Rules & Policies Agenda for Board Meeting
August 11, 2021

A. Rule Review Update
B. Proposed New Internal Management Rules 4731-30-04
C. Podiatric Scope of Practice
D. Updated Telemedicine FAQ's
E. Recommendations for Quality Assurance Committee
F. Legislative Update
MEMORANDUM

TO: Betty Montgomery, President
    Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: July 28, 2021

Attached please find the updated rule review schedule and spreadsheet.

**Requested Action:** No action requested.
**RULES AT CSI**

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Comment Deadline 5/14/21-Released from CSI on 6.2.21. Ready to file with JCARR

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**RULES SENT FOR INITIAL CIRCULATION**

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**RULES AT JCARR**

**Hearing held – 6/28/21 – going to Sept board for adoption**

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**No Change Rules-Filed 5-27-21 – JCARR jurisdiction ends 8/25/21**

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**Rules Needing Amendments Due to HB442**

The following rules need to be amended or rescinded to remove references to cosmetic therapy and oriental medicine:

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MEMORANDUM

TO: Betty Montgomery, President
    Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Proposed New Internal Management Rule 4731-30-04, Maintenance of List of
    Disqualifying Criminal Offenses

DATE: July 28, 2021

HB 263, signed into law on January 9, 2021, requires all licensing authorities to establish by October 9, 2021, “a list of specific criminal offenses for which a conviction, judicial finding of guilt, or plea of guilty may disqualify an individual from obtaining an initial license.”. The initial draft of the disqualifying offense list was provided to the Board at the May 12, 2021 meeting. The final draft will be on the Board agenda for the September 8, 2021 meeting.

The statutory changes do not provide a mechanism for the Board to update the list of disqualifying offenses. The attached internal management rule is provided for your review. The draft rule requires an annual review of the disqualifying offense list and allows the Board to approve the addition, deletion or modification of the specific criminal offenses on the list. The rule also requires the Board to post the disqualifying offense list on the Board’s website.

In order to ensure that the internal management rule can be effective by October 9, 2021, approval for circulation of the rule to interested parties is requested, so that the rule can be approved for adoption at the September Board meeting. Since this is an internal management rule, circulation to CSI and a JCARR public hearing is not necessary.

Requested Action: Approve circulation of the draft internal management rule to interested parties for a two-week comment period.
(A) For purposes of this rule, “list of disqualifying criminal offenses” is the list of specific criminal offenses authorized by section 9.79 of the Revised Code for which a conviction, judicial finding of guilt, or plea of guilty may disqualify an individual from obtaining an initial license to practice under chapters 4730., 4731., 4759., 4760., 4761., 4762., 4774., or 4778. of the Revised Code.

(B) For purposes of this rule, “board” means the state medical board of Ohio, a licensing authority under section 9.79(A) of the Revised Code.

(C) At least once per calendar year, the Board shall review the list of disqualifying criminal offenses. As part of the review, the board may approve the addition, deletion or modification of specific criminal offenses on the list of disqualifying criminal offenses.

(D) The board shall make the list of disqualifying criminal offenses available to the public on the board’s website.
MEMORANDUM

TO: Betty Montgomery, President
    Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Podiatric Scope of Practice

DATE: August 5, 2021

On June 15, 2021, a request for comments on the podiatric scope of practice issue was electronically sent to all MD, DO and DPM licensees (54,857), with a deadline of July 6, 2021. According to our data analytics, 15,979 or 29.1% of the recipients opened the e-mail with a click rate of 72 recipients. Approximately 38 comments were received as of July 6, 2021.

Given the low rate of response, a second request for comments was sent on July 26, 2021 to all MD, DO and DPM licensees (51,940) with a deadline of August 19, 2021. So far, the second e-mail has been opened by 16,301 recipients with a click rate of 59 recipients. To date, over 80 comments have been received. (Please note that the difference in the number of total licensees reflects the number of licensees who renewed their license effective July 1, 2021.)

Attached you will find a spreadsheet listing all of the commenters with a short summary of each comment. In addition, all comments are attached.

De-identified claims data for the supramalleolar osteotomy of the tibia or fibula (CPT 27705) was obtained from two State of Ohio sources, Ohio Department of Medicaid and Department of Administrative Services for the state employee health insurance plan. The information from the state employee health plan indicates that 27 total paid claims were incurred between FY17-FY21. Of these, one claim (post June 2019) was completed by a podiatrist. A spreadsheet with the de-identified Medicaid data is attached for your review.

Information regarding the license types credentialed to perform the two procedures has been requested from hospital systems in Ohio. To date, three systems (Aultman, OSU Wexner Medical Center, Fairfield Medical Center) have provided information that podiatrists are not credentialed to perform either procedure. We anticipate providing information from the remaining hospital systems at a future meeting.

No action requested.
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<tr>
<th>Name</th>
<th>Organization</th>
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<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Amanda Whitaker, MD, Assistant Professor-Practice, Orthopaedic Surgery</td>
<td>Nationwide Children's Hospital; OSU College of Medicine</td>
<td><a href="mailto:Amanda.Whitaker@nationwidechildrens.org">Amanda.Whitaker@nationwidechildrens.org</a></td>
<td>Does not believe that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity. This procedure requires careful planning and understanding of the relationship of the spine, hip, knee and gait. Podiatrists do not have the training, knowledge or expertise to perform the surgery or to treat complications. Supportive of podiatrists harvesting bone marrow aspirate from the proximal tibia. Fusions of the foot and ankle often require biologic assistance. Aspirating bone marrow is a low risk procedure that will promote better outcomes within podiatrist's scope of practice.</td>
</tr>
<tr>
<td>Amogha</td>
<td></td>
<td><a href="mailto:amogha94@gmail.com">amogha94@gmail.com</a></td>
<td>Not supportive of either procedure falling under the purview of a podiatrist.</td>
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<tr>
<td>Andrew J. Brown, DPM, FACFAS</td>
<td>Ankle and Foot Specialists of Marion</td>
<td>E-mailed from Mike Mathy, Ohio Foot and Ankle Association.</td>
<td>DPM has completed the following education and training and is qualified to perform bone marrow aspiration from the proximal tibia and osteotomy of the tibia. The training and education includes four years of undergraduate education in pre-medical sciences; four years of podiatric medication and surgical education in which the curriculum was the same as MD or DO medical school curriculum; passage of all podiatric medical boards as well as rigorous American Board of Foot and Ankle Surgery board certification that includes four examinations and a year-long case review process, three years of podiatric medical and surgical residency training that included over 12 months of service rotations at a large major university hospital. States he has had extensive training in both of the procedures and has been deemed competent by multiple physicians including MD and DO orthopedic surgeons during training. Has performed the procedures on patients with exceptional outcomes and results.</td>
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<tr>
<td>Anthony F. Guanciale, MD</td>
<td>Associate Professor, Orthopaedic Surgery - Univ of Cincinnati</td>
<td><a href="mailto:tguanciale@gmail.com">tguanciale@gmail.com</a></td>
<td>In the interest of patient care and safety, the two procedures should only be performed by a fellowship trained foot and ankle orthopaedic surgeon. The two procedures are both related to more complex surgical procedures. The reason that persons in medical training go into a multi year medical/surgical training and then foot and ankle subspecialty fellowship is to specialize in procedures like these two. The training that covers 6 or 7 years after medical school covers the entire musculoskeletal system in all its intricacies. Only extensive training like this allows a surgeon to correctly understand all of the biomechanics and perform the best treatments for patients.</td>
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<tr>
<td>Arvind Mistry</td>
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<td><a href="mailto:amistry44@yahoo.com">amistry44@yahoo.com</a></td>
<td>Not supportive of podiatrist performing supramalleolar osteotomy of the tibia or fibula. With respect to bone marrow aspirate, it depends on what part of the tibia is punctured to aspirate marrow.</td>
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<tr>
<td>Bryan D. Caldwell, DPM, MD, Senior Associate Dean of Academic Administration/Chief Academic Officer</td>
<td>Kent State Univ. College of Podiatric Medicine</td>
<td><a href="mailto:bcaldwe7@kent.edu">bcaldwe7@kent.edu</a></td>
<td>Practitioners who can show evidence of competency should be allowed to perform these procedures based on their residency training regardless of their medical degree.</td>
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<tr>
<td>C. David Paragas, Esq.</td>
<td>Counsel for Ohio Orthopaedic Society</td>
<td><a href="mailto:David.Paragas@bltlaw.com">David.Paragas@bltlaw.com</a></td>
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<tr>
<td>Casey Whale</td>
<td></td>
<td><a href="mailto:whalecasey@gmail.com">whalecasey@gmail.com</a></td>
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<tr>
<td>Charles Hoehn, DPM, FACFAS</td>
<td></td>
<td><a href="mailto:drhoehn2@gmail.com">drhoehn2@gmail.com</a></td>
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<tr>
<td>Christopher F. Hyer, DPM, MS; Mark A. Prissel, DPM, FACFAS; Gregory c. Berlet, MD FRCS, FAOA; Terrence M. Philbin, DO, FAOAO</td>
<td>Orthopedic Foot &amp; Ankle Center</td>
<td><a href="mailto:BishR1@orthofootankle.com">BishR1@orthofootankle.com</a></td>
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<td>Christopher J. Spieles, MD</td>
<td></td>
<td><a href="mailto:cdspieles@roadrunner.com">cdspieles@roadrunner.com</a></td>
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<td>Christopher L. Reeves, DPM, FACFAS</td>
<td></td>
<td><a href="mailto:docreeves1@yahoo.com">docreeves1@yahoo.com</a></td>
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<tr>
<td>Clay Carmody, MD</td>
<td>Fellowship trained, board certified orthopedic surgeon specializing in foot and ankle surgery</td>
<td><a href="mailto:clay.carmody@gmail.com">clay.carmody@gmail.com</a></td>
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<tr>
<td>Cody J. Togher, DPM, AACFAS</td>
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<td><a href="mailto:togherc@gmail.com">togherc@gmail.com</a></td>
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<tr>
<td>David Kaplansky, DPM</td>
<td>Kaplansky Foot and Ankle Centers</td>
<td><a href="mailto:mreeveskfc@gmail.com">mreeveskfc@gmail.com</a></td>
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Letter is the formal written response for the Ohio Orthopaedic Society, American Association of Orthopaedic Surgeons, American Orthopaedic Foot & Ankle Society and the American Medical Association. Under medical and legal analysis, it would be an inappropriate and unlawful expansion of the podiatric scope of practice under 4731-20-01, OAC and 4731.51, ORC to allow podiatrists to perform these two procedures. Supramalleolar osteotomy is performed above the medial, lateral, and posterior malleolus and is performed proximal to the distal tibial articular surface of the ankle joint or tibial plafond and does not constitute ankle surgery as defined by Rule 4731-20-01. A rule allowing podiatrists to perform supramalleolar osteotomy will exceed its statutory authority. With respect to harvesting bone marrow aspirate from the proximal tibia, this does not constitute ankle surgery as defined by Rule 4731-20-01 and is not statutorily allowed for podiatric scope of practice under R.C. 4731.51. The function of the knee and the ankle are very different and podiatrists know anatomically where to insert the bone marrow aspirate needle and trochar in the foot and ankle and where not to, secondary to an increased risk of complications. Podiatrists can address any foot and ankle complications occurring during a procedure on the foot and ankle. This is not the case for the knee. The American Board of Foot and Ankle Surgery has two certification pathways, Reconstructive Rearfoot Ankle Surgery and Foot Surgery. Podiatrists with Reconstructive Rearfoot Ankle Surgery meet ABFAS standards for performing ankle surgery. Rule 471-20-02 does not limit ankle surgery to podiatrists board certified in the Reconstructive Rearfoot Ankle Surgery pathway as other states, like Connecticut and New York. Promulgating a rule to allow podiatrists to perform the two procedures exceeds the Board’s rule making authority.

Podiatric education is grossly deficient for these procedures. Opposed to expansion of scope of practice in the absence of more regulated and rigorous training.

These procedures should be within the scope of podiatrists. Any PMSR36 podiatric residency program is doing these procedures daily. If podiatrist can fix an ankle fracture, they can complete a supramalleolar osteotomy. Harvest of bone marrow from the proximal tibia is easier than removing an ingrown toenail. Both procedures are simplistic in nature.

Procedures of supramalleolar osteotomies and bone marrow aspirate harvest from the tibia are within the scope of practice for podiatry. Procedures are used to correct deformities and treat arthritis. Limiting the availability of these procedures will restrict healthcare from patients in need. The physicians in this practice are a multi-specialty group of foot and ankle orthopedists and surgical podiatrists and they train podiatric surgery and orthopedic residents and fellows in all aspects of surgical care including these procedures. The opposition voiced to the Board’s clarification to the scope of practice is not based on any fact or incident of failure to meet quality of care standards.

Both procedures are beyond the scope of training for podiatrists. Questions who the podiatrist will turn to when there are complications with the procedures.

Practices in FL. Has published a paper on the topic of supramalleolar osteotomy with Robert Mendicino, DPM, Director of Foot and Ankle Surgical Residency at Grant Medical Center. Article included with comments. Would be impossible to adequately perform appropriate deformity correction of the foot and ankle without supramalleolar osteotomy being included in scope of practice and facility privileging.

Procedures are outside the scope of a podiatrist. Harvesting marrow aspirate is a procedure at the knee and specific training (5 years of orthopedic surgery residency after 4 years of medical school) is necessary to appropriately and safely perform this procedure. A supramalleolar osteotomy is a realignment of the leg and is a complex deformity correction surgical case that outside the scope of a podiatrist. Has significant concerns over patient safety.

It is permissible for podiatric surgeons to perform both procedures if they are board certified or qualified by the American Board of Foot and Ankle Surgeons.

Supportive of a rule that affirms the policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and to harvest bone marrow aspirate from the proximal tibia. Podiatric training and education make podiatric physicians uniquely qualified among medical professionals to treat conditions of the foot and ankle.
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<td>David M. Barbara, MD, FACS</td>
<td><a href="mailto:dmbarbara@gmail.com">dmbarbara@gmail.com</a></td>
<td>It is within the scope of practice of certain podiatrists to perform if they are specially trained and able to document experience in the pre-op, intra-op and post-op management of these procedures.</td>
</tr>
<tr>
<td>Derek Weyhrauch, MD</td>
<td><a href="mailto:derek.weyhrauch@gmail.com">derek.weyhrauch@gmail.com</a></td>
<td>Not in favor of permitting podiatrists to perform either procedure.</td>
</tr>
<tr>
<td>Doreen Dupont, MD</td>
<td><a href="mailto:sweepepi334@aol.com">sweepepi334@aol.com</a></td>
<td>Supportive of podiatrists doing both procedures so long as they are done in an accredited surgical center or hospital.</td>
</tr>
<tr>
<td>Dr. Kane, DPM</td>
<td><a href="mailto:kkmwestlake@aol.com">kkmwestlake@aol.com</a></td>
<td>Podiatrists should provide proof of previous training in residency prior to attempting these procedures.</td>
</tr>
<tr>
<td>Dr. Rashid Khalil</td>
<td><a href="mailto:rkhali75@gmail.com">rkhali75@gmail.com</a></td>
<td>Opposed to further expansion of podiatrist scope of practice as they are not well trained surgically and are unable to deal with neurovascular complications that can occur.</td>
</tr>
<tr>
<td>Dr. Susie Payson</td>
<td><a href="mailto:doctor.payson@gmail.com">doctor.payson@gmail.com</a></td>
<td>It is not permissible for a podiatrist to perform either procedure.</td>
</tr>
<tr>
<td>Dr. W. Rigano</td>
<td><a href="mailto:wrigano@aol.com">wrigano@aol.com</a></td>
<td>Not supportive of podiatrists performing these procedures. Operating outside the foot is not appropriate unless the podiatrist has been trained. Complications that arise from the additional operations will need other specialists to treat.</td>
</tr>
<tr>
<td>Duret S. Smith, MD</td>
<td><a href="mailto:duretsmith@gmail.com">duretsmith@gmail.com</a></td>
<td>Without a fellowship involving advanced extended surgery above the talus, allowing privileges for podiatrists for the two procedures is a bad idea.</td>
</tr>
<tr>
<td>Eugene R. Kubitz, DPM, MS,</td>
<td><a href="mailto:dmswetepi334@aol.com">dmswetepi334@aol.com</a></td>
<td>Supportive of podiatrists doing both procedures with the proper training.</td>
</tr>
<tr>
<td>Eugene R. Kubitz, DPM, MS,</td>
<td><a href="mailto:dmswetepi334@aol.com">dmswetepi334@aol.com</a></td>
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<td><a href="mailto:doctor.payson@gmail.com">doctor.payson@gmail.com</a></td>
<td>It is not permissible for a podiatrist to perform either procedure.</td>
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<td><a href="mailto:wrigano@aol.com">wrigano@aol.com</a></td>
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<td>Duret S. Smith, MD</td>
<td><a href="mailto:duretsmith@gmail.com">duretsmith@gmail.com</a></td>
<td>Without a fellowship involving advanced extended surgery above the talus, allowing privileges for podiatrists for the two procedures is a bad idea.</td>
</tr>
<tr>
<td>Furcitas Jugulion, MD</td>
<td><a href="mailto:fjmd@sbcglobal.net">fjmd@sbcglobal.net</a></td>
<td>Opposed to podiatrists doing either procedure. Orthopedists have more general knowledge of medicine and will be able to recognize complications.</td>
</tr>
<tr>
<td>Gage Caudell, DPM, FACFAS</td>
<td><a href="mailto:gcaudell@fwortho.com">gcaudell@fwortho.com</a></td>
<td>Not supportive of allowing podiatrists to do either procedure. There is no shortage of qualified medical doctors to perform these tasks. The technical ability may be an issue but the chief reason for objection to expanding podiatric privileges is that the doctor has observed a disturbing pattern of failure to follow evidence-based guidelines with an excess number of invasive surgical procedures by podiatrists in his career in primary care.</td>
</tr>
<tr>
<td>Gary R. Gibson, MD, FACP</td>
<td><a href="mailto:ggibson8900@yahoo.com">ggibson8900@yahoo.com</a></td>
<td>Over time, podiatrists at CCF have been granted full privileging. A PSR-36 trained DPM today has the privileges that have been called into question in Ohio. Revoking these existing privileges would be a disservice to institution, profession and patients. It would function as willful blindness towards the core competencies the podiatric profession has worked to achieve over the past few decades, resulting in both lengthier and more advanced podiatric residencies and fellowships. A good number of podiatrists, DOs and MDs do not routinely perform this procedure, for those who do such revisions and major hindfoot surgery to not be given similar surgical procedures as DO and MD equivalents would be wrong.</td>
</tr>
<tr>
<td>Georgeanne Botek, DPM, Head</td>
<td><a href="mailto:BOTEKG@ccf.org">BOTEKG@ccf.org</a></td>
<td>Recommend that there is documented and systemic widespread evidence prior to making changes to scope of practice.</td>
</tr>
<tr>
<td>Georgeanne Botek, DPM, Head</td>
<td><a href="mailto:goodmd1@aol.com">goodmd1@aol.com</a></td>
<td>He is a plastic surgeon and has worked with podiatrists who do these procedures. He thinks podiatrists are well qualified to do these procedures.</td>
</tr>
<tr>
<td>Georgeanne Botek, DPM, Head</td>
<td><a href="mailto:ghollandmd@me.com">ghollandmd@me.com</a></td>
<td>He is a plastic surgeon and has worked with podiatrists who do these procedures. He thinks podiatrists are well qualified to do these procedures.</td>
</tr>
<tr>
<td>Georgeanne Botek, DPM, Head</td>
<td><a href="mailto:gsgibson8900@yahoo.com">gsgibson8900@yahoo.com</a></td>
<td>Based on experience as an orthopedic traumatologist and joint reconstruction surgeon who has worked in a community with highly trained and competent podiatric surgeons and as program director of an orthopedic residency training program, podiatrists are able to safely perform both procedures. Appropriately credentialed podiatric surgeons are capable of reconstructing a taibial plafond fracture. A controlled osteotomy in the same region is not as difficult. With respect to harvesting bone marrow aspirate from the proximal tibia, there is no reason this safe and simple procedure should be excluded from a podiatric surgeon scope of practice.</td>
</tr>
<tr>
<td>Georgeanne Botek, DPM, Head</td>
<td><a href="mailto:goodmd1@aol.com">goodmd1@aol.com</a></td>
<td>Asks whether a podiatrist can admit to a hospital.</td>
</tr>
<tr>
<td>Georgeanne Botek, DPM, Head</td>
<td><a href="mailto:ghollandmd@me.com">ghollandmd@me.com</a></td>
<td>He is a plastic surgeon and has worked with podiatrists who do these procedures. He thinks podiatrists are well qualified to do these procedures.</td>
</tr>
<tr>
<td>Gregory Vrabec, MD, FRCs,</td>
<td><a href="mailto:VrabecG@ccf.org">VrabecG@ccf.org</a></td>
<td>Based on experience as an orthopedic traumatologist and joint reconstruction surgeon who has worked in a community with highly trained and competent podiatric surgeons and as program director of an orthopedic residency training program, podiatrists are able to safely perform both procedures. Appropriately credentialed podiatric surgeons are capable of reconstructing a taibial plafond fracture. A controlled osteotomy in the same region is not as difficult. With respect to harvesting bone marrow aspirate from the proximal tibia, there is no reason this safe and simple procedure should be excluded from a podiatric surgeon scope of practice.</td>
</tr>
<tr>
<td>Guang Li</td>
<td><a href="mailto:lighg@yahoo.com">lighg@yahoo.com</a></td>
<td>That's not good idea to allow podiatrists to do more than allowed ops.</td>
</tr>
<tr>
<td>Harold Slocum</td>
<td><a href="mailto:heslocum@gmail.com">heslocum@gmail.com</a></td>
<td>Competence probably varies with the podiatrist who should use judgment, but both procedures seem high in the extremity to be podiatry rather than orthopedics.</td>
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<tr>
<td>Ian Alexander MD</td>
<td><a href="mailto:alexandi22@gmail.com">alexandi22@gmail.com</a></td>
<td>Supramalleolar osteotomy which is very rarely indicated is not an ankle procedure and is beyond the scope of practice and training of podiatrists. Dr. has dealt with many complications due to podiatric procedures performed as a result of expansion of scope of practice. Dr. has never heard of aspiration of the proximal tibia for bone marrow. Aspiration of bone marrow is performed to harvest progenitor cells. The cells are plentiful in the iliac crest (pelvis) based on scientific studies they are much less in number in the proximal tibia calling in to question why podiatrists are requesting the right to aspirate from the proximal tibia.</td>
</tr>
<tr>
<td>Ian Barron, DPM, FACP, Chief Podiatry Division, Doctor's Hospital</td>
<td><a href="mailto:barronim13@gmail.com">barronim13@gmail.com</a></td>
<td>Supportive of podiatrists performing both procedures. They have been performed for decades by podiatrists within Ohio and podiatrists have written technique papers regarding the procedures. Podiatrists doing these procedures need to have the appropriate training and board qualification or board certification.</td>
</tr>
<tr>
<td>James R. Shope, MD, FACP, ACHE, SCCM</td>
<td><a href="mailto:j.shopemd@yahoo.com">j.shopemd@yahoo.com</a></td>
<td>Opposed to bone marrow aspiration of “non foot” bones and would recommend the practitioner consider using cadaveric graft.</td>
</tr>
<tr>
<td>Jeffrey R. DeSantis, DPM, President; James R. Christina DPM, CEO and Executive Director American Podiatric Medical Association</td>
<td><a href="mailto:CLAppel@apma.org">CLAppel@apma.org</a>; <a href="mailto:jchristina@apma.org">jchristina@apma.org</a></td>
<td>APMA is supportive of the Medical Board’s decision in June and September 2019. Agrees that supramalleolar osteotomy of the tibia or fibula constitutes ankle surgery. A supramalleolar osteotomy of the tibia and fibula if a joint-sparing surgical procedure that is used to treat the positional deformity of the ankle joint to improve intraarticular load distribution and slow degeneration of the ankle joint. The procedure is a mechanism to treat the ankle or hindfoot deformity that is within podiatric scope of practice to manage the progression of ankle arthritis. Podiatrists often perform procedures that may go beyond a prescribed anatomical demarcation or to treat ailments of the foot, including the ankle joint. Letter gives some examples of these procedures. Also supports Medical Board’s decision that harvesting bone marrow aspirate from the proximal tibia to be used for foot and ankle surgery is within the scope of practice of appropriately trained podiatric physician. Supports the statement that the expertise and skills needed to aspirate bone marrow are not dependent upon the donor site. If podiatric physicians cannot perform these procedures, patients may have to wait extended periods of time to obtain care from another qualified physician. According to the American Orthopaedic Foot and Ankle Society, only 43 AOFAS members are licensed in Ohio. Podiatrists are trained and credentialed to do these procedures.</td>
</tr>
<tr>
<td>John Dimar, MD</td>
<td><a href="mailto:jdimar2@aol.com">jdimar2@aol.com</a></td>
<td>Norton Childrens Hospital in Louisville KY requires both orthopedists and podiatrists to show expertise in complex foot procedures in children.</td>
</tr>
<tr>
<td>John Gillen</td>
<td><a href="mailto:bgillen@gmail.com">bgillen@gmail.com</a></td>
<td>Both procedures are beyond the training of all but residency trained/board certified orthopedic surgeons. A concern is whether a podiatrist is qualified to recognize and care for possible complications.</td>
</tr>
<tr>
<td>Jordan P. Grossman, DPM, FACP, FAC</td>
<td><a href="mailto:j.grossman@me.com">j.grossman@me.com</a></td>
<td>The June 2019 communication regarding these procedures was accurate and these procedures are within the scope of podiatrist. Whether a podiatrist has the training and education to perform the procedures should be determined by each hospital’s credentialing committee.</td>
</tr>
<tr>
<td>Kelly Whaley, DPM, President Ohio Foot and Ankle Medical Association</td>
<td>Sent by <a href="mailto:mmathy@ohfama.org">mmathy@ohfama.org</a></td>
<td>Requests that the Board advance a rule that mirrors its established policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and to harvest bone marrow aspirate from the proximal tibia. Supramalleolar osteotomy is commonly performed to realign previous ankle fractures, ankle deformities or mal-aligned ankle fusions that affect the function of the foot and ankle. Only a subset of podiatrists and orthopedists perform this procedure and it is crucial for the Board to continue to allow qualified practitioners to perform this procedure. Bone marrow aspirate is used to help bone and soft tissue healing in a variety of foot and ankle procedures.</td>
</tr>
<tr>
<td>Kevin Martin, DO</td>
<td><a href="mailto:dr.kevin.d.martin@gmail.com">dr.kevin.d.martin@gmail.com</a></td>
<td>As a board certified orthopedic foot and ankle surgeon, he is concerned with approval of the two procedures for podiatrists. The supramalleolar osteotomy would allow DPMs to go nearly up to the knee. This is entirely out of their scope of practice and requires knowledge of the entire extremity and the impact on the knee and hip. The bone marrow aspirate can be drawn from the Calcaneus (heel bone) so there is no need to go to the proximal tibia.</td>
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<td>Name</td>
<td>Institution</td>
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<tr>
<td>Kristin Englund, MD, MLS, President</td>
<td>Academy of Medicine of Cleveland and Northern Ohio</td>
<td><a href="mailto:Johns@amcno.org">Johns@amcno.org</a></td>
</tr>
<tr>
<td>Kuldeep Singh, MD</td>
<td></td>
<td><a href="mailto:Drsinghmd@yahoo.com">Drsinghmd@yahoo.com</a></td>
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<tr>
<td>Larry Isaacs</td>
<td></td>
<td><a href="mailto:Lmi5@aol.com">Lmi5@aol.com</a></td>
</tr>
<tr>
<td>Lawrence A. DiDomenico, DPM, FACFAS</td>
<td>NOMS Ankle &amp; Foot Care Centers</td>
<td>Sent by <a href="mailto:mmathy@ohfama.org">mmathy@ohfama.org</a></td>
</tr>
<tr>
<td>Leslie P. Niehaus, DPM, FACFAS</td>
<td>Alliance and Salem Foot and Ankle Clinics</td>
<td>Sent by <a href="mailto:mmathy@ohfama.org">mmathy@ohfama.org</a></td>
</tr>
<tr>
<td>Lisa Bohman Egbert, MD, President</td>
<td>Ohio State Medical Association</td>
<td>Sent by <a href="mailto:jhayhurst@osma.org">jhayhurst@osma.org</a></td>
</tr>
<tr>
<td>Lynette Gogol, DO</td>
<td></td>
<td><a href="mailto:Lynette@texasmoss.com">Lynette@texasmoss.com</a></td>
</tr>
<tr>
<td>M. Pierce Ebaugh, DO, Fellow</td>
<td>Orthopaedic Surgery, Univ of Texas - Houston</td>
<td><a href="mailto:Mpebaugh@gmail.com">Mpebaugh@gmail.com</a></td>
</tr>
<tr>
<td>Mark A. Hardy, DPM, FACFAS, Program Director, Assistant Dean</td>
<td>Kent State Univ. College of Podiatric Medicine</td>
<td><a href="mailto:Hardy@balancecle.com">Hardy@balancecle.com</a></td>
</tr>
<tr>
<td>Mark J. Berkowitz, MD, Director</td>
<td>Foot &amp; Ankle Dept, Cleveland Clinic</td>
<td><a href="mailto:Barnhab@ccf.org">Barnhab@ccf.org</a> (Blair Barnhart-Hinkle)</td>
</tr>
<tr>
<td>Mark Scioli</td>
<td></td>
<td><a href="mailto:Mscioli1956@icloud.com">Mscioli1956@icloud.com</a></td>
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<tr>
<td>Michael Canales, DPM, Chief of Podiatry and Residency Director</td>
<td>Sent by <a href="mailto:mmathy@ohfama.org">mmathy@ohfama.org</a></td>
<td>Supportive of a rule that affirms the policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and to harvest bone marrow aspirate from the proximal tibia. Podiatrists in Ohio are required to complete a residency and attain board qualified status from the American Board of Foot and Ankle surgery to perform ankle surgery. A supramalleolar osteotomy is commonly performed to realign previous ankle fractures, ankle deformities or mal-aligned ankle fusion procedures that directly affect the function of the foot and ankle.</td>
</tr>
<tr>
<td>Mona N. Arabi, MD, PA</td>
<td><a href="mailto:mmonaarabi@yahoo.com">mmonaarabi@yahoo.com</a></td>
<td>Although she worked with a podiatrist in PA who was technically good at treating complex fractures above the malleole, she does not support podiatrists doing the procedures because the MD has more foundation to handle the job.</td>
</tr>
<tr>
<td>Nick Cheney, DO, FAOAO, FAOOS</td>
<td><a href="mailto:dr.cheney@yahoo.com">dr.cheney@yahoo.com</a></td>
<td>Opposed to podiatrists doing supramalleolar osteotomies. Outlines concerns with podiatric training.</td>
</tr>
<tr>
<td>Nicole Nicolosi, DPM</td>
<td><a href="mailto:nicolon@ccf.org">nicolon@ccf.org</a></td>
<td>Supportive that the procedures are within podiatric scope of practice. Routinely performs proximal tibial bone marrow aspiration as part of her regimen for rearfoot arthrodesis procedures. Explains the process she went through to be credentialed to perform these procedures. DPMs are not performing these procedures to treat the leg or proximal structures.</td>
</tr>
<tr>
<td>Pete Edwards, MD</td>
<td><a href="mailto:pedward3@columbus.rr.com">pedward3@columbus.rr.com</a></td>
<td>Dr. Edwards is a practicing orthopedic surgeon with specialty training in sports medicine and foot and ankle and is aware of the differences in training in podiatry and orthopedic surgery. The two procedures are outside the scope of Podiatric training.</td>
</tr>
<tr>
<td>Peter Gerbino, MD</td>
<td><a href="mailto:peter.gerbino@gmail.com">peter.gerbino@gmail.com</a></td>
<td>The two procedures are outside the scope of podiatry. Harvesting bone marrow from the tibia brings them to the knee. Tibial supramalleolar osteotomy is above the ankle to correct tibial alignment. Where does it end?</td>
</tr>
<tr>
<td>Poonam Singh, MD</td>
<td><a href="mailto:poonampediatricmd@gmail.com">poonampediatricmd@gmail.com</a></td>
<td>Opposed to podiatrists doing either procedure.</td>
</tr>
<tr>
<td>Ramagopal Reddy Avutu, MD</td>
<td><a href="mailto:avutu12@gmail.com">avutu12@gmail.com</a></td>
<td>Both procedures are not within the scope of podiatric practice. Podiatrists are not trained to do these procedures and it will be harmful to the patients.</td>
</tr>
<tr>
<td>Robert Brarens, FACFAS, Director</td>
<td>Sent by <a href="mailto:mmathy@ohfama.org">mmathy@ohfama.org</a></td>
<td>Podiatric residents are trained to perform tibial osteotomies regularly for the treatment of the ankle and foot. This includes such procedures as total ankle replacements, tibial osteotomies for the treatment of talar fractures, ankle fusions, tibial torsion correction and infections. In many procedures, such as total ankle replacements, the need to realign an ankle joint prior to the implantation of the device is paramount to its short and long term success. Bone marrow aspiration and harvesting is an essential aspect of all bone surgeon’s armamentarium. This is greater for podiatry as they are commonly dealing with the most unhealthy and highest risk patients due to comorbidities. Cadaver based products tend to be expensive and are not as successful as an autogenous source.</td>
</tr>
<tr>
<td>Robert J. Miller, DO</td>
<td><a href="mailto:robertjmiller@live.com">robertjmiller@live.com</a></td>
<td>Supports allowing podiatrists in good standing to perform both procedures.</td>
</tr>
<tr>
<td>Robert Kulwin, MD</td>
<td><a href="mailto:rkulwin@gmail.com">rkulwin@gmail.com</a></td>
<td>Supramalleolar osteotomy is outside the scope of what a podiatrist should be doing. Needle aspiration from the proximal tibia while well away from the ankle is a simple enough procedure that it can likely be safely and competently performed by a podiatrist.</td>
</tr>
<tr>
<td>Robert Mendicino, DPM, FACFAS</td>
<td>Program Director, Grant Medical Center Foot and Ankle Surgical Residency</td>
<td>The two procedures are within the scope of practice of podiatrist and have been performed by podiatrists for decades in Ohio. Podiatrists must be individually evaluated on their training and practice experience and the board qualification or board certification to be credentialed to perform the procedures. Articles are attached.</td>
</tr>
<tr>
<td>Robert Raines, MD</td>
<td><a href="mailto:raines6666@gmail.com">raines6666@gmail.com</a></td>
<td>Opposed to allowing podiatrists to do both procedures based on the reality that a surgeon should be sufficiently trained to handle any complication of a procedure he or she performs. Podiatrists do not get experience with the knee or distal tibia. The podiatric training is not sufficient to allow them to safely operate in these areas.</td>
</tr>
<tr>
<td>Ronald E. Domen, MD, FACP, FCAP, Medical Director</td>
<td><a href="mailto:rdomen@pennstatehealth.psu.edu">rdomen@pennstatehealth.psu.edu</a></td>
<td>Raises concerns regarding the harvest of bone marrow from the proximal tibia. The tibia is not a good source for bone marrow and bone marrow aspirates are typically performed from the posterior iliac crest (pelvis). Provided information from the FSMB on the uses for hematopoietic stem cells. White paper is attached.</td>
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<tr>
<td>Ross E. Taubman, DPM, President and CMO</td>
<td>PICA Group (liability insurer)</td>
<td>sent by <a href="mailto:mmathy@ohfama.org">mmathy@ohfama.org</a></td>
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<tr>
<td>Samuel Makanjuola, DPM</td>
<td><a href="mailto:Smakanju@kent.edu">Smakanju@kent.edu</a></td>
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<tr>
<td>Samy Sakla</td>
<td><a href="mailto:sfsaak@hotmail.com">sfsaak@hotmail.com</a></td>
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<td>Sergio Ulloa, DO</td>
<td><a href="mailto:sergio_a_uullo@yahoo.com">sergio_a_uullo@yahoo.com</a></td>
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<tr>
<td>Seth Kearney, DPM, FACFAS, FAPWH</td>
<td>Holzer Health System</td>
<td><a href="mailto:skearney@holzer.org">skearney@holzer.org</a></td>
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<tr>
<td>Steven Carp, MD</td>
<td><a href="mailto:carp@carpcosmetic.com">carp@carpcosmetic.com</a></td>
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<tr>
<td>Sunil Hari</td>
<td><a href="mailto:sunilhari@gmail.com">sunilhari@gmail.com</a></td>
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<tr>
<td>Thomas S. Boniface, MD</td>
<td>System Director, Bon Secours Mercy Health Orthopedics; Professor and Chair, Orthopedic Surgery, NEOMED</td>
<td><a href="mailto:tsb@neomed.edu">tsb@neomed.edu</a></td>
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<tr>
<td>V. James Sammarco, MD</td>
<td>Orthopedic Foot and Ankle</td>
<td><a href="mailto:orthofoot@gmail.com">orthofoot@gmail.com</a></td>
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<tr>
<td>Vincent M. Monnier, MD</td>
<td><a href="mailto:vmm3@case.edu">vmm3@case.edu</a></td>
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<tr>
<td>William E. Saar, DO</td>
<td><a href="mailto:wasaar@windstream.net">wasaar@windstream.net</a></td>
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<tr>
<td>Zoltan Krudy, MD</td>
<td><a href="mailto:zkrudy@gmail.com">zkrudy@gmail.com</a></td>
<td></td>
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</tbody>
</table>
Hello Ohio Medical Board,

