorvaajankatu 7 00880 Helsinki FINLAND Internet / email www.planmed.com sales@planmed.com October 16, 2024

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

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Dear Chairperson Falahee:

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- 3D is the Medical Standard of Care for Management of the Head and Neck
The reference section of this letter (below) provides several example published papers from peer reviewed journals detailing the positive impacts that CBCT imaging provide which enhance the diagnostic processes of assessing the health of patients, whether used in Chiropractic or other health care techniques.

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Yours in Health,

## Dr Julie Mayer Hunt

Julie Mayer Hunt, DC, FCCJP, DICCP

Fellow in Chiropractic Craniocervical Junction Procedures (FCCJP - ICA)
Diplomate in Clinical Chiropractic Pediatrics (DICCP - ICA)
Past Board Member - Florida Board of Chiropractic Medicine (2013-2022)
Past Board Member - International Chiropractic Association
Past President - Society of Chiropractic Orthospinology
2022 Researcher of the Year - ICA Upper Cervical Care Council
2014 Chiropractor of the Year - ICA Upper Cervical Care Council
2016 Chiropractor of the Year - ICA Upper Cervical Care Council

#### **Reference – CBCT Published Papers**

- 1) Scholten J, Kos A, Richardson M, Campion K. CONE BEAM COMPUTED TOMOGRAPHY: TECHNOLOGY OVERVIEW, DOSE, AND UTILITY CONSIDERATIONS FOR CHIROPRACTORS AND REGULATORY BODIES. *JCC*. 2023;6(1):92-99.
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October 17,2024

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Having a CBCT in our office, Unbridled Spirit Healing Center, has revolutionized our analysis and therefore our results. Not to mention the diagnostic capabilities of a CT with such relatively low rad dosing. Yours in Health, Blaise Varady DC Cell: (734)363-4872

- Scholten J, Kos A, Richardson M, Campion K. CONE BEAM COMPUTED TOMOGRAPHY: TECHNOLOGY OVERVIEW, DOSE, AND UTILITY CONSIDERATIONS FOR CHIROPRACTORS AND REGULATORY BODIES. JCC. 2023;6(1):92-99.
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