I do not believe it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity. Deformity correction takes careful planning and understanding of the relationship of the spine, hip, knee, and gait. For orthopaedic surgeons, we are expected to do medical school (4+years), residency (5+years), and additional fellowships in deformity correction and courses to be able to correctly plan and execute these complex procedures. Podiatrists do not have the medical training, comprehensive knowledge or expertise to perform these complex procedures. In addition, they do not have the capability to treat the complications of these surgeries when they fail. For these reasons, podiatrists should not be permitted to perform supramalleolar osteotomies of the tibia or fibula to correct deformities.

I do believe podiatrists should be able to harvest bone marrow aspirate from the proximal tibia. Fusions of the foot and ankle often require biologic assistance, especially in the older population with comorbidities. Aspirating bone marrow is a low risk procedure that will promote better outcomes within their scope of practice.

Sincerely,

Amanda Whitaker, MD

Nationwide Children’s Hospital
Assistant Professor-Practice
Orthopaedic Surgery
The Ohio State University, College of Medicine
700 Children’s Drive T2E-2709
Columbus, OH 43205
Phone: (614)722-3390
Fax: (614) 722-3373

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Dear Kimberly,

I do not believe the following fall under the purview of Podiatrists. These are highly important and complicated procedures that should be conducted by professionals who have undergone significant training and continued education. Additionally, these procedures are of the utmost importance to patient care and providing the highest level of treatment and I believe that they will be significantly hampered by allowing podiatrists to perform them.

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

Thank you.

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To Whom It May Concern:

This letter is addressing the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia.

As a physician, I have been through four years of undergraduate education in pre-medical sciences. I have been through four years of podiatric medical and surgical education in which the curriculum was the same as MD or DO medical school curriculum. I have passed all Podiatric medical boards as well as a rigorous American Board of Foot and Ankle Surgery board certification that includes four examinations and a year-long case review process that was all conducted over three years. I was a part of three years of podiatric medical and surgical residency training that included over 12 months off service rotations at a large major university hospital that requires no difference between MD, DO, DPM training. I have had extensive training in both of these procedures listed above and have been deemed competent by multiple physicians including MD and DO orthopedics during my training. I have performed these procedures on patients with exceptional outcomes and results. I feel this point I am trained and am qualified to perform a bone marrow aspiration from the proximal tibia and also an osteotomy of the tibia and this should without regard be within my scope of practice.

ANDREW J. BROWN, D.P.M., F.A.C.F.A.S
Thank you for considering my comments. I believe that the need for supramalleolar surgery of any type and or need to harvest bone graft from the tibia are both related to more complex surgical procedures. One is not even involving the foot. The reason that persons in medical training go into a multi year medical/surgical training and then a foot and ankle surgery subspecialty fellowship is to specialize in just such procedures. This training, over a total 6-7 years after medical school, ends up covering the entire musculoskeletal system in all of its intricacies. Only this extensive training allows a surgeon to correctly understand all of the biomechanics of such and thus perform the best treatments for such patients.

It is therefore in the best interest of patients regarding care and safety that these procedures are only performed by a fellowship trained foot and ankle orthopaedic surgeon.

--
Thank You

Anthony F. Guanciale, M.D.
Associate Professor Dept Orthopaedic Surgery University of Cincinnati
Spine Surgeon/Fellowship trained
Kerlan-Jobe and Cleveland Clinic Foundation
Specializing in Minimally Invasive and Adult Deformity Surgery
Consultant Cincinnati Bengals and the University of Cincinnati
16 years of UC Academic Experience as Director of Spine Surgery
NASS Committee Member
MAOA Committee Member
tguanciale@gmail.com

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Dear Kim
The podiatrist scope of practice should not be extended to Supra malleolar since they are not orthopedic surgeons. Their limitation is up to feet and infra malleolar. As far as the marrow to be aspirated from tibia depends on what part of tibia is punctured to aspirate marrow.

Sent from Yahoo Mail for iPhone

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Hello Ms. Anderson

Thanks to you and the State Medical Board of Ohio for seeking public comments on podiatric scope of practice to assist with its rule-making process.

Determinations of scope should be based on legislation enacted to protect the public but without discrimination to any group based on items other than the competency of the individual practitioner. Those practitioners who can show evidence of competency should be allowed to perform these procedures based on their residency training regardless of their medical degree. OAC Rule 4731-20-02 appropriately addresses terms for the rule.

Thank you,

Bryan D. Caldwell, DPM, MD
Senior Associate Dean of Academic Administration/Chief Academic Officer
Professor
Kent State University College of Podiatric Medicine

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July 5, 2021

Via email: Kimberly.Anderson@med.ohio.gov

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215

In re: Response to Request for Podiatric Scope of Practice Rules

Dear Ms. Anderson:

Please allow this letter to serve as a formal written response on behalf of the Ohio Orthopaedic Society, American Association of Orthopaedic Surgeons, American Orthopaedic Foot & Ankle Society, and the American Medical Association pursuant to the State Medical Board of Ohio’s (the “Board”) request for comments on the proposed promulgation of podiatric scope of practice rules. Specifically, the Board is seeking written comments on following two specific procedures previously addressed in an opinion issued by the Board on June 12, 2019:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia to correct a deformity?

2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

In response to the Board opinion letter to Daniel Logan, DPM dated June 12, 2019 (the “Letter”), the undersigned expressed collectively that the foregoing procedures exceeded the statutory scope of practice for podiatrists (see attached). For the reasons outlined below and consistent with our previous letter, it is our medical and legal counsel’s opinion that podiatrists cannot perform the two procedures outlined above, as it would be an inappropriate and unlawful expansion of the podiatric scope of practice as set forth in Sec. 4731-20-01 of the Ohio Administrative Code and Section 4731.51 of the Ohio Revised Code. Accordingly, the promulgation of rules permitting the performance of the foregoing procedures are both inappropriate from a medical perspective and fall outside the legal authority of the Board.
Medical Analysis:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?"

In the Letter, the Board has offered the following analysis to question 1:

“The tibial plafond forms the articular surface of the distal tibia. The distal tibia and fibular act as the socket for the talus. Accordingly, a supramalleolar osteotomy of the tibia or fibula constitutes ankle surgery, as defined in Rule 4731-20-02, O.A.C.¹, and is within the podiatric scope of practice of an appropriately trained podiatric physician when performed in compliance with Rule 4731-20-02, O.A.C., and within the minimal standards of care. Finally, whether a podiatrist may perform the surgeries at a specific hospital or ambulatory surgical center is solely a matter of credentialing and privileging decisions.”

However, an osteotomy involves realigning a bone by cutting it, shifting the two ends relative to each other and/ or taking out or adding a wedge of bone between them, and then stabilizing the two bone ends in the corrected position typically with plates, screws or pins. A “supramalleolar osteotomy” is defined as osteotomy of the tibia or fibula “above” or “proximal” to the malleolus². As noted in the Letter, the tibial “plafond³” is defined as the articular surface of the distal tibia, which articulates with the articular cartilage of the talar dome within the ankle joint. Supramalleolar osteotomies of the tibia are performed in the bone “above” or “proximal” to the articular cartilage of the distal tibia. Additionally, for adequate stability and healing, these fixation devices need to extend even farther above the ankle than the osteotomy site.

Section 4731.51 of the Ohio Revised Code allows podiatrists to treat “ailments of the foot, the muscles and tendons of the leg governing the functions of the foot; and superficial lesions of the hand.” Sec. 4731-20-01, O.A.C., states: “‘Foot’, as used in section 4731.51 of the Revised Code, means the terminal appendage of the lower extremity and includes the ankle joint which consists of the tibial plafond, its posterolateral border (posterior malleolus), the medial malleolus, distal fibula (lateral malleolus) and the talus.”

By anatomical definition, a supramalleolar osteotomy of the tibia or fibula is performed “supra” or “above” the medial, lateral, and posterior malleolus, and is, also, performed proximal to the distal tibial articular surface of the ankle joint, or tibial plafond. Therefore, a supramalleolar osteotomy of the tibia or fibula clearly does not constitute ankle surgery, as defined by Sec. 4731-20-01, O.A.C. Furthermore, the supramalleolar tibia and fibula are clearly not part of the hand,

¹ The Board mistakenly referred to Rule 4731-20-02, O.A.C., instead of Rule 4731-20-01, O.A.C.
² https://medical-dictionary.thefreedictionary.com/supramalleolar
³ American Heritage Dictionary Entry: plafond (ahdictionary.com)
and they are bones, not muscles and tendons of the leg governing the functions of the foot. Consequently, supramalleolar osteotomies of the tibia and fibula are clearly not within the podiatric scope of practice statutorily allowed by Section 4731.51 of the Revised Code, irrespective of whether or not the podiatrist meets the criteria within Sec. 4731-20-02, O.A.C. Therefore, adoption of an administrative rule permitting this procedure by the Board will exceed its statutory authority as it did when it used a clearly erroneous conclusion to expand Dr. Logan’s scope of practice beyond statutorily permitted scope of practice for podiatrists.

2. “Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

With respect to Question 2, the Board previously concluded in the Letter as follows:

“Although the inquiry did not specify, this response is based upon the assumption that the bone marrow would be used for foot and ankle surgery. The harvesting of bone marrow aspirate does not require an incision but is performed by insertion of a needle into the cortex. The aspirate is typically mixed with an anticoagulant to prevent clotting and allow for concentration of the desired components or could be mixed with products such as bone chips to comprise an autograft equivalent. The Medical Board understands that the harvesting of bone marrow aspirate is a component of podiatric training, whether in podiatric medical school, residency, or continuing education.

It is clear that an appropriately trained podiatrist may aspirate bone marrow from the foot. The expertise and skills needed to aspirate bone marrow are not dependent upon the donor site because the same skills and principles must be applied whether the site is on the foot or proximal tibia. Accordingly, harvesting bone marrow aspirate from the proximal tibia to be used for foot and ankle surgery is within the scope of practice of an appropriately trained podiatric physician. The podiatric physician must perform the procedure in conformance with the minimal standards of care of similar practitioners under the same or similar circumstances. Finally, whether a podiatrist may perform the surgeries at a specific hospital or ambulatory surgical center is solely a matter of credentialing and privileging decisions.”

However, the articular surface of the proximal tibia is part of the knee joint. The proximal tibia is well proximal to the medial malleolus, lateral malleolus, posterior malleolus, and tibial plafond. Therefore, based on well-established anatomy, harvesting bone marrow aspirate from the proximal tibia clearly does not constitute ankle surgery, as defined by Sec. 4731-20-01, O.A.C. Furthermore, the proximal tibia is clearly not part of the foot or hand, and is a bone, not a muscle or tendon of the leg governing the functions of the foot. Therefore, harvesting bone marrow aspirate from the proximal tibia clearly is clearly not within the podiatric scope of practice statutorily allowed by Sec. 4731.51 of the Revised Code.
Interestingly, the Letter ratified this conclusion in its response to Question #2 (of the Letter) as follows:

“The above statute and rules provide that a podiatric physician may perform surgical treatment of the ailments of the foot, which includes the ankle, and may use such preparations, medicines, and drugs as may be necessary. The proximal tibia is not within the definition of "foot." In addition, a bone graft requires an incision at the donor site so that bone may be removed at the donor site. This minor surgical procedure at the proximal tibia also does not constitute the use of a preparation, medicine, or drug for the surgical treatment of the foot. Accordingly, harvesting of a bone graft from the proximal tibia to be used for foot and ankle surgery is not within the podiatric scope of practice as defined in the Ohio Revised Code and Ohio Administrative Code. [Emphasis added].”

Proximal tibial bone graft consists of structural bone fragments as well as the same bone marrow that is aspirated when performing a proximal tibial bone marrow aspirate. If the proximal tibia is not within the definition of “foot”, it is irrelevant whether or not structural bone is harvested in addition to bone marrow, whether or not the bone marrow aspirate is used for foot and ankle surgery, or whether or not an incision is used.

Sec. 4731.51 of the Revised Code allows podiatrists to harvest bone graft or bone marrow aspirate from the foot, and Sec. 4731-20-01, O.A.C. allows podiatrists who meet the requirements of Rule 4731-20-02, O.A.C. to harvest bone graft or bone marrow aspirate from the ankle. However, neither the Ohio Revised Code nor the Ohio Administrative Code authorize podiatrists to operate outside of their anatomical scope of practice to obtain bone graft or bone marrow aspirate from other parts of the body for use in foot and ankle surgery. The quality of bone graft and bone marrow aspirate is arguably better in the iliac crest and vertebral body than in the proximal tibia and foot. Nevertheless, it would still be beyond the statutory authority for the Board to allow podiatrists to operate on the pelvis or spine to obtain bone marrow aspirate for use in foot and ankle surgery, or as another example, to operate on the abdomen to obtain fat stem cells for use in foot and ankle surgery. While podiatrists are authorized pursuant to Revised Code Sec. 4731.51, “the use of such preparations, medicines, and drugs as may be necessary for the treatment of such ailments” of the foot, they are not statutorily allowed to obtain ingredients for preparations via surgery outside of their scope of practice. If the ingredients are not available commercially or from surgery within podiatric scope of practice, they can still be used if obtained by another health care provider operating within their scope of practice.

The Board correctly states in the Letter, “[I]t is clear that an appropriately trained podiatrist may aspirate bone marrow from the foot” and “is a component of podiatric training.” However, the Board’s Letter also irrelevantly and incorrectly states that “[T]he expertise and skills needed to aspirate bone marrow are not dependent upon the donor site because the same skills and principles must be applied whether the site is on the foot or proximal tibia.” The anatomy and
function of the ankle and knee are very different. Podiatrists know anatomically where to insert the bone marrow aspirate needle and trochar in the foot and ankle, and more importantly, where not to secondary to an increased risk of complications. Podiatrists can also address any foot and ankle complications occurring during a procedure on the foot and ankle. This is not the case for the knee where important vessels and nerves can be damaged with inappropriate needle and trochar placement, which may require an extension of the incision to address. Furthermore, if the knee joint penetrated, damaging the joint cartilage or menisci, a podiatrist would not have the statutory authority nor the knowledge and training, to repair them. This also applies to other areas where bone marrow may be aspirated from including the pelvis and vertebral body.

The statement in the Board Letter that, “...harvesting of bone marrow aspirate does not require an incision but is performed by insertion of a needle into the cortex,” does not waive the anatomical boundaries of the Sec. 4731.51 of the Revised Code and Sec. 4731-20-02, O.A.C. Moreover, it does not reflect an understanding of how proximal tibial bone marrow aspirate is typically performed. Most surgeons use an incision to accommodate the large size of the aspiration needle and the sharp trochar that fits inside of the needle and is hit with a mallet to penetrate the hard bone of the proximal tibia. Figure 1 demonstrates this in the technique article the Medical Board referenced as footnote 1 in its Letter.

The main certifying board for podiatric surgery, the American Board of Foot and Ankle Surgery (“ABFAS”) has two current board certification pathways, Reconstructive Rearfoot Ankle Surgery and Foot Surgery, with only the podiatrists in the Reconstructive Rearfoot Ankle Surgery pathway meeting the ABFAS standards for performing ankle surgery5. O.A.C. Sec. 4731-20-02 only requires individuals who did not have surgical privileges for ankle surgery before 1997 to have ABFAS board qualified status to perform ankle surgery in Ohio. However, unlike states such as Connecticut6 and New York7, O.A.C. Sec. 4731-20-02 does not require the board qualified status be in Reconstructive Rearfoot Ankle Surgery and allows podiatrists who are only board qualified in Foot Surgery to perform ankle surgery in Ohio. Therefore, since Sec. 4731-20-02, O.A.C. allows ankle surgery by podiatrists who do not even meet their own certifying board standards for performing ankle surgery; it would be particularly concerning to allow podiatrists with only Foot Surgery board qualification or certification to operate beyond the ankle in Ohio.

Legal Analysis:

Beyond the many issues highlighted above, the Board simply lacks the authority to promulgate these rules given the statutory mandate of the General Assembly. Executive bodies such as the Board derive their authority to adopt administrative rules from the statutes passed by

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5 Page 3 of [bedoc2019.pdf](http://abfas.org)
6 [Chapter 375 - Podiatry (ct.gov)](http://ct.gov)

The Board’s conclusions set forth in the Letter exceeded their clarifying authority in its responses to questions #1 and #3. Likewise, the adoption of rules authorizing the performance of these procedures by podiatrists would be in conflict with statute because the Medical Board seeks to add to the scope of practice for podiatrists as laid out by the General Assembly. Sec. 4731.51 of the Revised Code delineates the scope of practice for podiatrists as follows: “consists of the medical, mechanical, and surgical treatment of ailments of the foot, the muscle of the foot and tendons of the leg governing the foot.”

Adoption of a rule authorizing the procedure described in question 1 would allow podiatrists to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity. These procedures are outside the current podiatric scope of practice statutorily allowed by Revised Code Section 4731.51. The statute allows podiatrists to practice on the foot and the “muscles and tendons of the leg governing the functions of the foot.” The tibia and fibula are leg bones, not muscles and tendons governing the functions of the foot. Adoption of a rule authorizing podiatrists to perform medical procedures on additional bones is clearly an expansion of the scope of practice currently permitted by law. More importantly, the Board lacks statutory authority to permit such expansion.

The subject matter of the second question if incorporated in rule would allow podiatrists to harvest bone marrow aspirate from the proximal tibia. The proximal tibia is a part of the knee joint and outside the scope of podiatric practice that is set forth in Sec. 4731.51 of the Revised Code. The Board clarified in O.A.C. Sec. 4731-20-02 that podiatrists who meet certain requirements can harvest bone graft or bone marrow aspirate from the ankle. However, the General Assembly has never approved the harvesting of bone graft or bone marrow aspirate from outside a podiatrist’s anatomical scope of practice.

If you have any comments, questions or concerns, please feel free to contact the undersigned as counsel to the Ohio Orthopaedic Society.

Respectfully submitted,

C. David Paragas
FROM:  BARNES & THORNBURG LLP
41 SOUTH HIGH STREET, SUITE 3300
COLUMBUS, OHIO 43215-6104

TO:

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215

HAND DELIVERED

MEDICAL BOARD
JUL 06 2021
From: Casey Whale
To: Anderson, Kimberly
Date: Tuesday, June 15, 2021 6:38:53 PM

Podiatry education is grossly deficient for these procedures. I am adamantly opposed to expanding their scope of practice in the absence of more regulated and rigorous training.

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Ms. Anderson,

I may be late to the party, but the question is why aren't these two procedures within the scope already? Any PMSR36 podiatric residency program are doing these procedures daily. If podiatrists can fix an ankle fracture, they can certainly complete a supramalleolar osteotomy. As for the bone marrow harvest from the proximal tibial (tibial tuberosity), that particular procedure is easier than removing an ingrown toenail! Both of these procedures are simplistic in nature and I honestly don't know why these have not been approved.

Regards,

Charles Hoehn, DPM, FACFAS

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June 28, 2021

Dear Members of the Joint Committee for Agency Rule Review (JCARR) and the State Medical Board of Ohio,

We write to voice our strong support of the Board’s 2019 clarification on the scope of practice for podiatrists in the state of Ohio. We again affirm the procedures of supramalleolar osteotomies and bone marrow aspirate harvest from the tibia are within the scope of practice for podiatry. These important procedures are used to correct deformities and treat arthritis that affects our patients and fellow Ohioans every day. Limiting the availability of these procedures will only serve to restrict healthcare from patients in need.

We feel it is important to point out the difference between ‘scope of practice’ and ‘delineation of privileges’ as it relates to qualification and competency. For a practitioner to perform these specific and any other surgical procedures, they must prove competency and training to the hospital or ambulatory care center where they intend to provide this care. Often this will include documentation of surgical residency training, fellowship training, board certification and credentialing of similar procedures at other centers.

Not all orthopedists or surgical podiatrists will have the desire or training to perform these procedures and thus, they would not apply or be granted those privileges. However, supramalleolar osteotomies of the tibia and fibula, total ankle replacements, retrograde tibia-talar-calcaneal fusions with tibial nailing, ankle and subtalar fusions, complex ankle fracture repair, bone marrow aspiration, multi-planar circular external fixation device application with fixation into the tibia—all are within the scope of practice of podiatry in the state of Ohio. These procedures have all been performed and are currently done on a regular basis in Ohio and are available credentialed surgical privileges at most surgical care sites.

As a multi-specialty group of foot and ankle orthopedists and surgical podiatrists, we at The Orthopedic Foot and Ankle Center regularly train podiatric surgery and orthopedic residents and fellows in all aspects of surgical care including these procedures. We are a tertiary referral center and frequently care for patients through the state of Ohio, the Appalachian, Midwest regions, and international patients who travel here for complex care.

The opposition voiced to the Board’s clarification to the scope of practice is not based in any fact or incident of failure to meet quality of care standards, but rather
smacks of politics and an attempt for restraint of trade. We strongly encourage the
Board and the JCARR to again re-affirm the scope of practice of podiatry in Ohio to
include these procedures.

Sincerely-

Christopher F. Hyer, DPM, MS
Co-Director Foot and Ankle Fellowship, Orthopedic Foot and Ankle Center
President Board of Directors, Polaris Surgery Center
Past Residency Director, Grant Medical Center
Past Board of Directors, American College of Foot and Ankle Surgeons

Mark A. Prissel, DPM, FAOFAS
Co-Director Foot and Ankle Fellowship, Orthopedic Foot and Ankle Center
Fellowship Committee Member, American College of Foot and Ankle Surgeons
Member, Medical Advisory Committee, Polaris Surgery Center
Past Faculty Member, Grant Medical Center Podiatric Surgical Residency

Gregory C. Berlet, MD, FRCS(C), FAOA
Orthopedic Surgeon

Terrence M. Philbin, DO, FAOAO, AOAO Past President
Orthopedic Surgeon

Patrick E. Bull, DO, FAOAO
Fellowship Trained Foot & Ankle Surgeon, Board Certified Orthopedic Surgeon
The State Medical Board of Ohio is seeking public comments on podiatric scope of practice to assist with its rule-making process.

Under section 121.931, Ohio Revised Code, a party may petition an agency to
In June 2019, the State Medical Board of Ohio considered a request from a podiatrist as to whether five specific procedures were within the scope of practice of a podiatrist. The Board determined that four of the five procedures were within the scope of practice of a podiatrist. After the Board issued its determination on this issue, concerns were raised with respect to two of the specific procedures that were determined to be within the podiatric scope of practice:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

In May 2021, the State Medical Board appeared before the Joint Commission on Agency Rule Review (“JCARR”) for consideration as to whether the policy determination should be specified in a rule. Prior to receiving the determination from JCARR, the State Medical Board of Ohio decided to commence the rule-making process on this issue. Given the differences from the affected parties, the Board has decided to first solicit comments from interested parties to inform the rule-making process.

These links provide copies of the Medical Board rules related to podiatric scope of practice (4731-20-01 and 4731-20-02) and the June 2019 communication regarding the specific procedures.

Please provide any comments and supporting material that you would like the Medical Board to consider in drafting rules related to the above-listed specific procedures and whether they are within the scope of practice of a podiatrist.

Comments on the proposed rules must be received by August 19, 2021. Please provide comments to: Kimberly.Anderson@med.ohio.gov.
CAUTION: This is an external email and may not be safe. If the email looks suspicious, please do not click links or open attachments and forward the email to csc@ohio.gov or click the Phish Alert Button if available.
Kimberly Anderson, Chief Legal Counsel - State Medical Board Ohio

Dear Ms. Anderson:

My name is Chris Reeves, and I am writing today in response to the Request for comment on Podiatric Scope of Practice.

- Is it permissible for a podiatrist in Ohio to perform supramalleolar osteotomy of the tibia or fibula to correct a deformity?
- Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

I am a Doctor of Podiatric Medicine (DPM) and Board-Certified Foot and Ankle Surgeon by the American Board of Foot and Ankle Surgery and a recent Past President of the American College of Foot and Ankle Surgeons. I am also one of four Podiatric Surgeons along with four orthopedic surgeons who represent our respective national organizations on the National Joint Task Force of Orthopedic Surgeons and Podiatric Surgeons.

A Podiatric foot and ankle surgeon is a doctor who specializes in the surgical treatment of the foot, ankle, and related structures of the leg. We complete four years of training in a podiatric medical schools and three years of hospital medicine and surgery-based residency training. Ultimately, surgical DPMs who successfully meet the guidelines for demonstrating competency and proficiency in the art and science of foot and ankle surgery are board certified by the American Board of Foot and Ankle Surgery.

As a Doctor of Podiatric Medicine (DPM) performing reconstructive foot and ankle surgery in the state of Florida, I am privileged to perform surgical intervention of soft tissue and bone structures extending from the toes proximal to the tibial tuberosity. Both procedures in question to the State Medical Board of Ohio fall within my scope of practice and are necessary for me to provide comprehensive surgical treatment to patients with lower leg, ankle, and foot ailments. Specifically regarding supramalleolar osteotomy, it would be near impossible for me to adequately perform appropriate deformity correction of the foot and ankle without this procedure being included in my scope of practice and facility privileging. Additionally, I have published a peer-reviewed paper on the topic of supramalleolar osteotomy along with another DPM, Dr. Robert W. Mendicino, who is the director of foot and ankle surgical residency training at Grant Medical Center in Columbus, Ohio. The reference to this article is:


While these are questions are understood as well as the mechanism by which they came about, I would highly and professionally request that these procedures be deemed appropriate in the state of Ohio. It benefits the patients already undergoing reconstructive surgical intervention and could certainly be detrimental to their care should these procedures be deemed impermissible for Podiatric Foot and Ankle Surgeons to perform.

Thank you for your time and consideration and I am pleased to offer availability to speak with you.
on these topics should the need arise.

Best Regards.

Chris

Christopher L. Reeves, DPM, FACPAS

Reconstructive Foot & Ankle Surgery
Past President, American College of Foot & Ankle Surgeons
Director of Surgery - UpperLine Health
Faculty, Advent East Surgical Residency Program
Director of Research, Advent East Surgical Residency Program
Orlando, FL
Offc: 407-423-1234
Cell: 407-443-0166

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Hi,

i have reviewed each of the 5 procedures mentioned, and each of those is clearly outside the scope of a podiatrist. As a fellowship trained board certified orthopedic surgeon who subspecializes in foot and ankle surgery, I believe I have a relatively unique perspective on this matter.

Harvesting proximal tibia bone graft or marrow aspirate is a procedure at the knee, and thus specific training is required to appropriately and safely perform these surgeries (5 years of orthopedic surgery residency after 4 years of medical school).

Nail plate procedures of the hand are similarly outside their scope.

A supramalleolar osteotomy is a realignment of the leg and is a complex deformity correction surgical case that is also outside the scope of a podiatrist.

While I understand the desire to expand into these areas, I do have significant concerns over patient safety, and believe this change would be overall harmful to the public.

Sincerely,
Clay Carmody, MD

Sent from my iPhone

> On Jun 15, 2021, at 3:50 PM, Kimberly.Anderson@med.ohio.gov wrote:
> >
> > Yes, they will be attached to your name.
> >
> > Kimberly Anderson
> > Chief Legal Counsel
> > State Medical Board of Ohio
> > 30 East Broad Street, 3rd Floor
> > Columbus, Ohio 43215
> > o: 614-466-7207
c: 614-230-9077
> Kimberly.Anderson@med.ohio.gov
> >
Ok thanks, but will my comments be attached to my name?

Sent from my iPhone

On Jun 15, 2021, at 3:28 PM, Kimberly.Anderson@med.ohio.gov wrote:

Dr. Carmody,

Thank you for your inquiry. The comments are being sought in the course of the public rule-making process. The comments will be shared with the Medical Board and will be part of the public materials utilized by the Board in the rule-making process. The Board does want to hear from practitioners on this issue. The comments will be part of the public records around this rule.

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
o: 614-466-7207
c: 614-230-9077
Kimberly.Anderson@med.ohio.gov

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Hi Ms. Anderson,

I’m an orthopedic surgeon who is fellowship trained in foot and ankle (I practice in the Toledo, OH area), and I would like to weigh in on the podiatry scope of practice issue. Am I permitted to provide my opinion anonymously? I would fear potential retaliation/litigation. Thanks in advance for your time.

Sincerely,

Clay Carmody
Sent from my iPhone
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Dr. Carmody,

Thank you for your inquiry. The comments are being sought in the course of the public rule-making process. The comments will be shared with the Medical Board and will be part of the public materials utilized by the Board in the rule-making process. The Board does want to hear from practitioners on this issue. The comments will be part of the public records around this rule.

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-----Original Message-----
From: Clay Carmody <clay.carmody@gmail.com>
Sent: Tuesday, June 15, 2021 2:40 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: Podiatry scope of practice

Hi Ms. Anderson,
I’m an orthopedic surgeon who is fellowship trained in foot and ankle (I practice in the Toledo, OH area), and I would like to weigh in on the podiatry scope of practice issue. Am I permitted to provide my opinion anonymously? I would fear potential retaliation/litigation. Thanks in advance for your time.
Sincerely,
Clay Carmody

Sent from my iPhone

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available.
Kimberly,

I believe that it is permissible for pediatric surgeons in Ohio to perform both supramalleolar osteotomies of the tibia or fibula to correct deformity as well as harvest bone marrow aspirate from the proximal tibia if they are board certified or qualified by the nationally recognized board (American Board of Foot and Ankle Surgeons).

Thank you,

Cody J. Togher, DPM, AACFAS
Reconstructive Foot & Ankle Surgery
Orthopedic Foot & Ankle Center, Fellow
350 W. Wilson Bridge RD Suite 200
Worthington, OH 43085
C: (239) 293-3910
F: (614) 895-8810

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July 6, 2021

State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Dear Members of the State Medical Board of Ohio,

I am writing to urge you to develop a rule that affirms its policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow from the proximal tibia.

I am aware that there are going to be several letters coming from podiatrists and other healthcare providers in support of putting the State Medical Board of Ohio’s policy on this matter into rule. I would be surprised if any letters not supporting this course of action come from anyone other than orthopedic surgeons.

Please evaluate the specialty education, standards of training, hospital credentialing and board certification required for a podiatric surgeon to perform ankle surgery. Frankly, the education and training requirements are second to none, which makes pediatric physicians and surgeons uniquely qualified among medical professionals to treat conditions of the foot and ankle.

It is a fact that podiatrists are the innovators and responsible for the advancement of procedures and devices that have been and will continue to improve the lives of so many struggling with foot and ankle problems. I firmly believe the Board should continue to provide the opportunity for the trained foot and ankle surgeon to provide needed health services to his/her Ohio community in the form that meets their training and expertise.

There are orthopedic foot and ankle and podiatric surgeons that own businesses together to provide the best foot and ankle surgical treatment. There are also standalone podiatrists, as well as foot and ankle orthopedics who are trying to do the same in groups or even on their own. Each podiatric and orthopedic surgeon must stand out for some reason or another — and clear a robust credentialing and privileging process — in order to grow their practice and provide care to Ohioans. This is healthy competition among qualified practitioners and is what makes Ohio well known for producing some of the most renowned surgeons in the country.

Unfortunately, there will always be a small, yet loud, group of individuals who would rather compete by restricting access of patients to podiatry providers. It is my hope the Board will disregard the opinions of those who are seeking to restrict the trade of their competitors and instead put its policy on podiatrists performing supramalleolar osteotomies and harvesting bone marrow aspirate into a rule.

Thank you for the opportunity to share my thoughts and comments on this important issue. Please feel free to contact me should you have any questions.

David Kaplansky
Podiatrist
Concerning those two procedures in question, I believe that IF specifically trained and able to document experience in the pre-op, intraop-op, and post-op management of these procedures, then certain podiatrists would be within their “scope of practice” to perform.

David M Barbara MD, FACS

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Good afternoon,

In response to the call for commentary regarding the below issues, my reply would be No to each. I believe it is important to clearly delineate scope of practice and limit procedures to the foot for podiatrists - as a more significant example, if hip arthritis leads to foot pain, could a podiatrist perform a total hip replacement?

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity? No.
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia? No.

Thanks very much, best,

-Derek Weyhrauch, MD

--------- Forwarded message ---------
From: State Medical Board of Ohio <contact@med.ohio.gov>
Date: Mon, Jul 26, 2021 at 11:49 AM
Subject: Podiatric scope of practice - your input is requested
To: <derek.weyhrauch@gmail.com>
scope of practice to assist with its rule-making process.

Under section 121.931, Ohio Revised Code, a party may petition an agency to restate a policy in a rule. In June 2019, the State Medical Board of Ohio considered a request from a podiatrist as to whether five specific procedures were within the scope of practice of a podiatrist. The Board determined that four of the five procedures were within the scope of practice of a podiatrist. After the Board issued its determination on this issue, concerns were raised with respect to two of the specific procedures that were determined to be within the podiatric scope of practice:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

In May 2021, the State Medical Board appeared before the Joint Commission on Agency Rule Review (“JCARR”) for consideration as to whether the policy determination should be specified in a rule. Prior to receiving the determination from JCARR, the State Medical Board of Ohio decided to commence the rule-making process on this issue. Given the differences from the affected parties, the Board has decided to first solicit comments from interested parties to inform the rule-making process.

These links provide copies of the Medical Board rules related to podiatric scope of practice (4731-20-01 and 4731-20-02) and the June 2019 communication regarding the specific procedures.

Please provide any comments and supporting material that you would like the Medical Board to consider in drafting rules related to the above-listed specific procedures and whether they are within the scope of practice of a podiatrist.

Comments on the proposed rules must be received by August 19, 2021.
Please provide comments to: Kimberly.Anderson@med.ohio.gov.

View this email in your browser
You are receiving this email because of your relationship with State Medical Board of Ohio. Please reconfirm your interest in receiving emails from us. If you do not wish to receive any more emails, you can unsubscribe here.

This message was sent to derek.weyhrauch@gmail.com by contact@med.ohio.gov
30 East Broad Street, 3rd Floor, Columbus, Ohio, 43215
Unsubscribe | Manage Subscription | Forward Email | Report Abuse
Please see comment below.

Kind regards,

Jerica Stewart
Communication & Outreach Administrator
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, Ohio 43215-6127
614-620-2127
Jerica.stewart@med.ohio.gov

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From: DOREEN DUPONT <swetepi334@aol.com>
Sent: Monday, July 26, 2021 12:25 PM
Cc: Contact <Contact@med.ohio.gov>
Subject: Fwd: Podiatric scope of practice - your input is requested

I am in agreement as long as the procedures are done in an accredited surgical center or hospital.

Doreen Dupont MD
-At Large Director DECF
The State Medical Board of Ohio is seeking public comments on podiatric scope of practice to assist with its rule-making process.

Under section 121.931, Ohio Revised Code, a party may petition an agency to restate a policy in a rule. In June 2019, the State Medical Board of Ohio considered a request from a podiatrist as to whether five specific procedures were within the scope of practice of a podiatrist. The Board determined that four of the five procedures were within the scope of practice of a podiatrist. After the Board issued its determination on this issue, concerns were raised with respect to two of the specific procedures that were determined to be within the podiatric scope of practice:

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Please provide any comments and supporting material that you would like the Medical Board to consider in drafting rules related to the above-listed specific procedures and whether they are within the scope of practice of a podiatrist.

Comments on the proposed rules must be received by August 19, 2021. Please provide comments to: Kimberly.Anderson@med.ohio.gov.
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I believe the Podiatrist should have to provide proof of previous training in residency in such procedures. Some Podiatric residencies do more ankle work than others. They should have hands on training prior to attempting those procedures.

Dr. Kane DPM

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I am against further expansion of podiatrist scope of practice as they are not well trained surgically and are unable to deal with neurovascular complications that can occur.

Dr. Rashid Khalil

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It is not permissible for a podiatrist to perform either procedure detailed in the email below.

Thank you,
Dr Payson

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Podiatrist have limited training in surgery. Operating outside the foot is not appropriate unless they have been trained. Complications that arise from these additional operations will need other specialists to treat. These cases should be referred to orthopedic surgeons with foot/ankle fellowship. A podiatrist is not a medical doctor. No for me. Dr Rigano

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Without a fellowship involving advanced, extended (not a 2 or 3 week course) of surgery above the talus, this is a BAD idea, and I would NOT grant thee privileges.
Duret S. Smith MD

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The State Medical Board of Ohio is seeking public comments on podiatric scope of practice to assist with its rule-making process.

Comments due by 8/19/21

Podiatric Scope of Practice

med.ohio.gov/COVID-19

[External Content] This message is from an external source. Please exercise caution when opening attachments or links.

From: Eric Cwynar
To: Contact@med.ohio.gov
Subject: FW: [EXTERNAL] Podiatric scope of practice - your input is requested
Date: Tuesday, July 27, 2021 8:56:43 AM

Yes it should be permissible with the proper training.

From: Eric Cwynar
To: Contact@med.ohio.gov
Subject: Re: [EXTERNAL] Podiatric scope of practice - your input is requested
Date: Monday, July 26, 2021 3:53 PM
with respect to two of the specific procedures that were determined to be within the podiatric scope of practice:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

In May 2021, the State Medical Board appeared before the Joint Commission on Agency Rule Review (“JCARR”) for consideration as to whether the policy determination should be specified in a rule. Prior to receiving the determination from JCARR, the State Medical Board of Ohio decided to commence the rule-making process on this issue. Given the differences from the affected parties, the Board has decided to first solicit comments from interested parties to inform the rule-making process.

These links provide copies of the Medical Board rules related to podiatric scope of practice (4731-20-01 and 4731-20-02) and the June 2019 communication regarding the specific procedures.

Please provide any comments and supporting material that you would like the Medical Board to consider in drafting rules related to the above-listed specific procedures and whether they are within the scope of practice of a podiatrist.

Comments on the proposed rules must be received by August 19, 2021. Please provide comments to: Kimberly.Anderson@med.ohio.gov.
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Dr. Kubitz-

Thank you for your question. Attached is the Medical Board’s original communication on this issue. The additional allowed procedures dealt with ingrown nails and wart removal on hands.

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
o: 614-466-7207
c: 614-230-9077
Kimberly.Anderson@med.ohio.gov

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From: Geno Kubitz <drfootball@hotmail.com>
Sent: Monday, July 26, 2021 12:32 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: DPM scope

Hello, Can you please share with us the other two approved procedures that were granted to that DPM, though were not included in the topic of this email?

Thanks!
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No, I am not in favor of podiatrists doing supramalleolar surgeries. These should be performed by orthopedic specialists. Orthopedists have more general knowledge of medicine and will be able to recognize complications etc.

I do not favor podiatrists doing bone marrow biopsy either. This specialized procedure should be left to practitioners who hold M.D or D.O degrees with training in the procedure.

Felicitas Juguilon MD

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Kimberly,

Here is my opinion to the 2 questions -

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?

   In my opinion supramalleolar osteotomy should be in the scope of a podiatrist who is trained to perform these procedures. Meaning, the osteotomy is associated with the foot and ankle because it can assist in correcting deformity at that level. At the end of the day, if a podiatrist is well trained at performing these procedures, they should be allowed. It’s no different than an orthopedic surgeon who’s specialty is total joint replacements fixing an ankle fracture. If a total joint specialist is comfortable fixing ankle fracture it should be in their scope to do so but if they are not comfortable doing it, they should not be doing it.

2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia.

   Same answer as above, if a podiatrist is comfortable performing this procedure they should be allowed. All they are doing is harvesting biologic material, they are not making any cuts in the bone or placing hardware in the extremity. I don’t think of this much different than starting an IV line. Yes, it’s more invasive but it’s also not a complicated procedure to do.

Gage Caudell, DPM FACFAS

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Dear Ohio Board,

For protection of the health of Ohio citizens, and in the interest of reducing unnecessary health care costs, Podiatry’s scope of practice should not be expanded. In many Ohio counties, including those in Northeast Ohio where I reside, podiatrists outnumber orthopedic surgeons and podiatrists are almost as numerous as board certified primary care internal medicine medical doctors. It follows that an over-abundance of surgical providers will seek to expand their scope of practice.

The technical ability may be an issue, but that is not the chief reason I object to expanding podiatric privileges. I have observed a disturbing pattern of failure to follow evidence-based guidelines, with an excess number of invasive surgical procedures by podiatrists in my 38 years on practice in primary care in the Mahoning Valley.

Expanding the scope of practice to include procedures for which there is no shortage of qualified medical doctors to perform these same tasks would be detrimental to both quality of care Ohioans receive and to the cost of health care.

Expansion of the scope of billable podiatric procedures would be a grave mistake. There is no unmet need, and I can predict that unnecessary, and detrimental surgical procedures will result.

Gary R Gibson, MD, FACP

Clinical Assistant Professor of Medicine - NEOMED
IM Clerkship Director and Core Faculty - Western Reserve Health Education
Diplomate ABIM Internal Medicine

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July 30, 2021

Ms. Kimberly Anderson, Esq.
State Medical Board of Ohio
30 East Broad Street, 3rd Floor (submitted electronically to: Kimberly.Anderson@med.ohio.gov)
Columbus, OH 43215

Re: Rules - Podiatric Scope of Practice

Dear Ms. Anderson:

I have been on Staff as a Podiatric Surgeon within the Department of Orthopaedic Surgery at the Cleveland Clinic for twenty four years, and I have been Head of Podiatry for the past seven years. When I first started within the Orthopaedic department, the Cleveland Clinic did not allow the full privileges which the state licensed me to perform based on my surgical training. For instance, I did not have first ray privileges in 1996. However, with persistence and proof of competency, coupled with what I was already licensed to do, I gained such privileges.

With more thoughtful institutional consideration over time, podiatrists have been granted full privileging based on the training earned as members of the Orthopaedic Rheumatologic Institute. A PSR-36 trained DPM today has the privileges that have recently been called into question in the state of Ohio. Revoking these existing privileges would be a disservice to our institution, our profession, and more importantly, our patients. It would function as willful blindness towards the core competencies the podiatric profession has worked to achieve over the past few decades, resulting in both lengthier and more advanced podiatric residencies and fellowships.

The State Medical Board has been judicious and fair in using its statutory, administrative, and regulatory authority to determine the scope of practice for podiatrists. The Board’s Licensure and Scope of Practice Committee and the full Board held lengthy discussions on this issue in June 2019 and unanimously agreed that the procedures in question are within the scope of practice for podiatrists. The Board, after substantial due diligence, reaffirmed its decision that a podiatrist’s performing a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia is, indeed, within that podiatrist’s scope of practice. And while a good number of podiatrists (and DOs and MDs) do not routinely perform this procedure, for those of us who do such revisions and major hindfoot surgery, to not be given similar surgical procedures as our DO and MD equivalents, would be wrong.
The vote to reconsider the Board's June 12, 2019 decision was 1 for and 10 against, with 1 abstention. The only vote for the motion to reconsider came from an orthopaedic surgeon who serves on the Board. At this time, I respectfully request the Board advance a rule that mirrors its established policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia. I thank you for your time and thoughtful consideration of this important topic.

Georgeanne Botek, DPM, FACFAS

Kind Regards,

Georgeanne Botek, DPM, FACFAS
Thank you for reaching out for comments. I can only answer from a 30,000 foot perspective since I do not work in podiatry or orthopedics. If the scope of practice already exists for a practitioner to perform a procedure then limiting the scope of practice or removing a particular procedure should only follow documented and systemic, widespread evidence of an entire discipline not meeting an established standard of care. If there are no widespread problems with quality then why change this scope of privilege. If this is an extension of practice into a new area then there is a warranted need for scrutiny. Otherwise this all sounds very politically driven and can be construed as restraint of trade. Other disciplines in medicine should be concerned. What areas may be removed for other practitioners next. Just my thoughts.

thank you.

---

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I am a plastic surgeon and I worked with podiatrist who do these procedures. I think they’re well qualified. Unfortunately you have a board member who is an orthopedic foot and ankle surgeon that has its own interest. I don’t think his interest should be supported by the board unless you can show me a high case number of bad outcomes that are higher than community standards.

Greg Holland, M.D.

Sent from my iPhone
Can a podiatrist admit to a hospital?

Dr Stover

Sent from my iPhone
Dear Ms. Anderson,

I only very recently became aware that the State Medical Board of Ohio is seeking comments regarding scope of practice and specifically:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

I believe I have a unique perspective to offer as a fellowship trained orthopedic traumatologist and joint reconstruction surgeon with over 25 years’ experience, who has worked intimately in a community with highly trained and competent podiatric surgeons.

I am also a program director of an orthopedic residency training program who has had the honor of having highly trained podiatric surgeons as part of our teaching faculty.

This has given me the perspective of the level of training and expertise an appropriately credentialed podiatric surgeon has to take care of many complex periarticular issues surrounding the foot and ankle. Appropriately credentialed podiatric surgeons are capable of and credentialed to reconstruct often one of the most difficult injuries I know of as an orthopedic surgeon, that being a tibial plafond fracture. Yet to say the at these surgeons are incapable of a controlled osteotomy in the same region is inappropriate. I would challenge the osteotomy is a much simpler procedure than reconstructing the tibial plafond, or even a complex trimalleolar ankle fracture, yet a controlled osteotomy can be the key element in successful ankle reconstructive surgery. I fail to see any reason for limiting osteotomy from an appropriately trained and credentialed podiatric surgeon’s scope of practice.

While expensive bone substitute have certainly become the norm in augmenting bone healing, autologous graft is often still necessary particularly in difficult reconstruction cases. Aspiration from the subcutaneous border of the proximal tibia is no different than a CODE BLUE resuscitation team starting an intraosseous intravenous access line. If appropriately credentialed, there is no reason this simple and safe procedure should be excluded from a podiatric surgeon scope of practice.

Ultimately, the last line of credentialing comes down to the institutional level of each individual facility.
I can confidently say that based on my experience and training along with reviewing credentials, proctoring and direct practice observation of the appropriately trained, Board certified and credentialed podiatric surgeons, my answer to the above questions is a resounding YES!

Thank you for the opportunity to express my opinions. Please do not hesitate to contact me directly should you wish further information or discussion.

Sincerely,

Gregory Vrabec, MD, FRCS, FAOA
From: guang li
To: Anderson, Kimberly
Subject: That's not good idea to allow pad.to do more than allowed ops.
Date: Monday, July 26, 2021 6:13:20 PM

Sent from my iPhone

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Competence probably varies with the podiatrist who certainly should use judgement but both procedures seem high in the extremity to be podiatry rather than orthopedics.

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Dr. Alexander,

Thank you for taking the time to comment on this issue.

Best Wishes,

This information should not be considered as an legal advice or as an advisory opinion. Neither is given by this agency. For legal advice specific to your situation please contact the legal counsel at your organization or private legal counsel.

-----Original Message-----
From: Ian Alexander <alexandi22@gmail.com>
Sent: Sunday, July 25, 2021 11:31 AM
To: Contact <Contact@med.ohio.gov>
Subject: Regarding pediatric scope of practice

This is in response to a request for comment on the extension scope of practice for podiatric surgeons to include supramalleolar osteotomy and harvest by aspiration bone marrow from the proximal tibia.

It is clear that supramalleolar osteotomy is not an ankle procedure and beyond the scope of practice and training of podiatrists. If the board continues to expand the scope of podiatrist practice before long they will be fixing tibial shaft fractures and doing total knee replacements. Over the years I have dealt with many complications due to podiatric procedures performed as a result of expansion of their scope of practice. Often the complications were a result of the procedures being performed for the wrong indications or poorly technically. Expanding the scope of practice to include supramalleolar osteotomy, which is very rarely indicated, is just asking for more patients to be harmed by inappropriate or technically inadequate surgery. I am strongly against the expansion of podiatric scope of practice to include supramalleolar osteotomy.

With regards to aspiration of the proximal tibia for bone marrow, I have never heard of this, and for good reason. Aspiration of bone marrow is performed to harvest progenitor cells. Whereas these cells are plentiful in the iliac crest based on scientific studies they are much less in number in the proximal tibia therefore calling in question why to request the right to aspirate from the proximal tibia.

Ian Alexander MD

Sent from my iPhone

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Hello,

Podiatrists within Ohio should have access to perform supramalleolar osteotomies of the tibia and fibula to correct deformities and be able to harvest bone marrow aspirate from the proximal tibia for foot and ankle surgery. These procedures have been performed for decades by the podiatrists within Ohio, and there are even podiatrists that have written technique papers regarding the procedures that are utilized by both podiatric and orthopedic surgeons. Not every podiatrist in the state is performing these cases, however, and the granting of these privileges comes after the confirmation of specific training and proficiency in the procedures. Not every podiatrist within the state is requesting these privileges and they must be board qualified or certified to apply for the privileges. These procedures are utilized to correct foot and ankle deformities caused by various reasons. Many of the podiatrists within Ohio that are credentialed to perform these procedures are referred patients by their orthopedic colleagues within the community. We as podiatrists are experts of the foot and ankle and have 4 concentrated years of podiatric medical school and 3 years of foot and ankle specific surgical training. Our orthopedic colleagues that are permitted to perform these cases often have limited training experience in many foot and ankle problems and procedures that podiatrists perform, while we have 3 years of concentrated foot and ankle surgery.

In closing, it is permissible for podiatrists to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and to harvest bone marrow aspirate from the proximal tibia. The individuals credentialed to perform these cases are highly trained, specialized and have certification in these procedures. Non-certified individuals are not given the opportunity to perform these cases. There are specific members within the orthopedic community in Columbus that continue to have a personal vendetta against the profession of podiatry, which is widely known. This individual and his interest groups continue to try to limit our scope of practice. I feel that once you again review the material you will see his self-serving interests and that this is not outside our scope of practice.

I appreciate your time and consideration,

--

Ian Barron, DPM, FACFAS
Foot and Reconstructive Rearfoot/Ankle Surgery
Podiatry Division Chief Doctors Hospital, Columbus, OH
Doctors Hospital Site Coordinator for Grant Medical Center Podiatry Residency
Assistant Director of Research for the Foot and Ankle Surgery Residency Program Grant Medical Center

Clintonville Foot & Ankle Group a Division of Orthopedic Foot & Ankle Center (OFAC)
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I am opposed in theory to marrow aspiration of "non-foot" bones and would recommend the practitioner consider using cadaveric graft.

Regarding fingernail and wart removal of the hand, I have been a practicing Plastic Surgeon for nearly 30 years. In rural and suburban Ohio (not Hollywood) my practice entails 40% hand surgery. Long ago my professors were fond of saying "a foot is not a hand twisted sideways". Woe to the surgeon and patient who elects to proceed in violation of that statement.

James R Shope, MD, FACS, ACHE, SCCM
Board Certified Plastic Surgeon (1998-2028)

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July 6, 2021

The Honorable Betty Montgomery, Esq.
President
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus OH 43215

Re: Ohio Scope of Practice Law for Podiatric Physicians and Surgeons

Dear Ms. Montgomery,

On behalf of the American Podiatric Medical Association (APMA), I appreciate the opportunity to provide comments to the State Medical Board of Ohio (Medical Board) in response to proposed rulemaking related to the podiatric scope of practice. APMA is the premier professional organization representing a vast majority of the estimated 15,000 licensed doctors of podiatric medicine, also known as podiatrists or podiatric physicians and surgeons. Within APMA’s umbrella of organizations are 53 component societies in states, including Ohio, and other jurisdictions, as well as over 10 affiliated and related organizations.

At issue are two questions that have been previously addressed by the Medical Board.

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

The Medical Board reviewed these questions on June 12, 2019 and on September 11, 2019 and during both meetings, the Medical Board determined that these procedures are consistent with the podiatric scope of practice law for podiatrists.

The Ohio podiatric practice statute states, in relevant part, that the “Medical, mechanical, and surgical treatment of the foot; the muscles and tendons of the leg governing the functions of the foot; and superficial lesions of the hand other than those associated with trauma. Podiatrists are permitted the use of such preparations, medicines, and drugs as may be necessary for the treatment of such ailments.”

The Medical Board, through its authority given by the Ohio Legislature, promulgated rules effectuating the podiatric scope of practice by defining the foot “as used in section 4731.51 of the Revised Code, means the terminal appendage of the lower extremity and includes the ankle joint which consists of the tibial plafond, the posterolateral border (posterior malleolus), the medial malleolus, distal fibula (lateral malleolus) and the talus.”

APMA reaffirms its support for the Medical Board’s prior decisions. While APMA is pleased to submit comments, it is APMA’s position that the Medical Board used its authority appropriately to set policy

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based on a reasonable reading of the podiatric scope of practice statute and regulations. The Medical Board must now reaffirm its decision through rulemaking.

**Podiatric Physicians and Surgeons Authority to Perform Supramalleolar Osteotomy of the Tibia or Fibula to Correct a Deformity**

Podiatrists have the education, training, and experience to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity. APMA supports the determination of the Medical Board communicated in its June 12, 2019 letter to Daniel Logan, DPM, that the procedure is within the podiatric scope of practice in Ohio as the Medical Board determined the “tibial plafond forms the articular surface of the distal tibia. The distal tibia and fibular act as the socket for the talus. Accordingly, a supramalleolar osteotomy of the tibia or fibula constitutes ankle surgery.”

In Ohio, podiatrists are allowed to treat conditions affecting the ankle joint. An example condition is ankle arthritis. The most common cause of end-stage ankle arthritis is posttraumatic in nature. After a traumatic injury/event, or in some cases, a congenital deformity, the ankle joint or hindfoot may be misaligned, putting additional stress and strain on only a portion of the ankle joint cartilage. Over time, the wear pattern of a previously injured ankle joint changes due to malalignment and can lead to ankle arthritis. A supramalleolar osteotomy of the tibia and fibula is a joint-sparing surgical procedure that is used to treat the positional deformity of the ankle joint to improve intraarticular load distribution, and hopefully, slow degeneration of the ankle joint. This procedure is a mechanism to treat the ankle or hindfoot deformity that is within podiatric scope of practice and manage the progression of ankle arthritis. Supramalleolar osteotomies have been shown to delay ankle arthrodesis (fusion) or total joint replacement and in some cases, be performed to line up bony segments so an ankle replacement can be performed.

Similarly, podiatrists often perform procedures that may go beyond a prescribed anatomical demarcation to treat ailments of the foot, including the ankle joint. For example, to continue with the example above of treating the condition of ankle arthritis, podiatrists are performing total ankle replacements, some of which require a portion of the implant hardware to extend into the medullary canal of the tibia and tibio-talo-calcaneal fusions with retrograde nailing into the tibia to treat ankle and hindfoot arthritis. Podiatrists are surgically treating pilon, and other ankle fractures, which may require surgical exploration, alignment, and fixation extending proximal to the ankle joint. Podiatrists are also performing complex Charcot Neuroarthropathy reconstructions with external fixation frames to reposition a misaligned foot or ankle, and/or to heal Charcot-related plantar ulcerations in an attempt to preserve an at-risk lower extremity. These are all examples of how podiatrists are surgical treating conditions of the ankle.

**Podiatric Physicians and Surgeons Authority to Harvest Bone Marrow Aspirate From the Proximal Tibia**

Here again, APMA supports the Medical Board’s determination that “harvesting bone marrow aspirate from the proximal tibia to be used for foot and ankle surgery is within the scope of practice of an appropriate trained podiatric physician.” APMA also supports the rationale provided by the Medical Board, that “the expertise and skills needed to aspirate bone marrow are not dependent upon the donor site because the same skills and principles must be applied whether the site is on the foot or proximal tibia.” This determination is consistent with the podiatric scope of practice statute and the Medical Board regulations as the purpose of harvesting bone marrow aspirate is to treat ailments of the foot, including the ankle joint.
Similarly, podiatrists may take blood from the arm of a patient to obtain lab studies that will assist in the diagnosis and treatment of foot and ankle pathology, prepare a patient pre-operatively, or to spin down to create platelet rich plasma to treat a foot or ankle condition.

**Ensuring Patient Access**

APMA urges the board to take patient access to care into consideration. If podiatric physicians and surgeons are not allowed to perform procedures to treat conditions of the foot and ankle that they were educated and trained to perform, patients experiencing foot and ankle ailments will likely need to wait extended periods of time to see another appropriately qualified surgical physician. As the American Orthopaedic Foot & Ankle Society (AOFAS) mentioned in a June 27, 2019 letter to the State Medical Board of Ohio, there were only 43 AOFAS members licensed in the State of Ohio. Patients experiencing symptomatic ankle arthritis, ankle fractures, and diabetic foot complications, as examples, should be able to easily access care by physicians and surgeons, including doctors of podiatric medicine, trained to treat such conditions. If these conditions are not cared for in an appropriate and timely manner, patients may experience reduced quality of life, limitations to daily activities, loss of productivity, and, in the worst cases, lower extremity amputation.

**Podiatric Physicians and Surgeons Have the Education, Training, and Experience Comparable to their Allopathic and Osteopathic Colleagues**

As the Ohio scope of practice for podiatrists recognizes, podiatrists are qualified by their education, training, and experience to diagnose and treat conditions affecting the foot, ankle, and related structures of the lower leg, and doctors of podiatric medicine receive basic and clinical science education and training comparable to that of medical doctors:

- Four years of undergraduate education focusing on life sciences;
- Four years of graduate study in one of the nine accredited podiatric medical colleges; and,
- At least three years of postgraduate, hospital–based surgical residency training.

Podiatric medical college is a four-year program with the first two years focused on the basic sciences and the second two years focused on clinical education. The first two years are devoted to classroom and lab instruction in basic sciences including, but not limited to, anatomy, physiology, pathology, microbiology, biochemistry, and pharmacology. In addition to the general anatomy course, that is often attended alongside allopathic or osteopathic medical students, podiatric medical students take an additional course focusing solely on lower extremity anatomy. This course includes in depth education and lab dissection specific to the entire lower extremity, from the pelvis to the toes. During the third and fourth years, students engage in clinical education based in accredited hospitals, clinics, and private practice settings. During these third- and fourth-year rotations, students are afforded intense medical and surgical training related to the lower extremity, and they learn how to take patient histories, perform routine physical examinations, interpret diagnostic tests and findings, and make differential diagnoses.

During residency, podiatrists receive advanced training in podiatric medicine and surgery and participate in required clinical rotations in medical imaging, pathology, behavioral sciences, internal medicine and/or family practice, medical subspecialties, infectious disease, general surgery, surgical subspecialties,
anesthesiology, and emergency medicine. Throughout residency training, emphasis is placed on diagnosing and managing patients.

Privileging and Credentialing for Podiatric Physicians and Surgeons

As mentioned by the State Medical Board of Ohio in its response letter to Daniel Logan, DPM dated June 12, 2019, it expresses that whether a podiatrist may perform certain surgical procedures at a specific hospital or other surgical facility is solely a matter of credentialing and privileging decisions. Individual facilities grant privileges to providers. Podiatrists will receive the privilege of performing certain procedures based on their education, training, and experience. Like all physicians and surgeons, podiatrists without the necessary education, training, and experience would not receive the privileges to perform the procedures in question.

Furthermore, APMA believes that scope of practice should operate as a ceiling, not a floor. The scope of practice should never be the lowest common denominator for a medical profession or specialty; rather, it should represent the maximum level to which a medical professional can provide patient care. The degree to which podiatrists practice their specialty must be demonstrated by the individual’s requisite education, training, and experience. Just as allopathic and osteopathic doctors exercise medical and ethical judgment about their practices, doctors of podiatric medicine are required to do the same.

For almost 25 years, podiatrists have been permitted by Ohio law to treat and perform procedures of the foot, ankle, and tendons and muscles that govern the leg. We urge the Medical Board to continue to recognize the education, training, and experience of doctors of podiatric medicine and reaffirm its decision to permit podiatrists to perform supramalleolar osteotomy of the tibia or fibula to correct a deformity and to harvest bone marrow aspirate from the proximal tibia.

We thank you for the opportunity to provide comments. We are available to provide additional information, and please do not hesitate to reach out to APMA’s CEO and Executive Director James R. Christina, DPM at (301) 581-9200 or jrchristina@apma.org if we can be of further assistance.

Sincerely,

Jeffrey R. DeSantis, DPM
President
We require both Orthopedists and Podiatrists to show expertise in complex foot procedures in Children i.e. a fellowship for Orthopedists or proof of training/ or a 6 months of Pediatric Foot Rotation for our podiatrists (an alternative is a 2 year practice case list to review). I believe the same is true for Adult Total Joints ie a fellowship or 6 months residency training.

I am with Norton Childrens Hospital Louisville, Ky

Dr. Dimar

John R. Dimar II, MD
Clinical Professor of Orthopedic Surgery
University of Louisville
Norton Leatherman Spine Center
Chief of Pediatric Orthopedics Norton Childrens Hospital
Louisville, Kentucky

-----Original Message-----
From: Kimberly.Anderson@med.ohio.gov <Kimberly.Anderson@med.ohio.gov>
To: JOHN DIMAR II <jdimar2@aol.com>
Sent: Mon, Jul 26, 2021 12:28 pm
Subject: RE: Podiatrist Privileges

Dr. Dimar,

Which Children's Hospital are you with? We may have some follow-up questions about the credentialing process. Thank you.

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
o: 614-466-7207
c: 614-230-9077
Kimberly.Anderson@med.ohio.gov

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Kimberly

I agree these should be limited along with Total Joint Arthroplasties and all complex pediatric complex foot reconstructions for which they have inadequate training.

I can say this with certainty because I routinely credential them at our Children’s Hospital and review their training and case lists, only a few have this type of extra training.

Dr. John Dimar
Chief of Pediatric Orthopedics

Sent from my iPhone
Kimberly

I agree these should be limited along with Total Joint Arthroplasties and all complex pediatric complex foot reconstructions for which they have inadequate training.

I can say this with certainty because I routinely credential them at our Children’s Hospital and review their training and case lists, only a few have this type of extra training.

Dr. John Dimar
Chief of Pediatric Orthopedics

Sent from my iPhone

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Both of those procedures seem to be beyond the training of all but residency trained/board certified orthopedic surgeons. Of concern, as always in these requests to expand scope of practice, is the practitioner qualified to recognize and care for possible complications?

--

Thanks.

Please use jbgillen@gmail.com as my primary email address. Thank you.

John Gillen
513-2471720
513-236-3810 cell (preferred)

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Dear Ms. Anderson,

I am in receipt of the email sent from the State Medical Board of Ohio seeking comments regarding scope of practice and specifically:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

I feel that I am qualified to offer my opinion regarding the questions posed above. I have practiced as a Podiatric foot and ankle surgeon in the state of Ohio since 1999. I am board certified by the American Board of Foot and Ankle Surgeons in Foot and Reconstructive Rearfoot and Ankle Surgery. I completed a three-year residency program in Pittsburgh, PA and two fellowships. I have practiced as a foot ankle surgeon in the Department of Orthopedic Surgery at Cleveland Clinic Akron General for over 20 years. During this time I have had the opportunity to train both Orthopedic and Podiatric residents. I am a Past President of the American College of Foot and Ankle Surgeons, Past Scientific Chairman for the American College of Foot & Ankle Surgeons, Past residency director for St. Vincent Charity Hospitals Foot & Ankle Surgical Residency, Chief of Podiatry at Cleveland Clinic Akron General and Adjunct Clinical Faculty at the Kent State University College of Podiatric Medicine.

The answer to the above questions is quite simply, YES.

After reviewing the Scope of Practice verbiage and definition of “foot” by the OSMB, I’m confused as why this is even being questioned given the recent (June 2019) approval of these specific procedures. What has changed in the last 2 years?

Even in the description under Supramalleolar osteotomy, the OSMB clearly and accurately state “a supramalleolar osteotomy of the tibia or fibula constitutes ankle surgery, as defined in Rule 4731-20-02, OAC, and is within the podiatric scope of practice of an appropriately trained podiatric physician when performed in compliance with Rule 4731-20-02, OAC, and within the minimal standards of care. Finally, whether a podiatrist may perform the surgeries at a specific hospital or ambulatory surgical center is solely a matter of credentialing and privileging decision.”

With regards to Bone marrow aspirate from the proximal tibia, the OSMB clearly and accurately state the OSMB clearly and accurately state, “Accordingly, harvesting bone marrow aspirate from the proximal tibia to be used for foot and ankle surgery is within the podiatric scope of practice of an
appropriately trained podiatric physician. The podiatric physician must perform the surgery in conformance with the minimal standards of care of similar practitioners under the same or similar circumstances. Finally, whether a podiatrist may perform the surgeries at a specific hospital or ambulatory surgical center is solely a matter of credentialing and privileging decision.”

So, these procedures have already been reviewed and vetted by the OSMB and then concisely stated that these procedures are within the scope of practice by the Ohio revised code and that whether a podiatric physician can perform these procedures is SOLEY A MATTER OF HOSPITAL’S CREDENTIALING AND PRIVILEGING. I’ll ask again, What has changed since June of 2019 such that these procedures are now being disputed??

I think we can all agree that they’re a various levels of skill set in all professions. Some are simply more talented than others in any given occupation. With that being, not all podiatric physicians practicing in Ohio will request these privileges and all podiatric physicians practicing in Ohio should not be granted privileges to perform supramalleolar osteotomies and BMA harvesting from the proximal tibia. However, these procedures are certainly within the Ohio DPM scope of practice and should be determined by the training and board certification of each individual podiatric practitioner and the hospital’s credentialing where they are performing these surgeries.

I appreciate the opportunity to express my opinion regarding this matter. Please feel free to contact me if I can provide any additional information on this matter.

Best regards,

Jordan P. Grossman, DPM, FACFAS
Fellowship Trained Foot and Ankle Surgeon
Board Certified, Reconstructive Foot and Ankle Surgery
Past President, American College of Foot and Ankle Surgeons

Cleveland Clinic Akron General
Akron General Orthopedics
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 Akron, Ohio 44302
Office: 330-344-1980
Fax: 300-344-6038
Email: j.grossman@mac.com
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July 6, 2021

Ms. Betty Montgomery, JD
President
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Montgomery,

On behalf of the over 600 podiatric physicians and surgeons who compose the Ohio Foot and Ankle Medical Association (OHFAMA), thank you for the opportunity to submit comments on the scope of practice for podiatrists.

OHFAMA has always considered the State Medical Board of Ohio to be a valuable partner in protecting the safety of patients we are honored to serve in Ohio. Throughout the years, the Board has been judicious and fair in using the statutory, administrative, and regulatory authority granted to it by the Ohio General Assembly to determine the scope of practice for podiatrists.

Our organization strongly supports the Board’s unanimous June 2019 vote that confirmed it is within the scope of practice for qualified podiatric physicians and surgeons to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia.

It is clear the Board acted within its granted statutory authority when it issued guidance via a Policy Statement in response to a routine inquiry from an Ohio podiatrist, just as the Board had previously provided scope of practice guidance to podiatric physicians and surgeons on procedures ranging from the use and placement of external fixation apparatus to punch or shave biopsies of lesions on the lower leg or hand.

While our members do not feel filing an administrative rule is necessary, OHFAMA understands the Board’s recent decision to promulgate a rule to affirm a policy that was thoroughly discussed at the Licensure and Scope of Practice Committee and three Board meetings.

OHFAMA respectfully requests the Board advance a rule that mirrors its established policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia.

**Podiatric Education and Training**

Doctors of Podiatric Medicine receive medical education and training comparable to our allopathic and osteopathic colleagues, including four years of undergraduate education, four years of graduate education at one of nine accredited podiatric medical colleges, and three years of hospital-based residency training.

During residency, podiatrists receive advanced training in podiatric medicine and surgery and serve clinical rotations in medical imaging, pathology, internal medicine and/or family practice, medical subspecialties, infectious disease, general surgery, surgical subspecialties, anesthesiology, and emergency medicine.
Throughout the course of their training, podiatric residents have substantial involvement in more than 1,000 foot and ankle surgical procedures performed on more than 600 patients. All residency programs, which are accredited by the Council of Podiatric Medical Education (CPME), provide training resources that facilitate the resident’s sequential and progressive achievement of demonstrated competency in general medical and surgical management.

Following completion of a CPME-approved residency program, many podiatric physicians and surgeons seek Board Qualification in Foot Surgery or Reconstructive Rearfoot/Ankle Surgery from the American Board of Foot and Ankle Surgery (ABFAS). Board Qualified status, which involves extensive didactic and clinical testing, indicates a demonstrated level of capability in the diagnosis of general medical problems, including the diagnosis and surgical management of pathologic foot and ankle conditions, deformities, and/or trauma and of structures that affect the foot, ankle, and leg.

Ohio podiatric physicians must also complete a total of 50 hours Category 1 CME every two years to be eligible for license renewal.

Ohio Code Relating to Podiatric Physicians and Surgeons
Ohio Revised Code (ORC) and Ohio Administrative Code (OAC) have long recognized podiatric physicians and surgeons are uniquely qualified among medical professionals to diagnose and treat the foot, ankle, and related structures in the lower leg due to the depth and breadth of their education and training.

Section 4731 of ORC defines the practice of podiatric medicine and surgery as consisting of the “medical, mechanical, and surgical treatment of ailments of the foot, the muscles and tendons of the leg governing the functions of the foot; and superficial lesions of the hand other than those associated with trauma.”

The Board, using rulemaking authority granted to it by the Ohio General Assembly, created a rule to define the foot as the “terminal appendage of the lower extremity and includes the ankle joint which consists of the tibial plafond, its posterolateral border (posterior malleolus), the medial malleolus, distal fibula (lateral malleolus) and the talus.”

The Board further promulgated a 1997 rule that formally authorized qualified podiatric physicians and surgeons to perform surgery on the ankle joint provided they hold privileges to perform surgery from a hospital, ambulatory surgical center, or podiatric medical college.

This rule also requires a podiatric physician to complete a CPME-approved residency, attain Board Qualified status from ABFAS, and “demonstrate adequate education, training and experience needed to conform to minimal standards of care of similar practitioners.”

Credentialing and Privileging of Podiatric Physicians and Surgeons
As with our allopathic and osteopathic colleagues, the decision whether a podiatrist may perform certain procedures at a hospital or ambulatory surgical center is subject to a robust credentialing and privileging determinations at each facility.

This process is designed to ensure that every practitioner possesses the necessary skill and expertise to provide quality patient care. This process includes multiple layers and typically requires approval from a department chair, credentials committee, medical executive committee, legal counsel, and hospital administration.

The credentialing and privileging process, which routinely involves input from our allopathic and osteopathic colleagues, provides additional assurances to the public that podiatric physicians and surgeons are only authorized to perform services for which their education, training, and experience have qualified them.
Supramalleolar Osteotomies and Bone Marrow Aspirations
OHFAMA strongly supports the Board's assessment in its 2019 letter that “a supramalleolar osteotomy of the tibia or fibula constitutes ankle surgery, as defined in Rule 4731-20-02, OAC, and is within the podiatric scope of practice of an appropriately trained podiatric physician.”

A supramalleolar osteotomy is commonly performed to realign previous ankle fractures, ankle deformities or mal-aligned ankle fusions that affect the function of the foot and ankle. Since only a subset of podiatrists and orthopedists perform this procedure, it is crucial for the Board to continue to allow qualified practitioners to perform this procedure. Any change in policy would have an adverse impact on Ohioans who are experiencing quality-of-life challenges due to foot and ankle issues.

OHFAMA also agrees with the Board’s determination that “harvesting bone marrow aspirate from the proximal tibia to be used for foot and ankle surgery is within the scope of practice of an appropriate trained podiatric physician.” We support the Board’s commonsense position that “the expertise and skills needed to aspirate bone marrow are not dependent on the donor site because the same skills and principles must be applied whether the site is on the foot or proximal tibia.”

Bone marrow aspirate is used to help bone and soft tissue healing in a variety of foot and ankle procedures. It is a straightforward, sound method of enhancing healing in a variety of foot and ankle procedures, including Charcot reconstruction and ankle fusion.

Summary
In closing, podiatric physicians and surgeons have been permitted under Ohio law to treat and perform procedures of the foot, ankle, and tendons and muscles that govern the leg for decades.

The extensive education and training of podiatric physicians and surgeons – coupled with a robust privileging and credentialing process at hospitals and surgery centers – ensures that only qualified practitioners in Ohio are performing advanced foot and ankle procedures. To reinforce this point, there is no data we are aware of that any patient has been harmed by a podiatrist performing the procedures in question.

It is evident the Board acted within its statutory and regulatory authority when it unanimously determined it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia. We encourage the Board to formulate and advance a rule that mirrors its policy to ensure Ohioans requiring these procedures continue to have quality access to care.

Thank you again for the opportunity to share our perspective on an issue that impacts Ohio podiatric physicians and surgeons as well as the patients we serve. Please contact OHFAMA Executive Director Mike Mathy, CAE, at 614.457.6269 or via email at mmathy@ohfama.org should you have any questions.

Sincerely,

Kelly Whaley, DPM
President
Ohio State,

As a board certified Orthopedic foot and Ankle surgeon I’m very concerned with the approval. 
1. Supra-malleolar would allow DPMs to go nearly up to the knee. This is entirely out of their scope of practice. This level requires knowledge of the entire extremity and the impact on the knee and hip.
2. BMAC can be drawn from the Calcaneus no need to go proximal for the same reasons above.

Thanks
Dr Kevin Martin
--
Kevin D. Martin DO
Orthopedic Foot & Ankle Surgeon
Associate Professor
@drkevinmartin_ortho

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June 28, 2021

Kimberly Anderson  
Chief Legal Counsel  
Ohio State Medical Board  
30 E. Broad St., 30th Floor  
Columbus, OH 43215  

RE: Podiatry Scope of Practice

Dear Ms. Anderson:

Thank you for the opportunity to comment on podiatric scope of practice. The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), founded in 1824, is the region’s professional medical association, and the oldest professional association in Ohio. We are a non-profit 501(c)6 representing physicians and medical students from all the contiguous counties in Northern Ohio. We are proud to be the stewards of Cleveland’s medical community of the past, present and future.

The mission of the Academy of Medicine of Cleveland & Northern Ohio is to support physicians in being strong advocates for all patients and promote the practice of the highest quality of medicine.

In your communication, you asked for comments with respect to two specific procedures that were determined to be within the podiatric scope of practice:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?

2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

From our standpoint, we are comfortable with (2) being allowed within the scope of practice. This is a low-risk procedure and there may be no other reasonable location to obtain bone marrow aspirate. However, we are concerned with question (1). Supramalleolar osteotomy is a complex procedure that
requires careful planning and execution of the cut and the fixation. Additionally, this procedure essentially creates a tibia/fibula fracture, and fractures of the distal tibia and fibula are outside the scope of practice and training for podiatry.

Thank you again for the opportunity to provide comment.

Kristin Englund, MD, MLS
President, AMCNO
Correction, second paragraph, it should be 50 years! Not tears, sorry about it. Thank you Dr Singh

On Jul 26, 2021, at 6:21 PM, Kuldeep Singh <drsinghmd@yahoo.com> wrote:

GOOD AFTERNOON
Thank you for asking regarding the input of these complex ankle and leg procedures. First of all please allow me to introduce my self so that my opinion may have meaningful weight and help you to decide what is good for all parties concerned especially the patient, Podiatrists, Orthopedic Surgeons. My opinion will be unbiased because I am neither Podiatrist or a Orthopedic Surgeon. The Board has to ultimately decide to grant the permission to perform these procedures.

My name is Kuldeep Singh, MD from Cleveland Ohio. I have been living in Cleveland over 50 tears, at present time I am not working due to Co-vid 19 risk for my age group. I am Board Certified and Recertified General Surgeon, I did private practice in Surgery from 1976 to 2003 and then switched to Emergency Medicine in Cleveland Clinic and University Hospital Facilities. I have served as Director of Surgery and Chief of Surgery in the past at Deaconess Hospital of Cleveland Ohio, I have been involved in Podiatric Privileges issues at that time, I have Published 5 papers in the World literature, I was a Fellow of American College of Surgeons, International College of Surgeons and American College of Emergency Physicians.

My understanding of Podiatric Specialty is “ Surgery involving the Foot or any joint or ligament is a part of foot but not above the Ankle/Foot Joint. Bone aspiration from Proximal Tibia is definitely NOT PART OF FOOT and hence should not be an issue to decide.

To perform Supra malleolar osteotomy is again is not a part of FOOT, it is a part of Lower Leg and hence is a Grey Zone, but to perform osteotomy to correct deformity is a very complex procedure especially in Pediatric group which can be devastating if not done right.
Thank you, hope this information may of some help.
Kind regards
Kuldeep Singh, MD

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I believe that is above the ankle joint. & is really an orthopedic case. Foot & Ankle means something. Thumbs down.

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July 2, 2021

Betty Montgomery, JD
Acting President
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, Ohio 43215

Dear Ms. Montgomery, Members of the State Medical Board of Ohio, and Members of the Joint Committee for Agency Rule Review,

This letter is in support of the 2019 Board's scope of practice for Podiatric Surgeons in the State of Ohio relative to the surgical procedures consisting of supra malleolar osteotomies and harvesting of bone marrow aspiration from the tibia. These procedures are often necessary to treat many foot and ankle conditions. These procedures have been performed by many providers for many years. Specifically, Podiatric Surgeons have also been actively performing these procedures for many years. In some instances, certain conditions of the foot and ankle cannot be corrected appropriately without access to these procedures.

In order for any surgeon of any medical background to obtain these privileges for these specific procedures, the surgeon MUST demonstrate adequate education and training. Appropriate education and training is accomplished with graduation from an accredited Podiatric Medical School, or a Medical or Osteopathic School. Furthermore, a surgeon must graduate from an accredited residency training program, and/or fellowship program followed by passing surgical boards demonstrating competency, and finally demonstrating proficiency at the local hospital. This is approved at the local level based on a surgeon's surgical case experience and their outcomes. This is typically measured every two (2) years by most hospitals. Moreover, the Podiatric Surgeon must maintain his/her board certification every ten (10) years.

Typically, during a residency and fellowship training program, there are several attending doctors from various fields of medicine and surgery who provide evaluations of the Resident/Fellow - most commonly this includes Podiatric Surgeons and Orthopedic Surgeons as it relates to bone marrow aspirate and supra malleolar osteotomies. These attending doctors work one-on-one with the individual as he/she goes through their respective training programs. At this time, the individual is evaluated based on his/her talent, education, training or lack of talent, education or training. The individual who is being trained is held to this high standard and either meets the standard of care or does not meet the standard of care relative to these procedures. Again, these evaluations are done based on personal observation from the attending doctor, which can be either or both Podiatric Surgeons and/or Orthopedic Surgeons who performs these procedures. Most training programs have both specialty fields involved in the surgical training of an individual who is being trained in both bone marrow aspirate and supra malleolar osteotomies.

The mission of NOMS Healthcare is to provide excellent, personalized, team-based care.
The field of Foot and Ankle Surgery is very similar to many other fields of medicine and surgery. For example, hand surgery. Orthopedic Surgeons, Plastic Surgeons and General Surgeons all who have focused and specific training on the hand, perform hand surgery. Similarly spine surgery, there are Neurosurgeons and Orthopedic Surgeons who have specific education and training as it relates to the spine. Additionally, Oral Maxillofacial Surgery is often performed by Dentist with this training or Plastic Surgery with this training and/or an Ear Nose and Throat Surgeon with this specific training. As one can see, it's common to have cross over in many fields. One could also understand how this crossover can initiate both political and economic competition.

Not all Podiatric Surgeons or Orthopedic Surgeons perform these procedures. Those who perform them have specific interest and specific education and training for these procedures.

The attempted obstruction of bone marrow aspirate and supra malleolar osteotomies for those current and future Podiatric Surgeons who perform these procedures is not based on any fact, but rather it is based on economics and politics and an attempt to restrict the trade by an economic competitor.

Please consider this letter to support Podiatric Surgeons based on individual merit consisting of education, training and experience and not for economic and politically charged reasons.

Thank you in advance for your consideration.

Very truly yours,

Lawrence A. DiDomenico, DPM, FACFAS
Director of Residency Training, East Liverpool City Hospital
Director of Fellowship Training, NOMS Ankle and Foot Care
Section Chief, St. Elizabeth Medical Center
Past Board of Directors, American College of Foot and Ankle Surgeons
Adjunct Professor, Kent State University College of Podiatric Medicine
June 22, 2021

OFAMF
1960 Bethel Rd.
Ste. 140
Columbus, Ohio 43220

To Whom It May Concern: State of Ohio Medical Board,

This is a letter of comment on the scope of practice for a Podiatric Surgeon to do Supramalleolar Osteotomy of the fibula or tibia and the act to harvest the bone from the proximal tibia.

I have been a Podiatric residency director at Aultman Alliance Community Hospital for over 26 years now. We have enjoyed the incredible increase in the training our young Podiatric residents and the scope of procedure they assist and perform with their attending physicians. Those physicians include both Podiatric and Orthopedic Surgeons.

I have seen the number of ankle trauma cases and reconstructive rearfoot cases improve every year. Many Orthopedic groups are now adding these residents to their groups. Each residency will have attendings who do both internal and external fixation of ankles and Charcot joint reconstruction. These procedures have been taught in other States with less restrictive rules on the leg for at least the last 25 or more years.

When these Podiatrists return to Ohio they continue with their ability to do these complex procedures. My residents are all exposed to these procedures almost weekly. The Podiatric surgical residencies are all now 3 years long and I feel the state of Ohio should allow these highly trained doctors of Podiatric medicine to perform these cases. Their local credentialing committees will determine if they can demonstrate experience in their training.

Please consider this letter as to my experience of training of many Podiatrists over many years of training. I highly recommend the allowance of these complex procedures for those who have been trained to do them.

Sincerely,

Dr. Leslie P. Niehaus, DPM, F.A.C.F.A.S.
Aultman Alliance Community Hospital Podiatric Residency Director
Ms. Anderson,

The Ohio State Medical Association (OSMA) appreciates the opportunity to comment on the rules and previous events related to the podiatric scope of practice in the state of Ohio.

As you are aware, the OSMA has expressed great concern over the board’s 2019 determination that certain podiatric surgical services were within a podiatrist’s scope of practice. The issue at hand deals with the opinion letter that the board approved and subsequently sent to Dr. Daniel Logan, an Ohio licensed podiatrist. The OSMA continues to assert that the medical board should not have clarified this complex scope issue through the issuance of a letter.

While the OSMA will not be addressing the clinical aspects of this issue, we are aware that several state and national medical associations representing orthopedic physicians have reached out to the board to provide valuable clinical information regarding the procedures in question. The OSMA urges the board to carefully review and consider the clinical information provided.

Many have argued that the surgical tasks in question are not within the statutorily-defined scope of an Ohio-licensed podiatrist. The OSMA is unclear as to how the medical board will settle this dispute through the regulatory process. Unless the medical board is able to reach a clear consensus from medical experts that these surgical procedures are either allowed or prohibited by existing Ohio law, it seems that the proper venue to settle an unclear or contested scope of practice issue is the Ohio legislature.
The board’s decision to open the rules for comment and possible amendments provide a clear indication that the board is not confident that they were within their clarifying authority when they responded to the podiatrist seeking clarification of the existing rules. For this reason, the OSMA strongly urges the medical board to retract the scope determination letter sent to Dr. Logan until there is a clear decision that these surgical procedures are within, or outside of, the scope of an Ohio-licensed podiatrist.

We thank you for your consideration of our comments. If you have any questions, please feel free to contact the OSMA’s Director of Regulatory Affairs, Jennifer Hayhurst, at 614-527-6766 or jhayhurst@osma.org

Sincerely,

Lisa Bohman Egbert, MD
President

C: Todd Baker, CEO, OSMA
OSMA Council
From: Lynette Gogol
To: Anderson, Kimberly
Subject: Podiatric Scope of Practice
Date: Friday, July 30, 2021 12:42:45 PM

Supramalleolar osteotomy and harvest of bone graft from prox tibia: I think it is within the scope of practice for podiatric foot and ankle surgeons to perform this procedure as long as the procedure is granted within the delineation of privileges at the surgical facility.

Lynette Gogol DO

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In essence, podiatrists who now describe themselves as foot and ankle surgeons train only in the foot and ankle. Both the supramalleolar osteotomy and BMA tibial harvesting take place proximal to their training area. Orthopedic surgeons who specialize in hand surgery do not operate on the spine DESPITE having been trained in this area during residency.
The podiatric training not only contains zero training in the tibia, it is vastly inadequate to properly discern who would and would not benefit from a supramalleolar osteotomy. This procedure has a VERY narrow indication window and can be fraught with complications in the healthiest of patients. It require precise understanding of lumbar spine, hip, knee, ankle and hindfoot alignment; obviously they are not trained in the majority of aforementioned areas. Podiatrists would undoubtedly attempt to expand these indications in patients who do not know any better, run into problems and then these problems would end up on the door step of orthopedic surgeons to attempt to salvage someone's limb.
I performed my orthopedic surgery residency in Ohio. Ohio has always done a good job of protecting patients from the overreach of podiatry. Please remeber to keep patients safe. It is a very slippery slope expanding abilities of podiatrists, it may start at a supramalleolar osteotomy...it ends with below knee amputation in young people do to poor medical decision making in podiatrists who are NOT trained to make them. Thank you for your time.

--
M. Pierce Ebaugh, DO
Fellow, Orthopaedic Surgery
University of Texas at Houston
Houston, TX
813-505-7610

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Dear Ms. Anderson,

I am in receipt of the email sent from the State Medical Board of Ohio seeking comments regarding scope of practice and specifically:

1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

As a point of reference, I am the Program Director for the Mercy Health-Bon Secours Foot & Ankle Residency, Assistant Dean for Clinical Education at the Kent State University College of Podiatric Medicine, Past Scientific Chairman for the American College of Foot & Ankle Surgeons, Editorial Board member for the Journal of Foot and Ankle Surgery and a Partner at Balance Foot and Ankle Wellness Center.

Based upon the education and training currently provided in Ohio at the levels of Podiatric Medical School, Residency and Continuing Medical Education, answers to the above seems easy - Yes. Those trained, licensed and board certified in the above procedures should be allowed to continue their trade. Podiatrists are currently allowed to treat supramalleolar fractures of the fibula and tibia; now, someone is objecting to performing an osteotomy at the same level? Podiatrists are allowed to apply external fixation which employs wires and pins throughout the tibia for fracture reduction and stabilization; now, someone is objecting to placing a smaller size needle (vs a pin/wire) to withdraw BMA?

Preventing access to the above procedures appears to be a restriction in trade for those podiatrists trained and skilled in performing. Allowance of the procedures will still come down to the hospitals credentialing, privileging and proctoring bylaws (as currently undertaken for total ankle replacements, ankle fusions, intramedullary nailings, etc) but I find it curious that these procedures are being disputed.

Thank you for allowing me the opportunity to express my opinion.

Best,
Mark

Mark A. Hardy, DPM, FACFAS
Balance Foot & Ankle Wellness Center
14200 Madison Avenue
Lakewood, Ohio 44107 USA
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O | +1.216.658.0111
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F | +1.216.658.0110
E | hardy@balanceCLE.com
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July 2, 2021

Ms. Kimberly Anderson, Esq.
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Rules: Podiatric Scope of Practice

Submitted electronically via: Kimberly.Anderson@med.ohio.gov

Dear Ms. Anderson:

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching and research. With a footprint in Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 18 hospitals with approximately 6,000 staffed beds, 21 outpatient Family Health Centers, 11 outpatient surgery locations and numerous physician offices. Cleveland Clinic employs over 4,600 salaried physicians and scientists. Last year, our system cared for 2.4 million unique patients, including 10 million outpatient visits and 273,000 hospital admissions and observations. Below are our responses to the two questions posed by the Medical Board.

Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

We are concerned with allowing podiatrists to perform this procedure. Although proximal tibia bone marrow aspiration is not technically difficult, we perceive no compelling reason to allow podiatrists to perform a procedure that is proximal to the foot/ankle region when equally effective alternatives exist in the foot and ankle. Further, specifically with respect to bone marrow harvesting, a comparative study demonstrated no benefit to proximal tibia bone marrow harvest as compared to distal tibia and calcaneus bone graft. We would encourage the Board not to adopt a policy that may encourage more proximal surgery when distal options are equivalent.

Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?

We are concerned with allowing podiatrists to perform supramalleolar tibial osteotomy due to the complexity of this procedure. As a surgeon practicing in a large academic medical center with high complexity practice, I only perform two to three of these cases per year. Thus, it seems unlikely that a podiatrist will have the necessary repetition and experience with this complex procedure to perform it safely and competently. This procedure is extremely technically difficult and has a substantial risk of serious complications. Therefore, I do not think it is in the best interest of patients and patient safety to support the expansion of podiatric privileges to allow performance of this procedure.
Thank you for conducting a thoughtful process that allows us to provide input on such important issues. Should you need any further information, please don’t hesitate to contact me.

Sincerely,

Mark J. Berkowitz, MD
Director, Foot and Ankle Department
Podiatrists should not be performing supramalleolar osteotomies as they are not prepared to treat the potential complications of same. Trephine harvesting of bone or marrow for grafting from the tibia IS reasonable given the nature of the procedure, the reason for the procedure, and the minimal chance for issues with the procedure. There are many potential complications or additional procedures that are associated with performing a supramalleolar osteotomy. Podiatrists performing these procedures are then NOT performing “podiatric” procedures, but rather leg procedures, and this is beyond the scope of their training.

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June 30, 2021

To Whom It May Concern:

I am composing this letter to urge the State Medical Board of Ohio create a rule that mirror its policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia.

Podiatric physicians receive advanced training in podiatric medicine and surgery during their residency training and serve required clinical rotations in medical imaging, pathology, behavioral sciences, internal medicine and/or family practice, medical subspecialties, infectious disease, general surgery, surgical subspecialties, anesthesiology, and emergency medicine.

To perform ankle surgery, podiatrists in Ohio are required complete a residency in podiatric surgery approved by the Council on Podiatric Medical Education and attain board qualified status from the American Board of Foot and Ankle Surgery (ABFAS). Board qualification indicates a demonstrated level of expertise in the diagnosis and surgical management of pathologic foot and ankle conditions, deformities, and/or trauma and of structures that affect the foot, ankle, and leg. A supramalleolar osteotomy is commonly performed to realign previous ankle fractures, ankle deformities or mal-aligned ankle fusion procedures that directly affect the function of the foot and ankle.

To conclude, I respectfully request the Board advance a rule that mirrors its established policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia.

With sincerity,

Michael B. Canales, D.P.M.
St. Vincent Charity Hospital Spine & Orthopedic Institute
Chief of Podiatry, St. Vincent Charity Medical
Residency Director, Podiatric Medicine & Surgery, St. Vincent Charity Medical Center
Hi Kim

I, Mona N Arabi MD PA, license in FL MA MI MO PA. I work closely with a talented podiatric Dr at Lock Haven Susquehanna, PA. Dr X was talented and he does complex fracture above the malleole. He was good technically. However, I don't support the act because his work is reserved to MD orthopedic. The MD has more foundation to handle the job. You do not want to have a shoes maker come and pull your tooth because he knows how to extract a nail.

Mona N Arabi MD PA
313 5069151

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I am not in favor of allowing podiatrists to perform supramalleolar osteotomies. The level of residency training by DPM’s is not standard which is not the case with orthopedic residency training programs as they are very structured and standardized. It’s too hard to identify DPM’s who have trained in a program with sufficient education to perform more complex operations. Next they will want to treat tibial shaft fractures and just continue to move up leg if left unchecked. If they wanted to do those things, the option to go to medical school (MD or DO), graduate and matriculate into an orthopedic surgery residency program where the training is very well controlled from program to program is still an option for them.

As someone who has been involved in reviewing podiatric credentialing in a hospital setting, the very different training by them in their residency programs is a major concern in credentialing in hospitals. If everyone knew and admitted their limitations, we would not be in this situation. If we continue to allow individuals to expand out of their intended scope of practice that is when we run into patient care/safety issues. In the end, our job is to protect patients who don’t know the difference between an orthopedic surgeon or a podiatrist. I do not see where the links provided with the current rules approved/allowed/stated podiatrists could perform a supramalleolar osteotomy. Podiatrists are very good at their intended roles, however, many hope to become orthopedic surgeons without doing the appropriate training and that is not good for patients. Until the training is similar, it is not in a patient’s best interest to allow this expansion of the ability of podiatric doctors to perform this. Patient care is always first and this is a patient safety issue. Please do not hesitate to reach out with questions. Thank you.

Nick Cheney, DO, FAOAO, FAAOS
(614) 506-2483

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August 2, 2021

Ms. Kimberly Anderson, Esq.
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215
RE: Podiatric Scope of Practice

State Medical Board of Ohio:

I am writing to request the State Medical Board of Ohio develop a rule that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia. Aspirations are utilized to augment a variety of foot and ankle procedures to assist with bone healing. I routinely perform proximal tibial bone marrow aspiration as part of my regimen for rearfoot arthrodesis procedures. These composites may be combined with allograft preparations, resulting in a product that promotes osteoconduction, osteoinduction, and osteogenesis with limited morbidity. I am double board certified in foot and ankle surgery by ABFAS and ABPM. I had to submit 65 foot surgery cases and 30 reconstructive rearfoot/ankle surgery cases to obtain my certification. Case submission is only one of the five requirements towards achieving board certification, and board certification must be renewed every 10 years. DPMs are not performing these procedures to treat the leg or proximal structures. Any insinuation to the contrary is incorrect. I respectfully request the Board advance a rule that mirrors its established policy that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia.

If you have any questions, please contact me at 2162171203.

Sincerely,

Nicole Nicolosi, DPM
GOOD AFTERNOON

Thank you for asking regarding the input of these complex ankle and leg procedures. First of all please allow me to introduce myself so that my opinion may have meaningful weight and help you to decide what is good for all parties concerned especially the patient, Podiatrists, Orthopedic Surgeons. My opinion will be unbiased because I am neither Podiatrist or a Orthopedic Surgeon. The Board has to ultimately decide to grant the permission to perform these procedures.

My name is Kuldeep Singh, MD from Cleveland Ohio. I have been living in Cleveland over 50 years, at present time I am not working due to Co-vid 19 risk for my age group. I am Board Certified and Recertified General Surgeon, I did private practice in Surgery from 1976 to 2003 and then switched to Emergency Medicine in Cleveland Clinic and University Hospital Facilities. I have served as Director of Surgery and Chief of Surgery in the past at Deaconess Hospital of Cleveland Ohio, I have been involved in Podiatric Privileges issues at that time, I have published 5 papers in the World literature, I was a Fellow of American College of Surgeons, International College of Surgeons and American College of Emergency Physicians.

My understanding of Podiatric Specialty is “Surgery involving the Foot or any joint or ligament is a part of foot but not above the Ankle/Foot Joint. Bone aspiration from Proximal Tibia is definitely NOT PART OF FOOT and hence should not be an issue to decide.

To perform Supra malleolar osteotomy is again is not a part of FOOT, it is a part of Lower Leg and hence is a Grey Zone, but to perform osteotomy to correct deformity is a very complex procedure especially in Pediatric group which can be devastating if not done right.

Thank you, hope this information may of some help.

Kind regards
Kuldeep Singh, MD

Sent from Mail for Windows 10

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Hello, as a practicing orthopedic surgeon with specialty training in sports medicine and foot/ankle I am very aware of the differences in training in podiatry and orthopedic surgery. I strongly disagree that the proposed changes are appropriate. The scope of these procedures is clearly outside the scope of their training and the implication of these procedures is that they will be used in practice to include related treatments that are further outside the realm of their training. I am happy to discuss this further in person.

Thanks

Pete Edwards MD
Cell 614-314-8107

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Podiatrists are continually trying to expand their scope of practice. From originally being restricted to the foot, they now do all types of ankle surgery as well. Harvesting bone marrow from the tibia brings them to the knee. Tibial supramalleolar osteotomy is above the ankle to correct tibial
alignment. Next, they will want to treat tibial fractures. Where does it end? At some point we have to say you need to go to medical school and do an orthopedic residency to perform orthopedic surgery. My opinion is that they should not be allowed to operate above the ankle joint.

Peter Gerbino, MD

On Mon, Jul 26, 2021 at 8:50 AM State Medical Board of Ohio <contact@med.ohio.gov> wrote:
In May 2021, the State Medical Board appeared before the Joint Commission on Agency Rule Review (“JCARR”) for consideration as to whether the policy determination should be specified in a rule. Prior to receiving the determination from JCARR, the State Medical Board of Ohio decided to commence the rule-making process on this issue. Given the differences from the affected parties, the Board has decided to first solicit comments from interested parties to inform the rule-making process.

These links provide copies of the Medical Board rules related to podiatric scope of practice (4731-20-01 and 4731-20-02) and the June 2019 communication regarding the specific procedures.

Please provide any comments and supporting material that you would like the Medical Board to consider in drafting rules related to the above-listed specific procedures and whether they are within the scope of practice of a podiatrist.

Comments on the proposed rules must be received by August 19, 2021. Please provide comments to: Kimberly.Anderson@med.ohio.gov.
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Podiatry should not be allowed to do any BoneMarrow aspirate or Osteotomy
Thanks
Dr Poonam Singh

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Above mentioned procedures are not in the scope of their practice. It is better not to allow them to do those procedures. It will be harmful to the patients. They are not trained to do those procedures. From Ramagopal Reddy Avutu Md.

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To Whom It May Concern:

I am writing regarding the maintenance of Ohio’s Podiatric delineation of privileges. Currently, bone marrow aspirate/harvesting and supramalleolar osteotomies are in question. For simplicity’s sake I will address each of these individually.

Supramalleolar Osteotomy:
Podiatry as a profession is focused solely on the function, treatment and correction of the foot and ankle. Our physicians spend 4 years in podiatric medical school and three to four years in residency with many subsequently electing to continue in a fellowship program with one focus; how the foot and ankle work in relation to the body, ground, and mechanically and how to fix it when it’s not functioning correctly both conservatively and surgically.

As a Residency Director, our curriculum focuses on training competent physicians in all treatments of foot and ankle pathology. A supramalleolar osteotomy is employed to correct angular and rotational deformities of the distal tibia which directly impacts the function of the ankle and foot. These may be congenital, post-traumatic or Charcot in nature. As a podiatric surgeon we address these issues daily. The ability for a surgeon to correct a plafond deformity is necessary for the treatment success and in many cases, essential to provide the best outcome for the patient. Podiatric residents are trained to perform tibial osteotomies regularly for the treatment of the ankle and foot. This includes such procedures as total ankle replacements, tibial osteotomies for treatment of talar fractures, ankle fusions, tibial torsion correction and infections to name a few. In many procedures such as total ankle replacements, the need to realign an ankle joint prior to the implantation of the device is paramount to its short- and long-term success.

Bone marrow aspirate/harvesting:
To the same end, bone marrow aspiration/harvesting is an essential aspect of all bone surgeon’s armamentarium. For podiatry, this is greater than most as we are commonly dealing with the most unhealthy and highest risk surgical patients due to their comorbidities. These are often uncontrolled diabetics, vasculopathies with limited blood flow, and long-term smokers. Just these three examples account for some of the highest risk patients for fusion procedures. As a Podiatric surgeon, I perform surgeries on this sect of patients weekly. The ability to procure my own autogenous bone graft provides the very best product, the patient’s own marrow, to increase the success of boney unions. There are many cadaver-based products on the market, they tend to be expensive and are not as successful as an autogenous source. Today the gold standard for grafting, in spite our technological advances, remains an autogenous bone graft.
As Podiatrists, the argument, as I understand it, is that we are too proximal on the leg, therefore beyond our scope of practice. In our scope is the application of external fixation systems and the use of intermedullary nails for the treatment of foot and ankle pathology. These are secured to the tibia with half-pins and wires drilled into the tibia proximally. There is not a unique or special technical component that requires further training for marrow aspiration/acquisition to be performed. Podiatrists are already trained to acquire bone graft from the lower tibia and calcaneus, the proximal tibial is simply a source of more nutrient rich graft that remains in our “below the knee zone”. The goal here as always is to do what is best for the patient and is best for their outcome.

I hope this aids in the clarity of your decision regarding Podiatric surgical scope. If there are any further questions, I am happy to speak to anyone directly, or communicate via email at the below contact information. Thank you for your time and consideration on this matter.

Professionally,

Dr. Robert M. Brarens, FACFAS
Jewish Hospital-Mercy, Director of Podiatric Surgical Residency Program
SureStep Foot & Ankle Medical Center, Owner
I believe that podiatrist in the State of Ohio that are in good standing should be granted ALL the proposals that are outlined in the e-mail I received from the State Medical Board of Ohio. RobertJMlller D.O. #34005556
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I am Dr Robert Kulwin, orthopedic foot and ankle surgeon.

With regards to the two proposed limitations I think that a supramalleolar osteotomy is outside the scope of what a podiatrist should be doing.

I think the needle aspiration of bone marrow form the proximal tibia while well away from the ankle is a simple enough procedure that it can likely be safely and competently performed by a podiatrist.

I am happy to clarify my rationale further if requested or helpful.

Best,
Robert Kulwin, MD

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June 21, 2021

Betty Montgomery, JD
Acting President
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Montgomery and Members of the State Medical Board of Ohio,

I am writing to encourage the State Medical Board of Ohio to develop and advance a rule that codifies the Board’s existing policy that states that it is within the scope of practice for a podiatrist to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia.

These procedures have been performed by Doctors of Podiatric Medicine for decades in this state. There has been no complaints or issues of inappropriateness filed specific to the two procedures that I am aware of.

It is also important to remember that just because it is in our scope to perform these procedures does not mean ALL DPMs are performing them. Each INDIVIDUAL doctor is evaluated on their training and practice experience when provided privileges at hospitals and surgery centers. The process of granting these privileges is thorough and with many steps to protect the community and the patients we serve. The process occurs daily at institutions throughout the state and if the DPM is not qualified, they are not provided authorization to perform procedures.

At my institution, as an example, these procedures can be requested by a DPM. For that DPM to even apply for surgical procedures they must have completed a Council of Podiatric Medical Education (CPME) approved surgical residency. These types of residencies have specific guidelines that must be followed and adhered to in order to graduate from the program. There are detailed logs of courses, academic sessions and surgical logs that need to be maintained. There are enormous amounts of evaluations that are completed, and these are all required by CPME with the organization doing routine audits and reviews of each program in order for them to be an approved training site. I am intimately involved in this process since I am the current Program Director at Grant Medical Center.

Individuals also must supply documentation showing board qualification or certification by the American Board of Foot and Ankle Surgery (which also has a recertification requirement in order to maintain this certification) Not all podiatric physicians are qualified to take the Reconstructive Rearfoot and Ankle Section of our certification.
The examination has questions specific to these topics and is detailed and difficult to pass if not fully knowledgeable on the subject matter. I have close knowledge of the Board since I am a subject matter expert and have supplied questions for the board examination. Moreover, my own brother is a Past President of the American Board of Foot and Ankle Surgeons.

Once certified, podiatrists have the privilege to join the American College of Foot and Ankle Surgeons. The procedures in question are routinely covered in lectures, skills courses and peer reviewed literature for educational knowledge and review. I am full knowledgeable that this occurs since I have published on the topic, as I am the Past President of the American College of Foot and Ankle Surgeons and a current member of their Education and Scientific Committee.

Once the privilege is requested at our facility, a Department Chair reviews the request and, if acceptable, it is approved. It then goes in front of the credentials committee to approve. If all agree to the request, it then moves to the Medical Executive Committee to review and approve. It is then reviewed by the administration, legal counsel and finally signed off on by the hospital president. Throughout this process, there are numerous MDs and DOs that review the request and approve or reject requests of said privileges. None of this is taken lightly and the checks and balances are there to protect the citizens of Ohio.

Supramalleolar osteotomies and harvesting bone marrow aspirate are procedures performed for the treatment, function and repair of the foot and ankle. A supramalleolar osteotomy is commonly performed to realign previous ankle fractures, ankle deformities or mal-aligned ankle fusions that affect the function of the foot and ankle. Aspirations are utilized to augment a variety of foot and ankle procedures to help with bone healing. DPMs are not performing these procedures to treat the leg or proximal structures. Any insinuation to the contrary would be incorrect or misleading.

Additionally, there are many DPMs employed or affiliated with orthopedic practices throughout Ohio and their MD and DO partners refer these cases to them. I am personally employed with OhioHealth Physician Group and in their Orthopedic Group based at the Bone and Joint Center at Grant Medical Center. My orthopedic partners send these referrals to me and count on my expertise for helping their patients.

In fact, many have limited training or experience in many of the foot and ankle problems and procedures that foot and ankle surgeons perform. I even have a DO orthopedic foot and ankle surgeon that I share patients with and consult with on a regular basis. He is a faculty member of our surgical residency that I am the program director of here at Grant Medical Center. Furthermore, my partners never have expressed issues or concerns with this being outside of the scope for me as a DPM or privileging within OhioHealth.
In closing, I am in full agreement with the State Medical Board of Ohio’s policy that it is within the scope of practice for a podiatrist to perform a supramalleolar ostectomy of the tibia or fibula to correct a deformity and harvest bone marrow aspirate from the proximal tibia. I encourage the Board to put its existing policy into the rule it advances to the Joint Committee on Agency Rule Review.

This policy has already been debated at length by the Board on three separate occasions and the Board’s position has rightfully remained the same. While opponents of the Board’s policy have every right to challenge the scope of practice for podiatrists, it is a waste of resources when special interest groups, societies or specialties continue to challenge the Board’s statutory and regulatory authority simply because they do not like the outcome of a decision.

The individuals and groups that continue to question the Board’s decisions on this matter, in my opinion, are simply focused on limiting the scope of practice of podiatrists for their own financial and political benefit.

Thank you for your time, consideration and for your dedication to protecting the patients of Ohio. Please contact me if you have any questions.

Professionally,

Robert W. Mendicino, DPM, FACFAS
Foot and Ankle Surgery, OhioHealth Orthopedic Surgeons
Past President, American College of Foot and Ankle Surgeons
Program Director, Grant Medical Center Foot and Ankle Surgical Residency

Attachments: 2
MASTER TECHNIQUES IN PODIATRIC SURGERY:

THE FOOT AND ANKLE

THOMAS J. CHANG
INDICATIONS/CONTRAINDICATIONS

Ankle and distal tibial deformities can be complex and may be associated with aberrant pedal mechanics. The supramalleolar osteotomy is performed to address malalignment of the leg, decrease pedal symptomatology, and improve limb function. This osteotomy can correct deformities of the distal tibia in all planes: frontal plane (ankle and tibia varus/valgus), sagittal plane (procurvatum or posterior aligned distal tibial articular surface; recurvatum or anterior aligned distal tibial articular surface), and oblique plane (a combination of a frontal and sagittal plane deformity). Additionally, this procedure can be performed to correct deformities associated with a malaligned ankle arthrodesis. A mild to moderate ankle or distal tibial deformity is well tolerated by a mobile foot. This is a result of ample motion available at the hip, knee, subtalar, and forefoot joints. However, in patients without adequate compensatory motion, even small angular deformities can be problematic.

There are several advantages to the supramalleolar osteotomy. First and foremost, it is often a joint sparing procedure performed in a juxta-articular region, which allows its use in the younger population with congenital deformities. It is an alternative to multiple foot surgeries where the deformity is located above, at, or just distal to the level of the ankle joint. There are specific advantages to the focal dome osteotomy when compared to the straight cut osteotomy, including minimal bone necrosis due to the lack of saw usage and little to no periosteal dissection. Also, it is percutaneous, very stable, and has a large bone-to-bone contact area.

The primary disadvantage to the supramalleolar osteotomy is that the procedure does not correct and may in fact uncover midfoot and/or hindfoot deformities. Additionally, there is the possibility of translational malalignment when the osteotomy is not performed at the apex of the deformity or center of rotational angulation (CORA).

The focal dome osteotomy can eliminate many positional complications, as it accounts for both the angular and translational components of a typical opening or closing wedge osteotomy. An opening or closing wedge osteotomy performed remote to the CORA will result in translation and therefore needs to be realigned once the wedge is completed. The focal
dome osteotomy is performed based on a radial arm cut around the CORA and therefore does not result in malalignment. There is also no need for bone grafting or bone wedge removal.

When evaluating the indications and contraindications of these procedures it is important to evaluate the patient’s goals and ability to remain compliant with the postoperative regime. If a patient cannot tolerate non-weightbearing or immobilization, alternatives must be considered. The most common indication for a supramalleolar osteotomy is a juxta-articular tibial deformity or a malaligned previous ankle arthrodesis. These patients commonly present with chronic pain, which is often exacerbated with activity. Clinical deformities may or may not be evident. Obvious contraindications include impaired neurovascular status and active skin infection. Relative contraindications are determined in the evaluation of the patient’s other comorbid conditions.

PREOPERATIVE CONSIDERATIONS

Realignment principles of foot and ankle surgery should ensure that the forefoot is aligned to the hindfoot and the hindfoot is aligned to the leg. Therefore, a comprehensive pre- and postoperative radiographic and clinical evaluation is paramount to ensure success in managing a patient’s deformities and pathologic entities. Specific angular relationships are critical in appropriately identifying the level of deformity, and intraoperative imaging is necessary to achieve good surgical results.

Radiographic assessment should begin with standard AP (anterior posterior) and lateral x-rays of the foot and ankle. Additional images are needed to assess the alignment of the hindfoot to the tibia. These images include the “long leg calcaneal axial” and the “hindfoot alignment” views. The long leg calcaneal axial radiograph shows the relationship of the calcaneus to the leg and best visualizes the subtalar space (Figs. 35-1 and 35-2). The hindfoot alignment view allows a better view of the ankle joint and also demonstrates the relationship of the hindfoot to the leg, thus allowing a cross reference for the long leg calcaneal axial radiograph (Figs. 35-3 and 35-4). If it is found that the deformity is proximal in nature,

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**Figure 35-1.** Demonstration of the radiographic technique of the “long leg calcaneal axial” radiograph. The x-ray beam is oriented at 45 degrees to the posterior aspect of the calcaneus and the x-ray cassette is placed flat on the floor.

**Figure 35-2.** Long leg calcaneal axial radiograph demonstrating the relationship of the calcaneus to the leg and good visualization of the subtalar space.
Figure 35-3. Demonstration of the radiographic technique of the "hindfoot alignment (Saltzman)" radiograph. The x-ray cassette is oriented at 15 degrees from vertical. The x-ray beam is oriented perpendicular to the cassette.

Figure 35-4. Hindfoot alignment radiograph allowing for clear evaluation of the ankle joint orientation to the long axis of the tibia.
full leg radiographs may be necessary. These should include the knee and, in instances of limb length discrepancy, the hip. Angular assessment should be performed in order to determine the level of the deformity and the surgical goal should be to align these angles as close to normal values as possible. In procedures such as the supramalleolar osteotomy, radiographic assessment is a necessity in the preoperative planning of malalignment. Additionally, advanced imaging such as MRI or CT scans may be warranted to examine joint integrity. This will help to determine if a joint sparing or a joint destructive procedure is indicated.

A few basic terms must be understood prior to beginning radiographic evaluation:

1. Anatomic axis of tibia: mid-diaphyseal line of the tibia (Fig. 35-5).
2. Joint orientation angle: angle between the anatomic axis of a bone and the joint line either in the frontal or sagittal plane (Figs. 35-6 and 35-7).
3. Center of the ankle joint (AP): center point of the talus with reference to the mid-diaphysis of the tibia (Fig. 35-8).
4. Center of the ankle joint (lateral) represented by the lateral process of the talus when the foot is 90 degrees to the leg (Fig. 35-9). The ankle joint axis is shaped like a frustum of a cone with the lateral process being its central point.

Figure 35-5. A and B: Anatomic axis of the tibia. This is found by bisecting the long axis of the tibia. On the frontal plane this line usually will have a proximal point at the medial tibial spine and a distal point at the midpoint of the tibial plafond.
Figure 35-6. A and B: Joint orientation angle on the AP radiograph. The angle formed by the anatomic axis of the tibia and a line parallel to the joint.

Figure 35-7. A and B: Joint orientation angle on the lateral radiograph. The angle formed by the mid-diaphyseal line of the tibia on the lateral radiograph and a line parallel to the joint.
Figure 35-8. A and B: The center point of the talus is the midpoint of the talar articular surface with reference to the mid-diaphyseal line of the tibia shaft.

Figure 35-9. A and B: The center of the ankle joint range of motion is represented by the lateral process of the talus when the foot is at 90 degrees to the leg.
the frontal plane of the distal leg, the ankle joint orientation line is in slight valgus to midshaft of the tibia. The joint orientation line of the ankle and the anatomic axis of the make an angle that measures $89 \pm 3$ degrees. This angle is known as the lateral distal tibial angle or LDTA (Fig. 35-10A and B).

The anterior distal tibial angle (ADTA), formed by the mechanical axis of the tibia and orientation line of the ankle in the sagittal plane, measures $80 \pm 3$ degrees in the talocrural joint. The joint orientation line of the ankle and the anatomic axis of the make, an that measures $89$ degrees. This is known as the anterior distal tibial angle or ADTA (Fig. 35-10A and B).

The lateral foot radiograph is also evaluated in the sagittal plane. Mary’s angle (lateral calcaneal angle) and the calcaneal inclination angle are examined for alignment.

The key to the success of a realignment procedure is twofold. First, an attempt is made to correct abnormal angles to as close to normal as possible, and, second, there needs to be alignment of the center of the ankle joint to allow for proper biomechanical function. Any deviation of the ankle or distal tibia in these planes could result in significant joint deviation of not only the ankle but also adjacent joints.

Distal tibial deformities occur in four basic planes: frontal, sagittal, oblique, and rotational. The focal dome osteotomy is best performed for the frontal or sagittal plane deformities. Frontal plane abnormalities occur in varus or valgus directions. There is an increased risk of a varus deformity and a decreased LDTA with a valgus deformity. These deformities are compensated for at the subtalar joint and forefoot. Compensation depends on mobility of the subtalar joint and the forefoot. It is important to remember that there is up to 5 degrees of eversion and 30 degrees of inversion available for compensation at the subtalar joint. Evaluation of subtalar joint range of motion is vital as tibial osteotomies may unmask a subtalar deformity that will lead to further symptoms. Most deformities are well tolerated when compensation is available and become painful when the deformity falls outside the compensatory range of motion. Additionally, valgus deformities are better tolerated in varus deformities secondary to the increased compensatory motion (approximately 30 degrees) typically available.

Sagittal plane abnormalities present as procurvatum, recurvatum, equinus, or calcaneus deformities. These deformities are compensated at the ankle joint, forefoot joints, and the subtalar joint. Motion in the normal adult ankle is 20 degrees of dorsiflexion and 50 degrees of plantarflexion. As a result, recurvatum ankles are better compensated than procurvatum. In procurvatum, the cartilage of the distal tibia is directed more posterior than normal, so the ADTA is increased. Degeneration of this type of joint occurs later on in life; this deformity is less tolerated early on and is generally more painful. In ankle recurvatum, the tibial plate of the distal tibia is oriented more anterior and therefore the ADTA is decreased. Degeneration of this joint occurs much earlier due to the shearing that occurs across the joint; however, this deformity is better tolerated early on because of the large amount of plantar flexion compensation available at the ankle joint.
Figure 35-10. A and B: The LDTA is the lateral angle formed by the anatomic axis of the tibia and the ankle joint orientation line. Normal valgus range from 86–92 degrees. C and D: The ADTA is the anterior angle formed by the mid-diaphyseal line of the tibia on the lateral radiograph and the ankle joint orientation line. Normal valgus range from 77–83 degrees.
In the radiographic evaluation of tibial deformities, distal and proximal mid-diaphyseal lines of the deformity cross to form an apex. This is the center of rotation of angulation or CORA (Fig. 35-11). The goal of angular correction is to perform osteotomies as close as possible to the level of the CORA in order to minimize translation. When performing osteotomies away from the CORA the resultant correction will leave a translational component. This translational component will cause additional malalignment within the lower extremity. When the CORA falls at or near the level of the ankle joint, a focal dome osteotomy can be performed to minimize translation. A radius arm is placed at the level of the CORA, and the osteotomy is performed in a circular fashion around this radial arm within the metaphysis at the tibia. This is easily rotated in order to realign the lower extremity (Fig. 35-12).

Surrounding structures in the area of the osteotomy must be taken into account. Acute correction of these deformities can place stress on soft tissue structures, especially the posterior tibial nerve. Acute tarsal tunnel syndrome can be a sequela of acute varus or procurvatum correction. The senior author routinely performs a prophylactic tarsal tunnel release when performing a supramalleolar osteotomy to correct these deformities.

Figure 35-11. Example of the CORA forming proximal to the ankle joint. This point is found by bisecting the proximal and distal portions of the tibia.

Figure 35-12. Example of the CORA forming at the level of the ankle joint. Once it is found, that there is an abnormal ADTA or LDTA, a line forming a normal angle can be drawn in relation to the joint line. The point where this normal line intersects the mid-diaphyseal line is the CORA. This is an appropriate deformity for a focal dome osteotomy since the deformity is located at the articular level and not within the shaft of the tibia.
SURGICAL TECHNIQUE

Patient positioning is key to the success of these procedures. The patient is placed in the supine position. A bump is placed under the ipsilateral hip until the surgical limb is oriented with the ankle in the frontal plane. Next using a hand held Doppler, the anterior tibial dorsalis pedis artery is mapped and outlined with a skin marker (Fig. 35-13). Often the nerve is estimated and mapped as well for orientation. General or spinal anesthesia is induced and a thigh tourniquet may be considered for hemostasis. Sterile prep and drapes the lower extremity up to the knee. The tarsal tunnel release is performed first if indicated, and skin is closed prior to beginning the supramalleolar dissection.

The following operative procedure is for correction of a varus or valgus deformity. Evaluate the anterior aspect of the ankle and distal tibia. Under AP and lateral image intensification, a 5.0 mm half pin is percutaneously placed lateral to the artery (Fig. 35-14). The 5.0-mm half pin is placed anterior to posterior, perpendicular to the axis of the tibia, which is visualized with the AP and lateral fluoroscopy images. The pin is placed as near to the CORA as possible in the distal metaphyseal region of the tibia.

Figure 35-13. The surgeon maps the course of the vascular tree with a hand held Doppler prior to making a skin incision. This is done for the anterior tibial and the posterior tibial arteries.

Figure 35-14. Using fluoroscopic guidance, a stab incision is made just lateral to the anterior tibial artery and a 5.0-mm half pin is placed from anterior to posterior. This pin must be perpendicular to the long axis of the tibia in all planes.
This pin serves as the center of rotation for the osteotomy. When the CORA falls at the ankle joint, the pin cannot be placed in the joint but just proximal. This proximal placement of the half pin will create minimal translation. Next a lever arm guide is applied to the half pin, which will serve as the osteotomy template (Fig. 35-16). Any linear device with holes can be used. The author utilizes a DePuy/ACE three hole pin holder or the Smith and Nephew Rancho device. Under fluoroscopic intensification the level of the osteotomy is determined. This is performed in metaphyseal bone and the guide hole that is utilized is the one that will provide the ability for the osteotomy to exit both the medial and lateral cortices of the tibia (Fig. 35-17B and C). It is important to conceptually

Figure 35-15. A and B: The pin is placed as distal as possible in the metaphyseal bone and as close to the CORA as possible.

Figure 35-16. The lever arm is applied to the half pin to serve as the osteotomy guide. This will pivot on the half pin.
visualize the osteotomy under fluoroscopy to ensure that the osteotomy will exit both tibial cortices without invading the joint space. Next, create multiple percutaneous incisions (typically three), taking care to avoid neurovascular structures (Fig. 35-17). Incise the periosteum and retract. Create multiple percutaneous drill holes from anterior to posterior in the tibia through the incision sites (Fig. 35-18). Usually two to three drill holes can be made through each incision. These holes are made through the drill guide in the lever arm and form a dome-like appearance with the apex proximal (Fig. 35-19). These drill holes are similar to the perforated edges of a piece of paper. A drill guide is placed in the lever arm to protect the soft tissue structures. Now an osteotome is placed into the percutaneous incisions and the osteotomy is completed in a slow methodical manner from medial to lateral and anterior to posterior (Fig. 35-20). The osteotome should be narrow and essentially fractures the bone between the drill holes. Check the osteotomy with fluoroscopy to ensure that the osteotomy is complete. The more novice surgeon may consider performing this through a large incision so that they could visualize the entire tibial site. However, this results in more surgical dissection and peristeal stripping and can affect bone healing. The author prefers the percutaneous technique.

Once the tibial osteotomy is complete, a fibular osteotomy may need to be performed in order to gain correction. Make a 2.0–3.0-mm incision over the lateral aspect of the fibula at the level of the tibial osteotomy. Make a linear peristeal incision on the fibula and dissect the peristeum with a periosteal elevator. Perform the osteotomy of the fibula with a sagittal saw orientated proximal anterior to distal posterior (Fig. 35-21).

Next, under image intensification, manipulate the foot and ankle distal to the osteotomy and rotate in a varus or valgus direction (the direction to correct the deformity). Perform this maneuver until a normal lateral distal tibial angle (LDTA) is obtained. The author then fixes the tibial osteotomy using two 6.5-mm or 8.0-mm partially threaded cancellous crossing screws. One screw is oriented medial distal to proximal lateral, entering at the medial
Figure 35-18. Multiple percutaneous drill holes (2–3) are placed through each incision site. The osteotomy guide is used to orient the drill holes.

Figure 35-19. The drill holes form the outline of the focal dome osteotomy.

Figure 35-20. An osteotome is percutaneously manipulated to complete the osteotomy. The technique is methodical and typically performed under fluoroscopic guidance.

Figure 35-21. The fibula is osteotomized to allow for adequate correction. The orientation of the fibular osteotomy depends on the plane of correction of the tibial osteotomy. Fixation will follow after stabilization of the tibial osteotomy.
material is, and the other from anterior proximal to distal posterior, entering the tibia proximally at the osteotomy (Fig. 35-22). Figure the fibular osteotomy next with one or two 0.064-inch screws from anterior to posterior. Additional fixation is added on a case-by-case basis.

Now, examine the entire lower extremity under image intensification to ensure alignment of the tibia to the fibula and the hindfoot to the forefoot. Additional procedures such as a midfoot arthrodesis or osteotomy may sometimes be necessary to achieve appropriate alignment. Alternatively, external fixation may be warranted to augment or replace internal fixation. The decision is made on a case-by-case basis and influenced by many factors. These include confidence in the accuracy of initial internal fixation, and psychosocial issues of the patient, including compliance and postoperative convalescence.

Correction for pronation and eversion are performed in a similar manner. The initial approach is medial and the half pin is placed from medial to lateral just posterior to the ankle joint. Again, carefully choose the level of the osteotomy in order to ensure that the bone can wall off the tibia anterior and posterior without invading the joint surface. Have your incisions again approximately three and perform a similar drill hole technique. Complete the osteotomy percutaneously with no osteotome. The osteotomy of the fibula is difficult from dorsal lateral to proximal medial in the sagittal plane. Occasionally, a wedge of bone may need to be excised from the fibula in order to get good bone-to-bone contact when meeting the osteotomy posterior. Reduce the distal ankle and foot until the anterior distal tibial angle (ADTA) is in its normal anatomic position. Fixation as performed as previously described. Osteotomy, ankle joint debridement, and lateral fixation to ensure implantation is absent and range of motion is adequate. Occasionally, a posterior muscle tightening or Achilles lengthening may be necessary.

**POSTOPERATIVE MANAGEMENT**

Patients are educated on the complexity of the procedure and the importance of postoperative compliance. Patients must be aware that failed procedures may lead to further complex reconstructive procedures.
If only internal fixation is used, the patient is placed in a short leg non-weightbearing cast for at least 6–8 weeks. Serial radiographs are used to evaluate the osteotomy for healing. Consider progressing to weight bearing in a fracture boot when radiographs demonstrate that the osteotomy is healed. If external fixation is used, the same criteria are used for determining removal of the fixator. Up to removal of the fixator, a short leg cast is applied for 2–3 additional weeks. Remember the decision to use external fixation was based on criteria that may impair the healing process. Progress the patient to controlled weightbearing in a rocker bottom cast boot for 2–3 weeks. It is important to evaluate the need for physical therapy, as this is often necessary to maintain range of motion of the foot and ankle as well as to strengthen and retain the lower leg musculature. Activity is then gradually increased based upon each patient’s progress.

COMPLICATIONS

Complications can include nonunion of the tibial or fibular osteotomy site. Additional surgery consisting of nonunion resection and the use of bone grafting may be necessary. Proper surgical techniques can help prevent such complications. Adequate fixation and bone apposition of the osteotomy site is essential. The primary author has not had a delay of union when performing the local bone ostectomy with acute correction.

Nerve entrapment is another complication, especially with acute corrections. A prophylactic (mesenteric) release is often performed in acute varus and pronation corrections and can lead itself to complications on its own. Severe angular deformity may be best treated through gradual correction utilizing external fixation.

Additional complications may include prolonged external, which may be controlled with compression therapy. Wound dehiscence is rare with the percutaneous approach described here but does occur at times. These can usually be managed with proper wound care techniques. Occasionally, plastic surgical intervention is necessary. When using external fixation, pin site infections are common. These are managed with local wound care and daily cleansing of the pin sites. However, due to the percutaneous nature of this specific procedure, the author has had no significant complications to date.

Illustrative Cases for Technique

A 59-year-old female was referred with the complaint of right foot pain and abnormal foot position since an ankle fusion performed approximately 2 years previously. Physical examination revealed the ankle arthrodesis to be without motion; however, upon leaning of the foot, a constant abduction and valgus was present (Fig. 35·23). She had significant pain along the posterior-medial ankle along the course of the posterior tibial tendon. The patient admitted to having a flatfoot architecture most of her life that had progressed and became

![Figure 35.23](image-url)
Figure 35-24. A–C: Radiographic assessment showing previous malaligned ankle arthrodesis. The LDTA is decreased, which is consistent with ankle valgus and the foot radiographs show forefoot abductus.
symptomatic since her arthrodesis. A comprehensive radiographic assessment was performed (Fig. 35-24).

Hindfoot alignment and long leg calcaneal axial radiographs reveal a significant valgus malposition of the ankle arthrodesis (Fig. 35-25). She also has significant forefoot abductus around the midtarsal joint. A computerized gait analysis was consistent with these findings.

A stab incision was made at the level of the arthrodesis after the previous fixation was removed. A 5.0-mm half pin was introduced at the level of the arthrodesis perpendicular to the anatomic axis of the tibia both on the AP and lateral radiographic views (Fig. 35-26). A DePuy/ACE three hole pin holder was then placed over the half pin, and the appropriate hole for drilling was determined based on its ability to exit medially and laterally in the tibia metaphysis. Next, the anterior stab incisions were made and the drill holes were completed (Fig. 35-27). The osteotomy was completed by utilizing a narrow osteotome between the previously completed drill holes (Fig. 35-28). Provisional fixation was placed across the osteotomy once the deformity was corrected. Stress inversion and eversion and axial calcaneal radiographs were taken to ensure that a hindfoot deformity was not produced and the position was adequate (Fig. 29). The screws were then introduced and guided by the previously described radiographs (Fig. 35-30A). An Evans calcaneal osteotomy was performed to correct her foot deformity and was realigned with allogenic bone graft and wire fixation (Fig. 35-30B). The patient went on to heal and was fully active by 20 weeks.

Figure 35-25. A and B: Valgus is identified at the level of the ankle based on assessment of long leg calcaneal axial and hindfoot alignment radiographs.
**Figure 35-26.** Fluoroscopic guidance is used to place the 5-mm half pin in the distal metaphyseal bone at the level of the CORA.

**Figure 35-27.** Anterior stab incisions are created to allow for percutaneous drill hole placement. Three incisions are the standard.
Figure 35-28. A and B: The osteotome is inserted to complete the osteotomy under image intensification.

Figure 35-29. A and B: Intraoperative stress x-rays were evaluated to ensure that a hindfoot deformity was not produced.
Figure 35-30. A: Screws are placed percutaneously and oriented in a crossing fashion as previously discussed. Note the LDTA has been realigned to normal values. B: The Evans calcaneal osteotomy was also performed to correct the forefoot abductus. It is essential to evaluate the foot position once the ankle is realigned.

CLINICAL TIPS AND PEARLS

1. Perform appropriate preoperative radiographs: These will include ankle (AP and lateral), foot (AP and lateral), long leg calcaneal axial, and hindfoot alignment. Measure the following angles: anatomic axis of the leg, joint orientation angles, center of the ankle and its range of motion, LDTA, ADTA, and CORA.
2. The patient should be in a supine position on the operating room table, with the hip internally rotated so the ankle is in the frontal plane. Use towels or bumps to ensure that the patient’s leg is parallel to the table. This will prevent oblique osteotomies in the frontal plane.
3. Use a Doppler and map out the anterior tibial and posterior tibial arteries and mark their locations with a skin scribe to prevent injury during the procedure.
4. Making the osteotomy: place the half pin and take multiple AP and lateral images to ensure it is 90 degrees to the tibial axis on the AP and lateral views. This is one of the most important steps because the osteotomy is based around this pin. Apply the osteotomy.
guide and with live fluoroscopy determine which hole in the osteotomy guide will allow the osteotomy to be placed in the metaphysis and exit the cortex without invading the joint space. Make approximately three stab incisions and dissect to the periosteum and mobilize the soft tissues. Complete the drill holes in an on-off technique, minimizing bony necrosis from the heat of the drill. Connect the holes with a narrow osteotome. Continually check your alignment between each hole on one plane and make sure you are 90 degrees to the tibia in the opposite plane. This will make a perfect dome in one plane and a consistent osteotomy through and through on the other.

5. Realign the limb and print out radiographs once provisional fixation is placed. Break the assistant's surgical toolbox, and radiographically check the alignment. Make approximately three stab incisions and dissect to the periosteum and mobilize the soft tissues. Complete the drill holes in an on-off technique, minimizing bony necrosis from the heat of the drill. Connect the holes with a narrow osteotome. Continually check your alignment between each hole on one plane and make sure you are 90 degrees to the tibia in the opposite plane. This will make a perfect dome in one plane and a consistent osteotomy through and through on the other.

6. Always remember the soft tissue structures at risk or that are contracted, and surgically manage these when indicated (i.e., tendo-Achilles lengthening or gastrocnemius recession, tarsal tunnel decompression, common peroneal nerve decompression).

CONCLUSIONS

The focal dome supramalleolar osteotomy is relatively simple but requires a detailed preoperative evaluation both clinically and radiographically to ensure success. One's knowledge of the local anatomy coupled with the use of fluoroscopy will enhance the surgical outcome. Because of its percutaneous nature, multiple intraoperative fluoroscopic views decrease the amount of surgical errors that can occur. One should also have a general knowledge of external fixation since it may be necessary to augment or replace the internal fixation since it may be the only viable form of fixation in certain instances. Since there is minimal bone destruction and excellent end-to-end contact, the likelihood of osseous healing is higher. This procedure is an excellent addition to the reconstructive foot and ankle surgeon's surgical toolbox.

REFERENCES

Percutaneous Supramalleolar Osteotomy for Distal Tibial (Near Articular) Ankle Deformities

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Christopher L. Reeves, DPM, MS*

Supramalleolar osteotomies are performed to realign the distal tibia and to improve foot and ankle function. This procedure requires a thorough preoperative and intraoperative understanding of limb-deformity parameters and of the center of rotation of angulation method of surgical planning. Radiographic, gait, and clinical analyses along with intraoperative fluoroscopic images are paramount to deformity correction. This article describes the radiographic and clinical analyses and technical considerations in performing a focal dome supramalleolar osteotomy. (J Am Podiatr Med Assoc 95(1): 72-84, 2005)

Ankle and distal tibial deformities can be complex and may be associated with aberrant pedal mechanics. One must consider the position of the rearfoot, midfoot, and forefoot relative to the tibia when evaluating a patient with a distal tibial deformity. A supramalleolar distal tibial osteotomy may be indicated for talotibial pathology secondary to malunion associated with previous surgery or trauma, physeal arrest, paralytic disorders, tibial torsion, primary and secondary arthritis, and other painful disorders of the talotibial joint. A supramalleolar osteotomy can correct deformities of the distal tibia in all planes: the frontal plane (ankle and tibia varus/valgus), sagittal plane (procurvatum or posterior aligned distal tibial articular surface, recurvatum or anterior aligned distal tibial articular surface), and oblique plane (a combination of frontal and sagittal plane deformities). In addition, this procedure can correct deformities associated with a malaligned ankle arthrodesis. A mild-to-moderate ankle or distal tibial deformity is well tolerated when the rearfoot and midfoot are supple. However, in patients with inadequate compensatory motion (a stiff foot), even small angular deformities may be poorly tolerated.

There are several advantages of a supramalleolar osteotomy over arthrodesis procedures. First and foremost, this is a joint-sparing procedure performed in a juxta-articular region, making it an excellent choice of procedures in the pediatric and adolescent population to correct congenital deformities by avoiding joint fusions. Supramalleolar osteotomy is an alternative to multiple foot surgeries when the deformity is located above, at, or just slightly distal to the level of the ankle joint articulation. Supramalleolar osteotomies are usually wedge-cut, straight-cut, or focal dome osteotomies (Fig. 1). There are specific advantages to the focal dome osteotomy compared with the straight-cut osteotomy, including a lack of thermal necrosis because a bone saw is not used, minimal periosteal dissection (it can typically be performed percutaneously), and an inherent stability owing to excellent bone-to-bone contact.

The focal dome supramalleolar osteotomy follows the center of rotation of angulation method described by Paley. The osteotomy is performed around the radius of the ankle joint center of range of motion or articular deformity; thus it eliminates many positional complications because it accounts for the angular and translational components of a typical opening or...
closing wedge osteotomy performed away from the center of rotation of angulation. The focal dome-supramalleolar osteotomy is reliable, has a large cross-sectional area of bone contact, is stable, and minimizes the lengthening or shortening of the bone. An opening or closing wedge osteotomy performed remote to the center of rotation of angulation will result in translation and, therefore, needs to be realigned once the wedge is completed (Fig. 2). There is typically no need for bone grating or bone wedge removal.

**Indications**

The most common indication for a supramalleolar osteotomy is a foot-ankle equinus deformity or a malaligned weightbearing. These patients often present with chronic pain, which is often exacerbated by activity. Clinical deformities may or may not be evident. The literature is inconsistent regarding the amount of deformity that should be present before corrective surgery. Joint-of states that any deviation from normal is detrimental following distal tibial trauma. Graf et al. state that there should be significant distal tibial deformity before an osteotomy is considered. We base our surgical decision making on clinical signs and symptoms followed by an extensive radiographic assessment of lower-extremity alignment, and we determine whether the malalignment is the causative factor.

Obvious contraindications include impaired neurovascular status and active skin or bone infection. Relative contraindications are determined in the evaluation of the patient’s other concomitant conditions. This procedure requires an extended course of immobilization and non-weightbearing, unless external fixation is used. Patients must be able to tolerate this period of convalescence.

Realignment principles of foot and ankle surgery should ensure that the rearfoot is aligned with the leg and that the forefoot is aligned with the rearfoot. Therefore, comprehensive preoperative and postoperative radiographic and clinical evaluations are paramount to ensure success in managing a patient’s deformities and pathologic entities. Specific angular relationships are critical in appropriately identifying the level of deformity, and intraoperative imaging is necessary to achieve optimal surgical results.

Radiographic assessment should begin with standard anteroposterior and lateral radiographs of the foot and ankle. Additional images are needed to assess the alignment of the rearfoot with the tibia, including long leg calcaneal axial and rearfoot alignment views. These views help identify the level of deformity and can identify any superstructure skeletal malrotation. The long leg calcaneal axial view varies from a standard axial radiograph by its use of a 14 × 17 inch film, and the radiographic projection is aimed at the subtalar joint at 35° cephalad (Fig. 3). This radiograph allows visualization of the subtalar
Deformity Planning

The goal of a realignment procedure is to restore abnormal angles to as close to normal as possible and to realign the center of the ankle joint for proper biomechanical function. Any deviation of the ankle or distal tibia in these planes can result in pain or significant joint destruction of the ankle and adjacent joints.

Distal tibial deformities occur in four basic planes: frontal, sagittal, oblique, and rotational; the focal dome osteotomy is ideal for frontal and sagittal plane deformities. In the frontal plane of the distal tibia, the ankle joint orientation line is perpendicular or in slight valgus to the midshaft of the tibia. The joint orientation line of the ankle and the anatomical axis of the tibia make an angle that measures $89^\circ \pm 9^\circ$. This angle is known as the lateral distal tibial angle.
Figure 3. Patient positioning for the long leg Salter-Harris radiograph. The x-ray beam is directed at 45° to the posterior aspect of the calcaneus, and the x-ray cassette is placed flat on the floor.

Figure 5. Patient positioning for the posterior alignment (Cohey/Salzmann) radiograph. The x-ray cassette is centered at 45° from vertical. The x-ray beam is oriented perpendicular to the x-ray cassette.

(Fig. 3). The anterior distal tibial angle, located by the mechanical axis of the tibia and the joint orientation line of the ankle in the sagittal plane, measures 80°-90° in the normal lower extremity (Fig. 3). An increased anterior distal tibial angle represents a reposition deformity. A decreased anterior distal tibial angle represents a progression deformity.

In the sagittal plane of the leg, ankle joint motion is usually 30° of dorsiflexion and 90° of plantar flexion. Therefore, a reposition deformity is much more likely to be completely compensated for than a progression deformity because of the amount of compensatory motion available at the ankle (Fig. 3). Progression deformities occur in varus or valgus.

Figure 4. Long leg-horizontal axial radiograph demonstrating the relationship of the calcaneus to the leg and good visualization of the subchondral space.

Figure 6. Repeated alignment radiograph showing less clear evaluation of the ankle joint orientation to the long axis of the tibia.

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Figure 7. The lateral distal tibial angle (LDTA) is the lateral angle formed by the anatomical axis of the tibia and the ankle joint orientation line. Normal values range from 86° to 92°.

Figure 8. The anterior distal tibial angle (ADTA) is the anterior angle formed by the mid-diaphyseal line of the tibia and the ankle joint orientation line. Normal values range from 77° to 83°.

Figure 9. Ankle joint ossification and plaster fixation compensation for procurvation and recurvation deformities. A, Normal ankle or recurvation deformity (decreased anterior distal tibial angle [ADTA]) allows increased motion in the dorsiflexory direction; thus no impingement is created. B, Procurvation deformity (increased ADTA) allows decreased range of motion and anterior ankle impingement. C, The patient better tolerates recurvation deformities because no impingement symptoms are created, but shear forces created by the deformity lead to rapid joint degeneration. Procurvation deformities are less well tolerated because of impingement pain, but they degenerate less. ADTA, anatomical anterior distal tibial angle.
In the radiographic evaluation of tibial deformities, distal and proximal and distal tibial lines of the deformity cross to form an apex. This point is the center of rotation of angulation (Fig. 11). The goal of angular correction is to perform osteotomies as close as possible to the level of the center of rotation of angulation, thus minimizing translation. Performing osteotomies away from the center of rotation of angulation will result in correction of the primary deformity but will also cause a secondary translation, resulting in additional deformities in the lower extremity.

When the center of rotation of angulation falls at the level of the ankle joint, a focal bone osteotomy can be performed to minimize translation by centering the focal dome around the center of rotation of angulation using a radial arm, proximally so that the osteotomy can be performed in the metaphyseal bone (Fig. 11).

Adjacent soft-tissue structures must be evaluated. Acute correction of these deformities can place stress on soft-tissue structures, especially the posterior tibial nerve. Acute tibial tunnel syndrome can be
Figure 11. Example of the center of rotation of angulation (CORA) forming proximal to the ankle joint. This point is found by connecting the proximal and distal portions of the tibia.

Figure 12. Example of the center of rotation of angulation (CORA) forming at the level of the ankle joint. Once it is found that there is an abnormal anterior distal tibial angle or lateral distal tibial angle (LDTA), a line forming a normal angle can be drawn in relation to the joint line. The point where this normal line intersects the mid-diaphyseal line is the CORA. This is an appropriate deformity for a focal dome ostectomy.

A septum of an acute varus or procurvatum correction (Fig. 10). A prophylactic talar tunnel release should be considered when performing acute corrections. Severe deformities may require gradual correction through distraction osteogenesis to prevent neurologic or vascular compromise.

Surgical Technique

The patient is placed in the supine position. A pump is placed under the ipsilateral hip until the surgical limb is oriented with the tibial shaft in the frontal plane. The anterior tibial and distal peroneal arteries are identified using a handheld Doppler device and are outlined using a skin marker. Often, the deep peroneal nerve is estimated and mapped as well for orientation. General or spinal anesthesia is typically used, and a single tourniquet may be considered for hemostasis but is not frequently used owing to the peroneal-nerve course of the procedure. The lower extremity is surgically prepared and draped up to the knee. The talar tunnel release is performed first, if indicated.

Correction of Varus or Valgus Deformity

A stab incision is made lateral to the artery. Under image intensification, an appropriate half-pin is placed from anterior to posterior perpendicular to the long axis of the tibia (in the frontal and sagittal planes), which is visualized with anteroposterior and lateral fluoroscopic images. The pin is placed as near to the center of rotation of angulation as possible in the distal metaphyseal region of the tibia (Fig. 14). This pin serves as the center of rotation for the ostectomy. When the center of rotation of angulation falls at the ankle joint, the pin is placed a few millimeters proximal to the ankle joint. This proximal placement of the half-pin may create slight translation, but it is usually minimal and has little effect on the foot. A radial lever arm guide is then applied to the half-pin to serve as the ostectomy template (Fig. 15). We use a Sanders Cube (Smith & Nephew, Memphis, Tennessee; or DePuy/ACR pin holder, Warsaw, Indiana) as the radial arm guide. A standard femoral plate can also be considered as the radial arm guide when other equipment is unavailable. The guide hole and ostectomy level is selected on the basis of the ability of the ostectomy to exit the medial and lateral cortices of the tibia. One must visualize the ostectomy under fluoroscopic imaging to ensure that the ostectomy will exit both talus cortices in the metaphyseal region of the bone and to avoid violating the ankle joint articulation. Multiple perpendicular incisions (typically three) are created, taking
A acute bicipital-trochlear compression can lead to posterior tibial nerve compression secondary to the posterior bump of the distal tibia. Acute peroneal-trochlear compression can lead to posterior tibial nerve stretching or compression secondary to the medial bump created by the distal tibia. LDTA, lateral distal tibial angle. (Reprinted with permission from Paley D.)

To avoid neurovascular structures (Fig. 16), a periosteal incision is then created to allow for this tissue's protection while drilling. A drill guide is placed in the lateral area to protect the soft-tissue structures. Multiple perforations drill holes are placed from anterior to posterior at the incision sites. Usually two to three drill holes are made through each incision. These holes form a domino appearance based around the center of the defect (Fig. 17). An osteotome is then placed into the percutaneous incisions, and the osteotomy is completed in a slow, methodical manner from medial to lateral and anterior to posterior, essentially “connecting the dots” of drill holes. The osteotome should be narrow and essentially features the hom between the drill holes. The osteotomy is examined by fluoroscopy and is stressed both medially and laterally to ensure that the osteotomy is complete.

Figure 11: The pin is placed as distally as possible in the metaphyseal bone and as close to the center of rotation of the fragment as possible.

Figure 12: The lever arm is applied to the iliacpin to serve as the retractor guide.
Once the tibial osteotomy is complete, a fibular osteotomy may need to be performed to achieve all of the appropriate correction. When the fibular osteotomy is indicated, an incision of a few millimeters is made over the lateral aspect of the fibula near the level of the tibial osteotomy. A linear lateral percutaneous incision is then made on the fibula and dissected anteriorly and posteriorly with a periosteal elevator. An osteotomy of the fibula is performed with a sagittal saw oriented from proximal anterior to distal posterior (always in the sagittal plane) (Fig. 18).

The foot and ankle distal to the osteotomy is then manipulated and rotated in a varus or valgus direction (the direction to correct the deformity). This maneuver is performed under image intensification. The osteotomy is rotated until a normal lateral distal tibial angle is obtained. The tibial osteotomy is located using two 6.5- or 8.0-mm partially threaded cannulated crossing screws. One screw is inserted from medial distal to proximal lateral, entering at the medial malleolus, and the other from anterior proximal to distal posterior, entering the tibia proximal to the osteotomy (Fig. 19). The fibular osteotomy is fixed with one or two 4.0-mm screws from anterior to posterior.

The entire lower extremity is then evaluated under image intensification (long leg calcaneal, axial and rearfoot alignment views) to ensure alignment of the ankle with the tibia, the rearfoot with the ankle/tibia, and the forefoot with the rearfoot. The ankle joint should be taken through its range of motion to ensure that a deformity has not been created and that there is adequate motion (Fig. 20). Additional procedures, such as calcaneal and metatarsal osteotomies, are sometimes necessary to achieve appropriate alignment. External fixation may be warranted in lieu of internal fixation as the primary means of fixation or to augment the internal fixation. This decision is made on a case-by-case basis and is influenced by several factors, including confidence in the adequacy of the initial internal fixation and the patient’s ability to tolerate non-weightbearing. It is important to note that if external fixation is to be used, it is easier to
perform the osteotomy and tendinous release with their respective soft tissues and skin closure before application of the fixator. During closure, temporary fixation with wires or pins can be used to stabilize the osteotomy until the fixator can be placed. In extremely severe deformity, gradual correction may be considered. Gradual correction is obtained by use of the Ilizarov method or the Taylor Spatial Frame (Smith & Nephew). Description of these techniques is beyond the scope of this article, and they should be performed only by surgeons experienced with the Ilizarov technique.

Correction of Recurvatum or Procurvatum Deformity

Correction of procurvatum and recurvatum deformity is performed in a similar manner (Fig. 21). The

Figure 19. Anteroposterior (A) and lateral (B) ankle radiographs demonstrating screw fixation and post-surgical determination of the anterior distal tibial angle (ADTA).

Figure 20. Radiographs showing stress evasion (A) and stress inversion (B) demonstrating normal subtalar range of motion after surgical correction.
The ostectomy is completed posteroanteriorly with an osteotome. The ostectomy of the tibia is oriented from distal lateral to proximal medial in the sagittal plane when indicated. Occasionally, a wedge of bone may need to be removed in a reciprocating manner from the fibula to obtain adequate bone-to-bone contact when rotating the tibia anteriorly or posteriorly. The osteocutaneous segment is rotated until the interior distal tibial angle is in its normal anatomical position. Fibra-

Figure 2. A–D. Lateral (A and B) and anteroposterior (C and D) radiographs showing a procurvatum deformity. LDTA, lateral distal tibial angle; ADTA, anterior distal tibial angle. (Figure continues on next page.)
tion is performed as described previously. Ankle joint, dorsiflexion and plantarflexion are evaluated to ensure that the range of motion is adequate. A brace with iliobial band taping or gastrocnemius recession may be necessary in precurvatum cases to achieve this range of motion owing to its contracture.

**Postoperative Management**

The patient is placed in a short-leg non-weightbearing cast for approximately 4 to 6 weeks, when internal fixation is used across. Serial radiographs are taken to evaluate the osteotomy for healing. Progressive partial weightbearing is permitted when radiographs demonstrate that the osteotomy is healed. The same criteria are used for determining the time of removal of the brace when external fixation is used. Progression to controlled weightbearing in a rocker-bottomPlaster boot usually begins for 2 to 3 weeks. The physician must evaluate the need for physical therapy, as this is often necessary to maintain range of motion of the foot and ankle and to strengthen and retrain the lower leg musculature. Activity is then gradually increased on the basis of each patient's progress.

**Complications**

Complications can include necrosis of the tibial or talar osteotomy site, but this is rare because of the location of the osteotomy and its minimal periosteal disaster or bony loss. Adequate fixation and skin apposition of the osteotomy site are essential to avoiding angulation.

Nerve traction or entrapment is a potential complication with acute corrections. A prophylactic tarsal tunnel release is performed to eliminate this problem, or gradual correction may be considered.

Additional complications may include edema, which may be controlled with compression therapy. Wound dehiscence is rare with this percutaneous approach. Pseudoarthrosis is not uncommon when using external fixation and are managed with local wound care, daily cleansing of the pin sites, and antibiotics. Again, the percutaneous nature of this specific procedure decreases the complication rate relative to more traditional approaches.

**Conclusion**

The local form supramalleolar ostectomy is a relatively simple procedure, but requires a detailed preoperative evaluation, clinically and radiographically, to ensure success. Knowledge of the local anatomy and precise intraoperative imaging-intensification techniques enhance surgical success.

External fixation may be necessary either as a supplemental or a primary form of fixation. Therefore, a thorough knowledge of external fixation application and principles is essential.

This osteotomy is performed in the metaphysis.
region of bone and has an excellent healing rate, minimal bone and periosteal dissection or destruction, and stable bone-to-bone contact. This is an excellent procedural addition to the reconstructive foot and ankle surgeon's armamentarium.

**References**


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my name is robert raines, MD. i work in cincinnati. i am an orthopaedic surgeon who specializes in foot and ankle surgery. i have 22 years of clinical experience, both in private practice and as head of foot and ankle surgery at the cincinnati VA hospital. i am qualified to comment on this proposal.

I oppose permission of both requested procedures based on the reality that a surgeon should be sufficiently trained to handle any complication of a procedure her/she performs. Podiatrists do not get experience with the knee or distal tibia. they cannot rod tibias for fractures and cannot operate on knees. and for good reason. their training is not sufficient to allow them to safely operative in these areas. therefore, I oppose the suggestion that podiatrists a qualified to operate in these areas. this is not safe for our ohio patients. there are plenty of orthopaedic surgeons qualified to perform these procedures, so excluding podiatrists will not inconvenience our patients. thank you

robert raines

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Dear Ms. Anderson:

As a physician also licensed in the State of Ohio, I would like to comment on the proposed scope of practice consideration for podiatrists, specifically: “Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?” My response is, No.

Bone marrow aspirates from the tibia are typically only performed in younger children (eg, under 2 years of age) in order to assess/diagnose hematological disorders (eg, leukemia, lymphoma, etc). In older children and adults the tibia is not a good source for bone marrow and bone marrow aspirates are typically performed from the posterior iliac crest. Since podiatrists do not have expertise in examining the bone marrow for hematological disorders it is unclear to me why they would be performing this procedure. I can only surmise that they are wanting to perform bone marrow aspiration, not for diagnostic reasons (where they lack knowledge and expertise), but in order to procure bone marrow stem cells (hematopoietic stem cells) for use/injection in a wide range of purported therapies.

The attached “white paper”, or review, was performed by the Federation of State Medical Boards (FSMB) in 2017-18. I was a member of this working group. Our investigation found that there were/are many questionable uses for hematopoietic stem cells (HSC). The use of HSC should only be done under strict research protocols and by physicians with the requisite knowledge and expertise in cellular therapies. Podiatrists lack this expertise and should not be in the business of harvesting bone marrow for unproven therapeutic reasons.

As background, I was trained in Internal Medicine (St. Luke’s Hospital, Cleveland, OH), completed one year of fellowship in Hematology/Oncology (Ohio State, Columbus), completed a residency in Clinical Pathology (Laboratory Medicine) (Ohio State), and I am board-certified in Internal Medicine, Clinical Pathology, and Blood Banking/Transfusion Medicine. Currently, I am the Medical Director of Therapeutic Apheresis and the Hematopoietic Stem Cell Collection Unit/Program here at Penn State Hershey Medical Center/College of Medicine. In addition, I am the Vice Chair of the Pennsylvania State Board of Medicine. Please do not hesitate to contact me with any additional questions. Thank you.

Ron Domen

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Regenerative and Stem Cell Therapy Practices

Report and Recommendations of the Workgroup to Study Regenerative and Stem Cell Therapy Practices

Adopted as policy by the Federation of State Medical Boards
April 2018

Section One. Introduction and Charge:

The Federation of State Medical Boards (FSMB) Workgroup to Study Regenerative and Stem Cell Therapy Practices was convened in May of 2017 by FSMB Chair Gregory B. Snyder, M.D., DABR, in response to a letter (Attachment 1) from U.S. Senator Lamar Alexander (R-TN), Chairman of the U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee, urging the FSMB to develop best practices for state medical and osteopathic boards (hereinafter referred to as “state medical boards”) in regulating the promotion, communication, and practices of treatments received at stem cell clinics in the United States.

In order to address Senator Alexander’s request, Dr. Snyder charged the Workgroup with:

1) Evaluating the prevalence, promotional practices, and incidences of patient harm related to regenerative medicine and adult stem cell therapies in the U.S.;

2) Evaluating current regulatory approaches that will protect the public, recognizing the potential for improved patient outcomes through health innovation and technology;

3) Identifying best practices for state medical and osteopathic boards in investigating complaints of patient harm, fraud, and compliance with licensure requirements; and

4) Issuing a report on the Workgroup’s findings from prevailing research and recommending best regulatory practices and guidelines related to physicians’ use of regenerative medicine and adult stem cell therapies in a manner consistent with safe and responsible medicine.

Stem cell and regenerative therapies offer opportunities for advancement in the practice of medicine and the possibility of an array of new treatment options for patients experiencing a variety of symptoms and conditions. Despite significant momentum in research and development, and the potential for such medical advancements, there is reasonable concern about a growing number of providers and clinics in the United States that are undermining the field. Such providers and clinics have been known to apply, prescribe or recommend therapies inappropriately, over-promise without sufficient data to support claims, and exploit patients who are often in desperate circumstances and willing to try any proposed therapy as a last resort, even if there is excessive cost or scant evidence of efficacy.
The following report aims to raise awareness about regenerative and stem cell therapy practices generally, outline their potential benefits and risks, and provide basic guidance for state medical boards and licensed physicians and physician assistants. Central to all of the recommendations provided herein is a range of imperatives, including the importance of protecting the public, respecting patient autonomy, preventing patient exploitation, obtaining informed consent, and appropriately documenting care that is recommended and provided.

The Workgroup’s deliberations were aided by participants and subject matter experts who brought varying perspectives. For example, Dr. Ronald Domen has expertise in stem cell therapies, bioethics and humanities, and has served on numerous ethics committees at institutional, state, and national levels. Dr. Zubin Master of the Mayo Clinic has extensive training and education in cellular and molecular biology, bioethics and genetics, as well as research and publications on stem cell therapies. Mr. Douglas Oliver became known to the Workgroup through a recommendation by Senator Lamar Alexander of Tennessee, was a recipient of stem cell therapies himself, and has a foundation that advocates for stem cell therapies based on his own experiences and those of others like him. Dr. Bruce White has educational backgrounds in medicine, law, pharmacy and ethics and currently serves as Director of the Alden March Bioethics Institute at Albany Medical College and is Chair of Medical Ethics at the College. The Workgroup also received written comments from several external organizations. The sum of these perspectives aided the Workgroup in producing a balanced report on this emerging issue of national importance.

Section Two. Definitions:

Homologous (Allogeneic) Use: the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with a HCT/P (human cells, tissues, and cellular and tissue-based product) that performs the same basic function or functions in the recipient as in the donor, including when such cells or tissues are for autologous use.¹

According to the Food and Drug Administration’s (FDA) Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use / Guidance for Industry and Food and Drug Administration Staff (November 2017), the FDA “generally considers an HCT/P to be for homologous use when it is used to repair, reconstruct, replace, or supplement:

• Recipient cells or tissues that are identical (e.g., skin for skin) to the donor cells or tissues, and perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor; or
• Recipient cells or tissues that may not be identical to the donor’s cells or tissues, but that perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor.”²

¹ 21 CFR 1271.3(c)
Autologous Use: the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.³

Informed and Shared Decision Making: The process by which a physician discusses, in the context of the use of regenerative and stem cell therapies, the risks and benefits of such treatment with the patient.⁴ The patient is given an opportunity to express preferences and values before collaboratively evaluating and arriving at treatment decisions.⁵

Informed Consent:⁶ Evidence documenting appropriate patient informed consent typically includes the following elements:

- Identification of the patient, the physician, and the physician’s credentials;
- Types of transmissions permitted using regenerative and stem cell therapies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement from the patient with the physician’s determination about whether or not the condition being diagnosed and/or treated is appropriate for regenerative and stem cell therapy;⁷ and
- Express patient consent to forward patient-identifiable information to a third party
- An accurate description of the benefits and risks of treatment or intervention, based on scientific evidence, as well as an explanation of alternatives to treatment or an intervention, and the right to withdraw from treatment or an intervention without denial of standard of care to patients.

Minimal Manipulation: (minor processing including purification, centrifugation, washing, preservation, storage) – the Food and Drug Administration (FDA) argues that it has the authority to regulate anything beyond minimal manipulation and homologous use:
“(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement; and
(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.”⁸

Unproven Stem Cell Intervention: Stem cell therapy that lacks compelling evidence, based upon scientific studies, to validate its treatment efficacy.⁹

³ 21 CFR 1271.3(a)
⁶ With respect to informed consent for the purposes of research studies involving human subjects, researchers should be aware of the basic elements of informed consent outlined in 21 CFR Part 50.25 “Protection of Human Subjects.”
⁷ Federation of State Medical Boards (2014). Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.
⁸ 21 CFR 1271.3(f)
Section Three. Background, Prevalence and Marketing of Regenerative and Stem Cell Therapies:

Historically, many of the clinics providing unproven stem cell interventions fell under the definition of “stem cell tourism” because most patients seeking such interventions had to travel outside of North American jurisdictions to receive them. The landscape in the United States has evolved considerably over the last few years with hundreds of new clinics opening across the country and many more physicians willing to provide stem cell and regenerative therapies. A study identified 351 U.S. businesses with over 570 clinics engaged in direct-to-consumer (DTC) marketing of stem cell interventions.\textsuperscript{10} It has also been suggested that growth in this area of medicine, especially in terms of adult, amniotic, fat-derived and bone marrow stem cell therapies to treat a host of conditions and injuries, is accelerating, both in the U.S. and internationally, and, perhaps counterintuitively, such growth is noted to be most significant in jurisdictions with more stringent regulatory frameworks.\textsuperscript{11}

Stem cell clinics typically reach their patients through online DTC marketing, primarily through information provided on company websites. Data purportedly supporting unproven stem cell interventions commonly undermine information about risks and overemphasize information about benefits. Treatment options are described on such websites and are often accompanied by supporting information in the form of journal articles, patient testimonials, and accolades related either to the clinic itself or its affiliated physicians and researchers. Supporting information that accompanies marketing materials can appear to be legitimate, but can also overemphasize, exaggerate, inflate, or misrepresent information derived from legitimate (or even questionable) sources. A physician engaging in such practices of deceptive or false advertising can be in violation of a state’s \textit{Medical Practice Act}. Information provided on clinic websites should be represented accurately and come from reputable peer-reviewed publications or respected external organizations.

Some clinics, however, that are engaged in the provision of treatment modalities that lack evidence – or an appropriate rationale for application of that modality to particular medical conditions – often use what have been described as “tokens of scientific legitimacy” to lend credence to treatments offered or the quality of a clinic and its associated professionals. Examples of such tokens of legitimacy include patient or celebrity testimonials and endorsements, clinician affiliations or memberships in academic or professional societies, registrations in clinical trials, claims of various types of certifications or awards, and others.\textsuperscript{12} Further detail and explanations are provided in Table 1.

Physicians are ordinarily permitted to advertise themselves, their practice and services offered, provided that such advertisements do not contain claims that may be deceptive or are intentionally false or misleading. Further, physicians should be mindful of ways in which patient

testimonials, quality ratings, or other evaluative data is presented to prospective patients through advertisements. In advertising stem cell treatments to potential patients, physicians are responsible for ensuring that all information, especially in terms of risks, benefits and efficacy, is presented in an objective manner. Physicians must not deliberately misrepresent the expected outcomes or results of treatments offered. Physicians should be prepared to support any claims made about benefits of treatment(s) with documented evidence, for example with studies published in peer-reviewed publications.\textsuperscript{13}

Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients. This includes descriptions of one’s specialization and any specialty board certifications.\textsuperscript{14}

A recent study on the prevalence and marketing practices of businesses offering stem cell treatments internationally noted the presence of the following elements in their marketing practices:

- Mention of affiliations with a professional society or network
- Claims of partnerships with academic institutions
- Statements of receipt of FDA approval, or explicit mention of exemption from FDA oversight
- Mention of official endorsement from a local or other authority, or professional accreditation
- Listing of patents granted
- Statement that clinical trials of investigational stem cell-based interventions are being conducted\textsuperscript{15}

The marketing practices and information found on a business’ website can be important sources of data for state medical boards as they investigate complaints made against physicians affiliated with businesses providing regenerative and stem cell treatments. Even where an appropriate informed consent process seems to be in place, deceptive or fraudulent information on clinic websites and other marketing materials could mislead patients into consenting to treatment, thereby invalidating the informed consent process.

Physicians must make accurate claims about the enrollment process of subjects, treatments, and products in clinical trials and are responsible for ensuring that any research conducted and described in marketing materials is carried out according to accepted research protocols and recognized standards. Physicians should consider consulting with Institutional Review Boards (IRBs) to clarify processes and must seek IRB approval, where necessary. The National Institutes of Health (NIH) provides helpful guidance on clinical trials and research methods.\textsuperscript{16} Physicians are also encouraged to consult the guidance contained in the International Conference

\textsuperscript{13} Federation of State Medical Boards (2016). \textit{Position Statement on Sale of Goods by Physicians and Physician Advertising.}
\textsuperscript{14} Ibid.
\textsuperscript{16} National Institutes of Health, Office of Science Policy: https://osp.od.nih.gov/clinical-research/clinical-trials/
on Harmonisation’s Harmonised Tripartite Guideline for Good Clinical Practice to support acceptability of clinical data by patients, state medical boards, and other regulatory authorities.\textsuperscript{17}

\textbf{Table 1: Co-opted Tokens of Scientific Legitimacy}\textsuperscript{18}

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<td>Boards and advisers</td>
<td>Convening scientific or medical advisory boards featuring prominent business leaders and academic faculty members</td>
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<tr>
<td>Clinical study registration</td>
<td>Registering trials whose apparent purpose is solely to attract patients willing to pay to participate in them</td>
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<tr>
<td>Ethics review</td>
<td>Using the imprimatur of “ethics review” to convey a sense of legitimacy to their products or procedures</td>
</tr>
<tr>
<td>Location</td>
<td>Renting of laboratory or business space within a legitimate scientific or government institution</td>
</tr>
<tr>
<td>Membership</td>
<td>Joining established academic or professional societies to suggest legitimacy by association</td>
</tr>
<tr>
<td>Outcome registries</td>
<td>Publication of open-ended voluntary monitoring data sets rather than undertaking controlled clinical trials</td>
</tr>
<tr>
<td>Patenting</td>
<td>Suggesting that patent applications or grants indicate clinical utility rather than initiation of an application process or recognition of novelty and inventiveness</td>
</tr>
<tr>
<td>Publication</td>
<td>Publishing research and commentary in journals with limited anonymous peer review</td>
</tr>
<tr>
<td>Rationales</td>
<td>Citing preclinical and other research findings to justify clinical application without sufficient efficacy testing in humans</td>
</tr>
<tr>
<td>Self-regulation</td>
<td>Forming organizations to self-regulate in ways that support premature commercialization</td>
</tr>
<tr>
<td>Technical Language</td>
<td>Using scientific-sounding words that imply academic rigor</td>
</tr>
<tr>
<td>Testimonials and Endorsements</td>
<td>Providing expert opinions or celebrity comments on unsupported clinical uses or standing of the provider</td>
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\textbf{Section Four. Patient Perceptions:}

In seeking treatment for any condition, patients desire safety and efficacy, but may overlook risks to their own safety or a lack of evidence of efficacy in favor of access to treatment, particularly in circumstances where traditional treatment options seem limited or have been exhausted. The power of hope also is known to play a significant role in how patients attempt to gain control over their illness and its potential treatments, thereby putting them in a position of

\textsuperscript{17} International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (2016). ICH Harmonised Tripartite Guideline for Good Clinical Practice E6\textsuperscript{R2}.
increased vulnerability.\textsuperscript{19} This is especially the case when patients and their families have overcome various obstacles on the path to a treatment, including raising large sums of money to pay for it. This can lead to a psychological predisposition to anticipate and assume a positive outcome, regardless of the treatment in question or the availability of compelling evidence.

Given the vulnerable state of some patients who seek regenerative and stem cell therapies, perhaps without the requisite knowledge for making informed decisions, there is increased potential for patient exploitation. Physicians must therefore be mindful of the ways in which at-risk or susceptible patients may process information and arrive at decisions about their treatment options, expectations, and ultimately, the potential for success. A promising way of navigating such difficult circumstances, where treatment options are uncertain or complex, is through the use of shared decision making. This process, whereby the physician describes the risks and benefits of potential treatment options and the patient is given an opportunity to express preferences and values before collaboratively arriving at and evaluating treatment decisions,\textsuperscript{20} may help mitigate the risk of patient exploitation and ensure that consent to any treatment option has been provided in an informed manner.

The process of obtaining informed consent and engaging in shared decision making with patients involves conveying information about the reasonable effectiveness of a proposed treatment, as well as its risks and benefits. This can be particularly difficult with respect to regenerative and stem cell therapies, as this is an area of medicine that currently lacks substantive data on efficacy. Generation of relevant data and evidence has not occurred to a sufficient enough degree and this is often blamed on the difficulty involved in organizing large-scale, randomized controlled trials as part of the approval process for novel therapies. However, the FDA has recently argued that a statistically significant 100\% improvement in an outcome measure ($\alpha = 0.05$, $\beta = 0.1$) may be detected with a randomized trial involving as few as 42 participants.\textsuperscript{21}

The lack of a formal mechanism for reporting outcomes of unproven stem cell interventions, both positive and negative, adds to the difficulty involved in generating data on the effectiveness of such interventions, as does the fact that there is neither a requirement, nor a mechanism, for reporting adverse events related to interventions administered outside of clinical trials and investigations. In the current environment, this increases the importance of appropriate documentation of treatment(s) and ongoing care in patients’ medical records. A centralized cell therapy registry for reporting treatment and outcomes may improve the current information available about the effectiveness of such therapies and interventions. It may also dissuade unscrupulous practitioners from engaging in the provision of unproven interventions without an adequate or appropriate basis in theory or peer-acknowledged practice, a pre-requisite for the provision of any intervention, whether proven or not.\textsuperscript{22}

Section Five. Regulatory Landscape:

The current state of affairs for regulatory oversight on regenerative and stem cell therapies (including human cells and tissues), at both the federal and state level, is evolving and will continue to change in the coming years. In November 2017, the FDA released two guidance documents to explain the Agency’s current thinking on stem cell policy. However, this thinking, as well as the agency’s jurisdiction and authority, may evolve in the future.

Until recently, the regulatory landscape for stem cell and regenerative therapies has been at times restrictive, allowing patients to access stem cell interventions only under the Expanded Access to Investigational Drugs for Treatment Use program. Treatments are eligible under this program if they are undergoing testing in a clinical trial and are subject to approval by the FDA. Three-quarters of the states in the nation have passed “Right to Try” legislation, however, which allows terminally ill patients to receive experimental therapies that have passed phase 1 trials without seeking FDA approval. The U.S. Congress is also considering similarly proposed legislation and in August of 2017, the U.S. Senate passed S. 204, Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017.

The 21st Century Cures Act (Public Law 114–255), signed into law in December of 2016, represents legislative efforts at the federal level to expand and accelerate patient access to treatment, in addition to promoting innovation in medical products and treatments. With respect to regenerative medicine, the Act amends Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) by requiring expedited review for regenerative medicine therapies, including human cells and tissues, intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, where there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs. There are also ongoing efforts at the federal level to ensure even greater access to treatments that are not subject to FDA approval prior to administration to patients.

Regulation in the regenerative and stem cell therapy arena is continuing to evolve. Human cells, tissues, and cellular or tissue-based products (HCT/Ps) are currently regulated under Sections 351 and 361 of the Public Health Service Act. However, a HCT/P can be regulated solely under Section 361 of the PHS Act if it is:

1. Minimally manipulated,
2. Intended for homologous use only,
3. Not combined with another article, and
4. Either:
   a. Does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

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23 Lancet Commission: Stem Cells and Regenerative Medicine. Published Online October 4, 2017 http://dx.doi.org/10.1016/S0140-6736(17)31366-1
24 The Public Health Service Act of 1944 outlines a policy framework for federal and state cooperation in health services and provides for the licensing of biological products.
b. Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is for autologous use, use in a first or second-degree blood relative, or reproductive use.\textsuperscript{25}

The difference between an HCT/P that is regulated under both sections of the Public Health Service Act, as opposed to solely under Section 361, is significant for providers of stem cell treatments since the requirements for pre-market authorization of a product are much more stringent under Section 351 and require conducting clinical investigations under an investigational new drug (IND) application and obtaining a biologics license through the FDA, whereas requirements under Section 361 focus only on the prevention of communicable diseases.\textsuperscript{26} This represents a lower regulatory threshold for HCT/Ps; their use and transplantation can be considered to fall under the practice of medicine and would, therefore, be regulated by state medical boards.

In regulating this evolving area of medical practice, state medical boards will need to strive to achieve an appropriate balance between respecting the autonomy of patients as they seek viable and reasonable treatment options, and adequately safeguarding them against the risks presented by novel, but often unproven and potentially dangerous, interventions. Results from a 2017 survey of its member boards conducted by the FSMB indicate that a third (n = 17) of the 51 responding boards have investigated complaints against physicians related to regenerative medicine or stem cell therapy, and that eight of those boards have taken disciplinary action against physicians for issues relating to regenerative medicine or stem cell therapy.

In ensuring that physicians offer regenerative and stem cell therapies in a manner that is consistent with safe and responsible practices, state medical boards should ensure that any treatment offered to patients is informed by an appropriate history and physical examination; such informed consent is obtained after an explanation has been provided describing risks, benefits, alternative treatment options, expected convalescence, and expected treatment outcomes; that relevant information about the clinical encounter and ongoing care plans has been documented in the patient’s medical record; that the physician is appropriately trained in, and knowledgeable about the proposed treatment; and that the patient has not been coerced in any way into receiving treatment(s) or exploited through the charging of excessive fees.

In order to implement best practices for regenerative and stem cell therapies, physicians must understand the relevant clinical issues and should obtain sufficient targeted continuing education and training.\textsuperscript{27}

The recommendations in the final section of this report provide further detail on various requirements that apply to the provision of regenerative and stem cell therapies that state medical boards may wish to consider.

\textsuperscript{25} 21 CFR 1271.10(a)
\textsuperscript{26} United States Food and Drug Administration: Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use
\textsuperscript{27} Federation of State Medical Boards (2017). \textit{Guidelines for the Chronic Use of Opioid Analgesics}.
Section Six. Recommendations:

The recommendations that follow address the regulation of the provision of stem cell and regenerative therapies, as well as their promotion and communication to patients, and documentation of treatments provided. The recommendations do not address which uses are appropriate or not for specific conditions or symptoms, as this area of medicine continues to be dynamic and subject to change. Rather, they focus on sensible and necessary principles of patient safety, autonomy, and non-exploitation.

The FSMB recommends that:

1. Where evidence is unavailable for a particular treatment in the form of clinical trials or case studies, physicians must only proceed with an appropriate rationale for the proposed treatment, and justification of its use, in relation to the patient’s symptoms or condition. Novel, experimental, and unproven interventions should only be proposed when traditional or accepted proven treatment modalities have been exhausted. In such instances, there must still be a basis in theory or peer-acknowledged practice.  

2. State medical boards raise awareness among licensees of applicable federal and state legislation and guidelines regarding regenerative and stem cell therapies, including “right to try” legislation existing or pending at the state and federal levels. State medical boards should also keep their licensees and the public apprised of new developments and regulations in the field of regenerative and stem cell therapies. This may include educational resources, guidance documents, and appropriate industry and stakeholder information on a state medical board’s website. State medical boards should further provide information as to reporting procedures of adverse actions related to stem cell interventions.

3. State medical boards should examine their policies and rules addressing informed consent and consider expanding these to include a shared decision making framework that includes the following general elements at a minimum:
   - An explanation, discussion, and comparison of treatment options with the patient
   - An assessment of the patient’s values and preferences
   - Arrival at a decision in partnership with the patient
   - An evaluation of the patient’s decision in partnership with the patient

4. State medical boards should review professional marketing materials and claims, including any office/clinic and/or doctor websites, and information publicly available about an office/clinic or licensee on online blogs or social media, as information sources in the investigation of complaints made against physicians.

5. State medical boards should pro-actively monitor warning letters sent to licensees that are made publicly available on the FDA website in order to ascertain information, and consider opening an investigation, about licensees who may be engaged in other unscrupulous or

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unprofessional practices related to the provision of regenerative and stem cell therapy. State medical boards should investigate such practices, when appropriate, in conjunction with applicable state laws, policies, and procedures.29

6. Physicians must only offer treatments to patients for which they have a bona fide physician-patient relationship. Physicians must have received adequate and appropriate training, and be able to perform any proposed intervention safely and competently.30

7. Physicians should employ a “shared decision making” process when discussing treatment options with patients. Physicians must avoid any claims that may be deceptive or are intentionally or knowingly false or misleading, especially in terms of making promises about uncertain or unrealistic outcomes.

8. Physicians should not use gag orders (rulings that a case must not be discussed publicly) or disclaimers as a way to circumvent liability.

9. Physicians should be prepared to support any claims made about benefits of treatments or devices with documented evidence, for example with studies published in peer-reviewed publications.

10. Physicians should refrain from charging excessive fees for treatments provided. Further, physicians should not recommend, provide, or charge for unnecessary medical services, nor should they make intentional misrepresentations to increase the level of payment they receive.31

11. Physicians should consult and educate patients about stem cell interventions and alert them to important resources available to the community. A list of selected resources is provided in Appendix A.

29 The FDA’s warning letters are available at the following address: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
30 Federation of State Medical Boards (2014). Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.
31 American Medical Association, Code of Medical Ethics, Opinion 11.3.1.
WORKGROUP TO STUDY REGENERATIVE AND STEM CELL THERAPY PRACTICES

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APPENDIX A: SAMPLE LIST OF EDUCATIONAL RESOURCES ON REGENERATIVE AND STEM CELL THERAPY PRACTICES

The Australian Stem Cell Handbook 2015

Stem Cell Basics (National Institutes of Health)

Stem Cell Patient booklet (Albany Medical College)

A closer look at Stem Cells (International Society for Stem Cell Research)

Patient Handbook on Stem Cell Therapies (International Society for Stem Cell Research)

Stem Cell Tourism (California Institute for Regenerative Medicine)

The Power of Stem Cells (California Institute for Regenerative Medicine)

SCOPE: Learn About Stem Cells in Your Native Language (The Niche)
United States Senate  
WASHINGTON, DC 20510  
April 21, 2017

Gregory B. Snyder, MD, DABR  
Chair-Elect  
Federation of State Medical Boards  
1300 Connecticut Ave NW, Suite 500  
Washington, DC 20036

Dear Dr. Snyder:

Doctors, researchers, and patients have identified regenerative medicine and adult stem cell therapies as potential treatments to heal damaged, diseased, or deteriorated tissues and organs. In recent years, some of that promise has been realized. There are new therapies to treat burn and skin wounds, diabetic ulcers, and damaged knee cartilage, and clinical trials are underway for currently untreatable diseases.\(^1\) Doug Oliver, a constituent of mine who was diagnosed with macular degeneration, a rare form of macular degeneration, participated in a clinical trial that used his own adult bone marrow stem cells to restore his eyesight.\(^2\) His remarkable progress is a testament to the potential of these treatments, and one of the reasons it was so important to pass the 21\(^{st}\) Century Cures Act to provide clarity for regenerative medicine regulated by the Food and Drug Administration.

Unfortunately, recent reports indicate that some patients have been harmed by unproven or investigational treatments received at stem cell clinics. In one evaluation, published in The New England Journal of Medicine, three patients developed severe bilateral vision loss as a result of an injection of adult adipose tissue-derived stem cells.\(^3\) Other reports find stem clinics advertising their therapies as having the potential to treat diseases like Parkinson’s or multiple sclerosis, including in circumstances where little, if any, evidence of their efficacy exists.\(^4\)

Therefore, I urge your organization to develop best practices for state medical and osteopathic regulatory boards to follow regarding promotion, communication, and practices at stem cell clinics. I also seek information on the following questions:

1. How do state medical boards investigate complaints against stem cell clinics?
2. How are the existing false claims best practices enforced or used by state medical boards?
3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?

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3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?
4. Are there standards for education necessary before implementing novel technology, such as adult stem cell procedures?

Thank you.

Sincerely,

Lamar Alexander
U.S. Senator
Regenerative and Stem Cell Therapy Practices

Report and Recommendations of the Workgroup to Study Regenerative and Stem Cell Therapy Practices

Adopted as policy by the Federation of State Medical Boards
April 2018

Section One. Introduction and Charge:

The Federation of State Medical Boards (FSMB) Workgroup to Study Regenerative and Stem Cell Therapy Practices was convened in May of 2017 by FSMB Chair Gregory B. Snyder, M.D., DABR, in response to a letter (Attachment 1) from U.S. Senator Lamar Alexander (R-TN), Chairman of the U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee, urging the FSMB to develop best practices for state medical and osteopathic boards (hereinafter referred to as “state medical boards”) in regulating the promotion, communication, and practices of treatments received at stem cell clinics in the United States.

In order to address Senator Alexander’s request, Dr. Snyder charged the Workgroup with:

1) Evaluating the prevalence, promotional practices, and incidences of patient harm related to regenerative medicine and adult stem cell therapies in the U.S.;

2) Evaluating current regulatory approaches that will protect the public, recognizing the potential for improved patient outcomes through health innovation and technology;

3) Identifying best practices for state medical and osteopathic boards in investigating complaints of patient harm, fraud, and compliance with licensure requirements; and

4) Issuing a report on the Workgroup’s findings from prevailing research and recommending best regulatory practices and guidelines related to physicians’ use of regenerative medicine and adult stem cell therapies in a manner consistent with safe and responsible medicine.

Stem cell and regenerative therapies offer opportunities for advancement in the practice of medicine and the possibility of an array of new treatment options for patients experiencing a variety of symptoms and conditions. Despite significant momentum in research and development, and the potential for such medical advancements, there is reasonable concern about a growing number of providers and clinics in the United States that are undermining the field. Such providers and clinics have been known to apply, prescribe or recommend therapies inappropriately, over-promise without sufficient data to support claims, and exploit patients who are often in desperate circumstances and willing to try any proposed therapy as a last resort, even if there is excessive cost or scant evidence of efficacy.
The following report aims to raise awareness about regenerative and stem cell therapy practices generally, outline their potential benefits and risks, and provide basic guidance for state medical boards and licensed physicians and physician assistants. Central to all of the recommendations provided herein is a range of imperatives, including the importance of protecting the public, respecting patient autonomy, preventing patient exploitation, obtaining informed consent, and appropriately documenting care that is recommended and provided.

The Workgroup’s deliberations were aided by participants and subject matter experts who brought varying perspectives. For example, Dr. Ronald Domen has expertise in stem cell therapies, bioethics and humanities, and has served on numerous ethics committees at institutional, state, and national levels. Dr. Zubin Master of the Mayo Clinic has extensive training and education in cellular and molecular biology, bioethics and genetics, as well as research and publications on stem cell therapies. Mr. Douglas Oliver became known to the Workgroup through a recommendation by Senator Lamar Alexander of Tennessee, was a recipient of stem cell therapies himself, and has a foundation that advocates for stem cell therapies based on his own experiences and those of others like him. Dr. Bruce White has educational backgrounds in medicine, law, pharmacy and ethics and currently serves as Director of the Alden March Bioethics Institute at Albany Medical College and is Chair of Medical Ethics at the College. The Workgroup also received written comments from several external organizations. The sum of these perspectives aided the Workgroup in producing a balanced report on this emerging issue of national importance.

Section Two. Definitions:

Homologous (Allogeneic) Use: the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with a HCT/P (human cells, tissues, and cellular and tissue-based product) that performs the same basic function or functions in the recipient as in the donor, including when such cells or tissues are for autologous use.¹

According to the Food and Drug Administration’s (FDA) Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use Guidance for Industry and Food and Drug Administration Staff (November 2017), the FDA “generally considers an HCT/P to be for homologous use when it is used to repair, reconstruct, replace, or supplement:

- Recipient cells or tissues that are identical (e.g., skin for skin) to the donor cells or tissues, and perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor; or
- Recipient cells or tissues that may not be identical to the donor’s cells or tissues, but that perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor.”²

¹ 21 CFR 1271.3(c)
Autologous Use: the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.³

Informed and Shared Decision Making: The process by which a physician discusses, in the context of the use of regenerative and stem cell therapies, the risks and benefits of such treatment with the patient.⁴ The patient is given an opportunity to express preferences and values before collaboratively evaluating and arriving at treatment decisions.⁵

Informed Consent:⁶ Evidence documenting appropriate patient informed consent typically includes the following elements:

- Identification of the patient, the physician, and the physician’s credentials;
- Types of transmissions permitted using regenerative and stem cell therapies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement from the patient with the physician’s determination about whether or not the condition being diagnosed and/or treated is appropriate for regenerative and stem cell therapy;⁷ and
- Express patient consent to forward patient-identifiable information to a third party
- An accurate description of the benefits and risks of treatment or intervention, based on scientific evidence, as well as an explanation of alternatives to treatment or an intervention, and the right to withdraw from treatment or an intervention without denial of standard of care to patients.

Minimal Manipulation: (minor processing including purification, centrifugation, washing, preservation, storage) – the Food and Drug Administration (FDA) argues that it has the authority to regulate anything beyond minimal manipulation and homologous use:
“(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and
(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.”⁸

Unproven Stem Cell Intervention: Stem cell therapy that lacks compelling evidence, based upon scientific studies, to validate its treatment efficacy.⁹

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³ 21 CFR 1271.3(a)
⁶ With respect to informed consent for the purposes of research studies involving human subjects, researchers should be aware of the basic elements of informed consent outlined in 21 CFR Part 50.25 “Protection of Human Subjects.”
⁷ Federation of State Medical Boards (2014). Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.
⁸ 21 CFR 1271.3(f)
Section Three. Background, Prevalence and Marketing of Regenerative and Stem Cell Therapies:

Historically, many of the clinics providing unproven stem cell interventions fell under the definition of “stem cell tourism” because most patients seeking such interventions had to travel outside of North American jurisdictions to receive them. The landscape in the United States has evolved considerably over the last few years with hundreds of new clinics opening across the country and many more physicians willing to provide stem cell and regenerative therapies. A study identified 351 U.S. businesses with over 570 clinics engaged in direct-to-consumer (DTC) marketing of stem cell interventions.\(^{10}\) It has also been suggested that growth in this area of medicine, especially in terms of adult, amniotic, fat-derived and bone marrow stem cell therapies to treat a host of conditions and injuries, is accelerating, both in the U.S. and internationally, and, perhaps counterintuitively, such growth is noted to be most significant in jurisdictions with more stringent regulatory frameworks.\(^{11}\)

Stem cell clinics typically reach their patients through online DTC marketing, primarily through information provided on company websites. Data purportedly supporting unproven stem cell interventions commonly undermine information about risks and overemphasize information about benefits. Treatment options are described on such websites and are often accompanied by supporting information in the form of journal articles, patient testimonials, and accolades related either to the clinic itself or its affiliated physicians and researchers. Supporting information that accompanies marketing materials can appear to be legitimate, but can also overemphasize, exaggerate, inflate, or misrepresent information derived from legitimate (or even questionable) sources. A physician engaging in such practices of deceptive or false advertising can be in violation of a state’s Medical Practice Act. Information provided on clinic websites should be represented accurately and come from reputable peer-reviewed publications or respected external organizations.

Some clinics, however, that are engaged in the provision of treatment modalities that lack evidence – or an appropriate rationale for application of that modality to particular medical conditions – often use what have been described as “tokens of scientific legitimacy” to lend credence to treatments offered or the quality of a clinic and its associated professionals. Examples of such tokens of legitimacy include patient or celebrity testimonials and endorsements, clinician affiliations or memberships in academic or professional societies, registrations in clinical trials, claims of various types of certifications or awards, and others.\(^{12}\) Further detail and explanations are provided in Table 1.

Physicians are ordinarily permitted to advertise themselves, their practice and services offered, provided that such advertisements do not contain claims that may be deceptive or are intentionally false or misleading. Further, physicians should be mindful of ways in which patient

testimonials, quality ratings, or other evaluative data is presented to prospective patients through advertisements. In advertising stem cell treatments to potential patients, physicians are responsible for ensuring that all information, especially in terms of risks, benefits and efficacy, is presented in an objective manner. Physicians must not deliberately misrepresent the expected outcomes or results of treatments offered. Physicians should be prepared to support any claims made about benefits of treatment(s) with documented evidence, for example with studies published in peer-reviewed publications.\(^\text{13}\)

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A recent study on the prevalence and marketing practices of businesses offering stem cell treatments internationally noted the presence of the following elements in their marketing practices:

- Mention of affiliations with a professional society or network
- Claims of partnerships with academic institutions
- Statements of receipt of FDA approval, or explicit mention of exemption from FDA oversight
- Mention of official endorsement from a local or other authority, or professional accreditation
- Listing of patents granted
- Statement that clinical trials of investigational stem cell-based interventions are being conducted\(^\text{15}\)

The marketing practices and information found on a business’ website can be important sources of data for state medical boards as they investigate complaints made against physicians affiliated with businesses providing regenerative and stem cell treatments. Even where an appropriate informed consent process seems to be in place, deceptive or fraudulent information on clinic websites and other marketing materials could mislead patients into consenting to treatment, thereby invalidating the informed consent process.

Physicians must make accurate claims about the enrollment process of subjects, treatments, and products in clinical trials and are responsible for ensuring that any research conducted and described in marketing materials is carried out according to accepted research protocols and recognized standards. Physicians should consider consulting with Institutional Review Boards (IRBs) to clarify processes and must seek IRB approval, where necessary. The National Institutes of Health (NIH) provides helpful guidance on clinical trials and research methods.\(^\text{16}\) Physicians are also encouraged to consult the guidance contained in the International Conference

\(^{14}\) Ibid.
\(^{16}\) National Institutes of Health, Office of Science Policy: https://osp.od.nih.gov/clinical-research/clinical-trials/
on Harmonisation’s Harmonised Tripartite Guideline for Good Clinical Practice to support acceptability of clinical data by patients, state medical boards, and other regulatory authorities.17

Table 1: Co-opted Tokens of Scientific Legitimacy18

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<tr>
<td>Boards and advisers</td>
<td>Convening scientific or medical advisory boards featuring prominent business leaders and academic faculty members</td>
</tr>
<tr>
<td>Clinical study registration</td>
<td>Registering trials whose apparent purpose is solely to attract patients willing to pay to participate in them</td>
</tr>
<tr>
<td>Ethics review</td>
<td>Using the imprimatur of “ethics review” to convey a sense of legitimacy to their products or procedures</td>
</tr>
<tr>
<td>Location</td>
<td>Renting of laboratory or business space within a legitimate scientific or government institution</td>
</tr>
<tr>
<td>Membership</td>
<td>Joining established academic or professional societies to suggest legitimacy by association</td>
</tr>
<tr>
<td>Outcome registries</td>
<td>Publication of open-ended voluntary monitoring data sets rather than undertaking controlled clinical trials</td>
</tr>
<tr>
<td>Patenting</td>
<td>Suggesting that patent applications or grants indicate clinical utility rather than initiation of an application process or recognition of novelty and inventiveness</td>
</tr>
<tr>
<td>Publication</td>
<td>Publishing research and commentary in journals with limited anonymous peer review</td>
</tr>
<tr>
<td>Rationales</td>
<td>Citing preclinical and other research findings to justify clinical application without sufficient efficacy testing in humans</td>
</tr>
<tr>
<td>Self-regulation</td>
<td>Forming organizations to self-regulate in ways that support premature commercialization</td>
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<tr>
<td>Technical Language</td>
<td>Using scientific-sounding words that imply academic rigor</td>
</tr>
<tr>
<td>Testimonials and Endorsements</td>
<td>Providing expert opinions or celebrity comments on unsupported clinical uses or standing of the provider</td>
</tr>
</tbody>
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Section Four. Patient Perceptions:

In seeking treatment for any condition, patients desire safety and efficacy, but may overlook risks to their own safety or a lack of evidence of efficacy in favor of access to treatment, particularly in circumstances where traditional treatment options seem limited or have been exhausted. The power of hope also is known to play a significant role in how patients attempt to gain control over their illness and its potential treatments, thereby putting them in a position of

increased vulnerability. This is especially the case when patients and their families have overcome various obstacles on the path to a treatment, including raising large sums of money to pay for it. This can lead to a psychological predisposition to anticipate and assume a positive outcome, regardless of the treatment in question or the availability of compelling evidence.

Given the vulnerable state of some patients who seek regenerative and stem cell therapies, perhaps without the requisite knowledge for making informed decisions, there is increased potential for patient exploitation. Physicians must therefore be mindful of the ways in which at-risk or susceptible patients may process information and arrive at decisions about their treatment options, expectations, and ultimately, the potential for success. A promising way of navigating such difficult circumstances, where treatment options are uncertain or complex, is through the use of shared decision making. This process, whereby the physician describes the risks and benefits of potential treatment options and the patient is given an opportunity to express preferences and values before collaboratively arriving at and evaluating treatment decisions, may help mitigate the risk of patient exploitation and ensure that consent to any treatment option has been provided in an informed manner.

The process of obtaining informed consent and engaging in shared decision making with patients involves conveying information about the reasonable effectiveness of a proposed treatment, as well as its risks and benefits. This can be particularly difficult with respect to regenerative and stem cell therapies, as this is an area of medicine that currently lacks substantive data on efficacy. Generation of relevant data and evidence has not occurred to a sufficient enough degree and this is often blamed on the difficulty involved in organizing large-scale, randomized controlled trials as part of the approval process for novel therapies. However, the FDA has recently argued that a statistically significant 100% improvement in an outcome measure ($\alpha = 0.05, \beta = 0.1$) may be detected with a randomized trial involving as few as 42 participants.

The lack of a formal mechanism for reporting outcomes of unproven stem cell interventions, both positive and negative, adds to the difficulty involved in generating data on the effectiveness of such interventions, as does the fact that there is neither a requirement, nor a mechanism, for reporting adverse events related to interventions administered outside of clinical trials and investigations. In the current environment, this increases the importance of appropriate documentation of treatment(s) and ongoing care in patients’ medical records. A centralized cell therapy registry for reporting treatment and outcomes may improve the current information available about the effectiveness of such therapies and interventions. It may also dissuade unscrupulous practitioners from engaging in the provision of unproven interventions without an adequate or appropriate basis in theory or peer-acknowledged practice, a pre-requisite for the provision of any intervention, whether proven or not.

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Section Five. Regulatory Landscape:

The current state of affairs for regulatory oversight on regenerative and stem cell therapies (including human cells and tissues), at both the federal and state level, is evolving and will continue to change in the coming years. In November 2017, the FDA released two guidance documents to explain the Agency’s current thinking on stem cell policy. However, this thinking, as well as the agency’s jurisdiction and authority, may evolve in the future.

Until recently, the regulatory landscape for stem cell and regenerative therapies has been at times restrictive, allowing patients to access stem cell interventions only under the Expanded Access to Investigational Drugs for Treatment Use program. Treatments are eligible under this program if they are undergoing testing in a clinical trial and are subject to approval by the FDA. Three-quarters of the states in the nation have passed “Right to Try” legislation, however, which allows terminally ill patients to receive experimental therapies that have passed phase 1 trials without seeking FDA approval.23 The U.S. Congress is also considering similarly proposed legislation and in August of 2017, the U.S. Senate passed S. 204, Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017.

The 21st Century Cures Act (Public Law 114-255), signed into law in December of 2016, represents legislative efforts at the federal level to expand and accelerate patient access to treatment, in addition to promoting innovation in medical products and treatments. With respect to regenerative medicine, the Act amends Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) by requiring expedited review for regenerative medicine therapies, including human cells and tissues, intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, where there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs. There are also ongoing efforts at the federal level to ensure even greater access to treatments that are not subject to FDA approval prior to administration to patients.

Regulation in the regenerative and stem cell therapy arena is continuing to evolve. Human cells, tissues, and cellular or tissue-based products (HCT/Ps) are currently regulated under Sections 351 and 361 of the Public Health Service Act.24 However, a HCT/P can be regulated solely under Section 361 of the PHS Act if it is:

1. Minimally manipulated,
2. Intended for homologous use only,
3. Not combined with another article, and
4. Either:
   a. Does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

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23 Lancet Commission: Stem Cells and Regenerative Medicine. Published Online October 4, 2017 [http://dx.doi.org/10.1016/S0140-6736(17)31366-1](http://dx.doi.org/10.1016/S0140-6736(17)31366-1)

24 The Public Health Service Act of 1944 outlines a policy framework for federal and state cooperation in health services and provides for the licensing of biological products.
b. Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is for autologous use, use in a first or second-degree blood relative, or reproductive use.25

The difference between an HCT/P that is regulated under both sections of the Public Health Service Act, as opposed to solely under Section 361, is significant for providers of stem cell treatments since the requirements for pre-market authorization of a product are much more stringent under Section 351 and require conducting clinical investigations under an investigational new drug (IND) application and obtaining a biologics license through the FDA, whereas requirements under Section 361 focus only on the prevention of communicable diseases.26 This represents a lower regulatory threshold for HCT/Ps; their use and transplantation can be considered to fall under the practice of medicine and would, therefore, be regulated by state medical boards.

In regulating this evolving area of medical practice, state medical boards will need to strive to achieve an appropriate balance between respecting the autonomy of patients as they seek viable and reasonable treatment options, and adequately safeguarding them against the risks presented by novel, but often unproven and potentially dangerous, interventions. Results from a 2017 survey of its member boards conducted by the FSM B indicate that a third (n = 17) of the 51 responding boards have investigated complaints against physicians related to regenerative medicine or stem cell therapy, and that eight of those boards have taken disciplinary action against physicians for issues relating to regenerative medicine or stem cell therapy.

In ensuring that physicians offer regenerative and stem cell therapies in a manner that is consistent with safe and responsible practices, state medical boards should ensure that any treatment offered to patients is informed by an appropriate history and physical examination; such informed consent is obtained after an explanation has been provided describing risks, benefits, alternative treatment options, expected convalescence, and expected treatment outcomes; that relevant information about the clinical encounter and ongoing care plans has been documented in the patient’s medical record; that the physician is appropriately trained in, and knowledgeable about the proposed treatment; and that the patient has not been coerced in any way into receiving treatment(s) or exploited through the charging of excessive fees.

In order to implement best practices for regenerative and stem cell therapies, physicians must understand the relevant clinical issues and should obtain sufficient targeted continuing education and training.27

The recommendations in the final section of this report provide further detail on various requirements that apply to the provision of regenerative and stem cell therapies that state medical boards may wish to consider.

25 21 CFR 1271.10(a)
26 United States Food and Drug Administration: Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use
27 Federation of State Medical Boards (2017). Guidelines for the Chronic Use of Opioid Analgesics.
Section Six. Recommendations:

The recommendations that follow address the regulation of the provision of stem cell and regenerative therapies, as well as their promotion and communication to patients, and documentation of treatments provided. The recommendations do not address which uses are appropriate or not for specific conditions or symptoms, as this area of medicine continues to be dynamic and subject to change. Rather, they focus on sensible and necessary principles of patient safety, autonomy, and non-exploitation.

The FSMB recommends that:

1. Where evidence is unavailable for a particular treatment in the form of clinical trials or case studies, physicians must only proceed with an appropriate rationale for the proposed treatment, and justification of its use, in relation to the patient’s symptoms or condition. Novel, experimental, and unproven interventions should only be proposed when traditional or accepted proven treatment modalities have been exhausted. In such instances, there must still be a basis in theory or peer-acknowledged practice.\(^{28}\)

2. State medical boards raise awareness among licensees of applicable federal and state legislation and guidelines regarding regenerative and stem cell therapies, including “right to try” legislation existing or pending at the state and federal levels. State medical boards should also keep their licensees and the public apprised of new developments and regulations in the field of regenerative and stem cell therapies. This may include educational resources, guidance documents, and appropriate industry and stakeholder information on a state medical board’s website. State medical boards should further provide information as to reporting procedures of adverse actions related to stem cell interventions.

3. State medical boards should examine their policies and rules addressing informed consent and consider expanding these to include a shared decision making framework that includes the following general elements at a minimum:
   - An explanation, discussion, and comparison of treatment options with the patient
   - An assessment of the patient’s values and preferences
   - Arrival at a decision in partnership with the patient
   - An evaluation of the patient’s decision in partnership with the patient

4. State medical boards should review professional marketing materials and claims, including any office/clinic and/or doctor websites, and information publicly available about an office/clinic or licensee on online blogs or social media, as information sources in the investigation of complaints made against physicians.

5. State medical boards should pro-actively monitor warning letters sent to licensees that are made publicly available on the FDA website in order to ascertain information, and consider opening an investigation, about licensees who may be engaged in other unscrupulous or

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unprofessional practices related to the provision of regenerative and stem cell therapy. State medical boards should investigate such practices, when appropriate, in conjunction with applicable state laws, policies, and procedures.\(^9\)

6. Physicians must only offer treatments to patients for which they have a bona fide physician-patient relationship. Physicians must have received adequate and appropriate training, and be able to perform any proposed intervention safely and competently.\(^0\)

7. Physicians should employ a “shared decision making” process when discussing treatment options with patients. Physicians must avoid any claims that may be deceptive or are intentionally or knowingly false or misleading, especially in terms of making promises about uncertain or unrealistic outcomes.

8. Physicians should not use gag orders (rulings that a case must not be discussed publicly) or disclaimers as a way to circumvent liability.

9. Physicians should be prepared to support any claims made about benefits of treatments or devices with documented evidence, for example with studies published in peer-reviewed publications.

10. Physicians should refrain from charging excessive fees for treatments provided. Further, physicians should not recommend, provide, or charge for unnecessary medical services, nor should they make intentional misrepresentations to increase the level of payment they receive.\(^1\)

11. Physicians should consult and educate patients about stem cell interventions and alert them to important resources available to the community. A list of selected resources is provided in Appendix A.

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\(^9\) The FDA’s warning letters are available at the following address: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

\(^0\) Federation of State Medical Boards (2014). Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.

\(^1\) American Medical Association, Code of Medical Ethics, Opinion 11.3.1.
WORKGROUP TO STUDY REGENERATIVE AND STEM CELL THERAPY PRACTICES

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FSMB Director-at-Large
Past President, Arizona Board of Osteopathic Examiners in Medicine and Surgery

Debbie J. Boe
Former Public Member, Minnesota Board of Medical Practice

Sandra L. Coletta
Public Member, Rhode Island Board of Medical Licensure and Discipline

Sarah L. Evenson, JD, MBA
Former Public Member, Minnesota Board of Medical Practice

H. Joseph Falgout, MD
Chair, Alabama Board of Medical Examiners

Joseph E. Fojtik, MD, FACP
Deputy Medical Coordinator, Illinois Department of Financial & Professional Regulation

Gary R. Hill, DO
Member, Alabama Medical Licensure Commission

Howard R. Krauss, MD
Member, Medical Board of California

SUBJECT MATTER EXPERTS
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Penn State College of Medicine

Zubin Master, PhD
Mayo Clinic

Douglas Oliver, MSW
Patient Appointee
Founder and Executive Director, Regenerative Outcomes Foundation

Bruce D. White, DO, JD
Alden March Bioethics Institute

EX OFFICIOS
Gregory B. Snyder, MD, DABR
Chair, FSMB

Patricia A. King, MD, PhD, FACP
Chair-elect, FSMB

Humayun J. Chaudhry, DO, MS, MACP, MACOI
President and CEO, FSMB

STAFF SUPPORT
Jonathan Jagoda, MPP
Director, Federal Government Relations, FSMB

Mark Staz, MA
Director, Continuing Professional Development
APPENDIX A: SAMPLE LIST OF EDUCATIONAL RESOURCES ON REGENERATIVE AND STEM CELL THERAPY PRACTICES

The Australian Stem Cell Handbook 2015
Stem Cell Basics (National Institutes of Health)
Stem Cell Patient booklet (Albany Medical College)
A closer look at Stem Cells (International Society for Stem Cell Research)
Patient Handbook on Stem Cell Therapies (International Society for Stem Cell Research)
Stem Cell Tourism (California Institute for Regenerative Medicine)
The Power of Stem Cells (California Institute for Regenerative Medicine)
SCOPE: Learn About Stem Cells in Your Native Language (The Niche)
United States Senate  
WASHINGTON, DC 20510  
April 21, 2017

Gregory B. Snyder, MD, DABR  
Chair-Elect  
Federation of State Medical Boards  
1300 Connecticut Ave NW, Suite 500  
Washington, DC 20036

Dear Dr. Snyder:

Doctors, researchers, and patients have identified regenerative medicine and adult stem cell therapies as potential treatments to heal damaged, diseased, or deteriorated tissues and organs. In recent years, some of that promise has been realized. There are new therapies to treat burn and skin wounds, diabetic ulcers, and damaged knee cartilage, and clinical trials are underway for currently untreatable diseases.[1] Doug Oliver, a constituent of mine who was diagnosed with macular debranese, a rare form of macular degeneration, participated in a clinical trial that used his own adult bone marrow stem cells to restore his eyesight.[2] His remarkable progress is a testament to the potential of these treatments, and one of the reasons it was so important to pass the 21st Century Cures Act to provide clarity for regenerative medicine regulated by the Food and Drug Administration.

Unfortunately, recent reports indicate that some patients have been harmed by unproven or investigational treatments received at stem cell clinics. In one evaluation, published in The New England Journal of Medicine, three patients developed severe bilateral vision loss as a result of an injection of adult adipose tissue-derived stem cells.[3] Other reports find stem clinics advertising their therapies as having the potential to treat diseases like Parkinson’s or multiple sclerosis, including in circumstances where little, if any, evidence of their efficacy exists.[4] Therefore, I urge your organization to develop best practices for state medical and osteopathic regulatory boards to follow regarding promotion, communication, and practices at stem cell clinics. I also seek information on the following questions:

1. How do state medical boards investigate complaints against stem cell clinics?
2. How are the existing false claims best practices enforced or used by state medical boards?
3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?

3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?
4. Are there standards for education necessary before implementing novel technology, such as adult stem cell procedures?

Thank you.

Sincerely,

[Signature]
Lamar Alexander
U.S. Senator
July 9, 2021

Betty Montgomery, JD
Acting President
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

RE: Section 4731.51, ORC and Rules 4731-20-01 and 4731-20-02 OAC

Dear Ms. Montgomery and Members of the State Medical Board of Ohio:

I am writing to you in support of Rules 4731-20-01 and 4731-20-02 OAC that authorize a podiatric physician to perform surgery on the ankle joint as defined. Specifically, as relates to the performance of a supramalleolar osteotomy of the tibia or fibula to correct a deformity or the harvesting of bone marrow aspirate from the proximal tibia.

Founded in 1981, PICA is the largest professional liability insurer of podiatric physicians in the United States, currently insuring the majority of podiatrists in the United States, including in the State of Ohio. As such, we have the largest data bank of podiatric-specific claims data in the United States, including more than 25,000 claims. A review of our database indicates we have not had any claims reported related to the performance of these procedures.

We continue to review our podiatric professional liability claims to determine if there is an increase in malpractice claim frequency and/or severity for states in which our insured podiatric physicians perform ankle procedures compared to states in which our insured podiatric physicians do not perform ankle procedures. Our conclusion is there is no significant increase in claim frequency nor severity in states that allow podiatrists the performance of ankle procedures.

I am available to discuss this further.

Sincerely,

Ross E. Taubman, DPM
PICA Group, President and Chief Medical Officer
After reading OAC rule 4731-20-01 and 4731-20-02 as well as the June 2019 communication, it's clear to me that the State Medical Board of Ohio came to appropriate conclusions in the 2019 communication. It is clear to me and seemingly many others I've spoken with that both of the specific procedures that the Board is seeking comment on, do in fact fall within the scope of practice of a podiatric physician. Having come to this conclusion, it's also clear that specifying the determination within a rule would be helpful to avoid any future confusion. It should be made clear that podiatric physicians meeting all the other mentioned prerequisites can in fact perform a supramalleolar osteotomy of the tibia or fibula as well as harvest bone marrow aspirate from the proximal tibia. Further, since this already falls within the scope of a podiatric physician and specification is simply a courtesy to the medical community as a whole, those opposing such a rule specification must be doing so in bad faith and with mal-intent.

Hence I write to wholeheartedly voice my support for specification that these procedures ARE within the scope of practice for an appropriately trained podiatric physician.

Samuel Makanjuola, DPM
University Hospitals PGY-1

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My understanding that they can do surgeries in the foot up to the ankle. Hence supramalleolar is above the ankle and should not be allowed. Bone marrow aspirate from proximal tibia should not be allowed for the same reason, and the purpose of that aspirate is beyond his/her duties. Thank you.

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Supramalleolar osteotomy and harvesting tibia bone marrow should be reserved for orthopedic surgeons. Complications from nonunion and tibia fractures are out of scope of their practice. Surgeons should only do procedures that they can address complications.
Sergio Ulloa DO

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I personally do not have the surgical privileges to do the procedures in question, nor do I know how to do them. However, I do know a lot of Podiatrists in Ohio and other states that do have the training for those procedures and do them when needed. As with all specialties, A doctor should be able to do the procedures within their anatomical area and training. I would leave those procedures on the available Ohio scope of practice for Podiatry. I also do not know any Orthopedists, the closest specialty concerning these bone procedures, that do those procedures in Ohio.

Seth A. Kearney, DPM FACFAS, FAPWH
Podiatrist-Athens/Jackson Branches
Staff member-Holzer Wound Care Center
Holzer Health System
2131 E. State St.
Athens, Ohio 45701
740-589-3100
skearney@holzer.org

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Public comment on podiatric scope of practice. 4731-20-01 and -02

As a reconstructive surgeon I believe it is inappropriate for a podiatrist to perform surgery above the foot, and to harvest bone marrow.

Steven Carp, MD
American Board of Plastic Surgery
www.carpcosmetic.com

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I feel it is NOT permissible for a podiatrist to perform a supramalleolar osteotomy of tibia or fibula. This is out of the scope of practice for a podiatrist, this is in the realm of practice for an orthopedic surgeon. Essentially, "not distal enough" for a podiatrist.

I feel it is NOT permissible for a podiatrist to perform a bone marrow aspirate from the proximal tibia. This is way outside the scope of practice for a podiatrist, and next level question: What will the podiatrist do with the results? Refer to a medical doctor. Bone marrow aspiration is for medical doctors to perform and interpret and act upon.

--
Sunil Hari
sunilhari@gmail.com
(513) 658-1496

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Dear Ms. Anderson,

I understand the State Medical Board of Ohio is seeking public comments on podiatric scope of practice to assist with its rule-making process. I would like to offer my perspective. I have been practicing Orthopedic Surgery in Youngstown since 1988, of which very little is foot although the ankle has been a routine part of my work, primarily with Trauma, as ours is a Level One facility (St. Elizabeth’s Youngstown). I have held numerous leadership and committee positions and the issue of Podiatry scope of practice has been an endemic matter throughout. This is a challenging problem due in large part to the highly variable qualification, training, and interests of individual podiatrists, compounded by often large disparities in the standards of care between Orthopedics and Podiatry. While we work in the same facilities we look at similar problems from often different perspectives, most often this takes the form of a lower threshold for surgery from the Podiatry perspective. Currently our Ministry is struggling with this as the cost of care by Podiatry is excessive, in part due to their more frequent pursuit of surgical methods, as well as their tendency to utilize the newest and most expensive tools / implants, which have not been shown to improve outcomes.

For these reasons I would be hesitant to extend the reach of Podiatry into the supramalleolar region, or elsewhere for that matter. To be precise, the supramalleolar region of the tibia is a notoriously challenging bone to work with, and the expertise and equipment to stabilize this portion is complicated, difficult to use, and very expensive. This procedure should have extremely limited indication, however my experience with Podiatry would suggest there is a risk of overutilization should this be allowed in their scope of practice, with potential harm to individual patients, and the health system as a whole.

I acknowledge the facility and institution bear the ultimate responsibility in credentialing any of us in the work we do in those settings, however if the state allows something in the scope of practice it is difficult if not impossible to deny such a privilege. Therefore in my opinion these procedures should not be extended to the Podiatric scope of practice in the State of Ohio.

I appreciate your time and consideration of my thoughts.

Sincerely,

Thomas S. Boniface, MD
System Director, Orthopedics, Bon Secours Mercy Health
Clinical Professor and Chair, Orthopedic Surgery, NEOMED
Fellow, AAOS, AAHKS
CAUTION: This is an external email and may not be safe. If the email looks suspicious, please do not click links or open attachments and forward the email to csc@ohio.gov or click the Phish Alert Button if available.
My concern is in the management of complications. A practitioner should be able to manage their own complications to an extent. Were a bone marrow aspiration to develop a post-op infection, the chance of developing osteomyelitis or septic knee joint would be great. An orthopaedist would then be called on to manage the infection since the podiatrist cannot operate on the knee.

As podiatrists now have privileges to use external fixation devices that extend into the tibia, I have seen similar complications from seemingly benign procedures where the tibia is fractured due to errant fixation wire placement for external fixators where the knee (in one case a knee replacement) becomes infected, or a tibial shaft fracture is caused by an improperly placed pin. These complications are incredibly difficult to manage and often the patient is faced with amputation if infection becomes an issue.

Tibial osteotomies (ie. supramalleolar osteotomy) are pretty challenging procedures in the best circumstances. Non-unions can occur, and when they do, they usually require pretty extensive bone grafting and plates or rods that extend well into the midshaft and proximal tibia. My concern with who will manage the complex problems that occur when these types of procedures go awry are the same as for the tibial aspiration. WHO is going to take care of the problems. My concern is heightened for supramalleolar tibial osteotomy over tibial aspiration due to its complexity.

--

V. James Sammarco, MD
vjsammarco@gmail.com

8099 Cornell Road
Cincinnati, OH 45249
Phone: 513-793-3933

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1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?
2. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

Any judgement on these issues should consider the following points:

a) Has the practitioner received full training in these procedures and their complications in a center and by a mentor with recognized expertise in the field? This implies that the practitioner has obtained broader and recognized training in surgical techniques and solving complications that stem from the surgery. Such training is typically provided as part of training in orthopedic surgery. If the podiatrist has clearly obtained broader as well as specific training in these techniques, then he/she should be permitted to do the said procedures. If not, he/she should not be approved for these procedures.

b) Will the procedure be performed in a state of the art environment that can address any complication from these treatments? For the sake of the patient's health any of the proposed procedures should only be performed in an environment that can address broader medical problems, such as heart attack, anesthesia-related problems, blood clots, allergic reactions to drugs etc etc. If the podiatrist has clearly obtained such training, then he/she should be permitted to do the said procedures. If not, he/she should not be approved for these procedures.

The analogy is that of a license to pilot a plane. It's not just about how to fly a plane, it's that *and* navigation as a whole that determines if one is fit to be a pilot.

Finally, there may be the question of standards as they are defined by the specialty boards that need to be considered too.

Hope this helps.

Sincerely,

Vincent M Monnier, MD
Shaker Heights, OH

---

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To whom it may concern,
I will try to keep my points succinct and on point. Regarding the consideration of allowing podiatrists to perform supramalleolar osteotomies, as well as proximal tibial bone graft harvesting - I believe this to be a very poor decision on behalf of the state medical board (should this be approved) and one that lacks insight into the possible ramifications.

I have had the opportunity to work with many talented podiatrists; very skilled and knowledgeable in their field. With that said, podiatrists are by definition limited in their practice of medicine/surgery.

My primary concerns are two fold in this proposal. First; I truly believe that a physician/surgeon should not only be capable, but also licensed to handle a majority (if not all) of the potential complications that should arise from their surgical practice. When doing a proximal tibial bone graft harvest (or malleolar osteotomy for that matter) - what happens if the patient should become infected and diagnosed with osteomyelitis? Are we then going to allow privileges to be expanded yet again to include I/D to bone of the proximal tibia, and even further - a BKA or AKA??

This relates to my second concern- once practice privileges start to expand for physicians who are by law ‘limited’, where does it end?

In a few years, will it then be acceptable for podiatrists to perform high tibial osteotomies for purposes of malalignment of the lower extremity?? The argument will be, ‘Why not, we are already privileged for bone grafting in that area, and we perform osteotomies in the foot?’

I believe these issues should be looked at with extreme caution by the board. From personal experience, the variability involved in the surgical training of podiatrists should be the primary reason these surgical procedures in question are not approved for podiatrists. However; a podiatrist who has completed a high volume, three year surgical residency; followed by an approved ‘fellowship’ with an orthopedic sub specialist would likely be more than qualified for such procedures…..but that is a whole different subject that would have to be broached!

Just my humble opinion. Good luck in navigating these difficult topics.

Sincerely,
William E. Saar, D.O.

Sent from my iPhone

CAUTION: This is an external email and may not be safe. If the email looks suspicious, please do not click links or open attachments and forward the email to csc@ohio.gov or click the Phish Alert Button if available.
1. Is it permissible for a podiatrist in Ohio to perform a supramalleolar osteotomy of the tibia or fibula to correct a deformity?

No. This is beyond the scope of practice of podiatry. I would not be comfortable with a patient of mine to have such a procedure performed by a podiatrist.

1. Is it permissible for a podiatrist in Ohio to harvest bone marrow aspirate from the proximal tibia?

No. This is beyond the scope of practice of podiatry. I would not be comfortable with a patient of mine to have such a procedure performed by a podiatrist.

Respectfully,
Zoltán Krudy, MD

CAUTION: This is an external email and may not be safe. If the email looks suspicious, please do not click links or open attachments and forward the email to csc@ohio.gov or click the Phish Alert Button if available.
Procedure: supramalleolar osteotomy of the tibia or fibula
CPT Code: 22705
Run: 7/22/21

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Members represent total Medicaid members
Total counts are distinct and are not the sum of the patients/members in each region (due to moving regions)
OOS = Out of State

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Last Claim Indicator = Y
Non Duplicate Encounter Indicator = Y
MEMORANDUM

TO: Betty Montgomery, President
    Members, State Medical Board of Ohio

FROM: Nathan T. Smith, Senior Legal and Policy Counsel

DATE: August 5, 2021

RE: Updated Telemedicine Frequently Asked Questions

At its July 14, 2021 meeting, the Medical Board approved the Telemedicine FAQs. Since the Telemedicine FAQs were published on the Board’s website on July 16, 2021, the Medical Board has received questions seeking clarification and also several situation specific questions. While the Board is unable to give specific legal advice, we would like to provide the general decision-making framework of telemedicine in Ohio to help licensees and other interested parties apply that to their particular situations.

This updated Telemedicine FAQs document adds FAQs 1-5 (located under the General Questions heading on pages 1-2) which are intended to provide that framework for understanding telemedicine as well as references to more specific information in other FAQs in this document. The rest of the FAQs are substantively the same as approved in July, with the exception of minor grammar and language consistency edits as well as renumbering.

**Action Requested:** Review and approve the attached updated Telemedicine Frequently Asked Questions for publication on the Board’s website.
Telemedicine Frequently Asked Questions

(Note: These FAQs were approved by the State Medical Board of Ohio on _____ and reflect the laws and rules in effect on that date.)

Since the telemedicine FAQs were published on July 16, 2021, the Medical Board has received several situation specific questions. While the Board is unable to give specific legal advice, we would like to provide the general decision-making framework of telemedicine in Ohio to help licensees and other interested parties apply that to their particular situations. This first set of General Questions are intended to provide that framework for understanding telemedicine as well as references to more specific information in other FAQs in this document.

General Questions:

Q1: I am a physician who wants to treat a patient via telemedicine. When can I treat patients through telemedicine in Ohio?

A: A physician who wants to treat a patient through telemedicine must answer “yes” to these questions for each particular patient situation in which telemedicine is being considered:

(1) Am I licensed as a physician or physician assistant in Ohio? See FAQs 12-16 for more information about licensure and telemedicine in Ohio and in other states.

(2) Can I meet the standard of care for providing telemedicine in this particular situation? See FAQs 19 and 20 for more information on the standard of care for telemedicine in Ohio.

(3) If the telemedicine patient visit will involve or is likely to involve prescribing, am I able to comply with the Medical Board’s prescribing laws and rules? See FAQs 21-29 for more information about the Medical Board’s prescribing laws and rules affecting telemedicine in Ohio.

Q2: I am a physician assistant licensed in Ohio who last did an in-person physical examination of a patient in January of 2020. Can I see that patient via telemedicine now?

A: It depends. Can you meet the standard of care for providing telemedicine to this patient for the particular medical issue that is the subject of the upcoming visit? See FAQs 19 and 20 for more information.

If the standard of care can be met, will this telemedicine visit likely involve prescribing? If the telemedicine visit will not involve prescribing and the standard of care can be met, you should be able to see that patient via telemedicine.

If the telemedicine visit is likely to involve prescribing, then you should refer to FAQs 21-29 for more information on the Medical Board laws and rules affecting whether you can do telemedicine in your particular situation.
Q3: Are the Medical Board prescribing laws and rules that may affect my ability to do telemedicine new?

A: No, these laws and rules and the physician and physician assistant’s responsibility to comply with them existed before the Covid-19 pandemic. What has changed is that more providers are utilizing telemedicine to treat patients than ever before. The Medical Board is using these Telemedicine FAQs and other communication opportunities to remind its licensees of their obligations under these laws and rules. For information on Medical Board enforcement of these laws and rules, please see FAQs 6-11.

Q4: I am a physician whose patient mix includes patients who are on Medicaid. How does the Medicaid telehealth rule (OAC 5160-1-18) affect my obligation to follow the Medical Board laws and rules regarding standard of care and prescribing?

A: The Medicaid telehealth rule in OAC 5160-1-18(C) states:

(C) Provider responsibilities when providing services through telehealth.

(1) It is the responsibility of the practitioner to deliver telehealth services in accordance with all state and federal laws including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and any HIPAA related directives from the office for civil rights (OCR) at the department of health and human services (HHS) issued during COVID-19 national emergency and 42 C.F.R. part 2 (January 1, 2020).

(2) It is the responsibility of the practitioner to deliver telehealth services in accordance with rules set forth by their respective licensing board and accepted standards of clinical practice.

(3) The practitioner site is responsible for maintaining documentation in accordance with paragraph (C)(1) of this rule for the health care service delivered through the use of telehealth and to document the specific telehealth modality used.

(4) For practitioners who render services to an individual through telehealth for a period longer than twelve consecutive months, the telehealth practice or practitioner is expected to conduct at least one in-person annual visit or refer the individual to a practitioner or their usual source of clinical care that is not an emergency department for an in-person annual visit.

So, the Medicaid telehealth rule requires physicians and physician assistants licensed in Ohio to follow the Medical Board’s laws and rules regarding standard of care and prescribing.

Q5: I am a social worker who was recently talking to two friends (one is a chiropractor and the other is a nurse) about the requirements for doing telehealth in Ohio. Can you tell me what the Medical Board’s requirements are for me and my friends to do telehealth?

A: The Medical Board’s telemedicine rules and laws only apply to physicians and physician assistants. Social workers, nurses, and chiropractors should contact their respective licensing boards for telehealth requirements in those occupations.

Effect of the COVID-19 Pandemic State of Emergency on Telemedicine in Ohio

Q6: What did the Medical Board do at the beginning of the Covid-19 pandemic regarding enforcement of its laws and rules requiring in-person patient visits in Ohio?

A: On March 18, 2020, the Medical Board issued the following guidance to licensees: Effective March 9,
2020 until Executive Order 2020-01D (declaration of a state of emergency for Ohio for the COVID-19 pandemic) expires, providers can use telemedicine in place of in-person visits, without enforcement from SMBO. This includes, but is not limited to:

• Prescribing controlled substances
• Prescribing for subacute and chronic pain
• Prescribing to patients not seen by the provider
• Pain management
• Medical marijuana recommendations and renewals
• Office-based treatment for opioid addiction

Providers must document their use of telemedicine and meet minimal standards of care. The Medical Board will provide advance notice before resuming enforcement of the above regulations when the state emergency orders are lifted.

Q7: What is the Medical Board’s recent updated guidance on its laws and rules requiring in-person patient visits?
A: At its June 9, 2021 meeting, the Medical Board agreed to resume enforcement of its laws and rules requiring in-person patient visits 90 days after the termination of the state of emergency for Ohio. The purpose of this announcement was to give advance notice to hospitals, practice groups, physicians, physician assistants, and most importantly patients.

Q8: Since Governor DeWine ended the state of emergency on June 18, 2021, when will the Medical Board resume enforcement of its laws and rules requiring in-person patient visits?
A: The Medical Board will resume enforcement on September 17, 2021.

Q9: What is the effect of Ohio ending its state of emergency before the end of the President’s declaration of a national emergency and/or the U.S. Department of Health and Human Services’ declaration of a public health emergency for COVID-19?
A: While the federal government has temporarily relaxed requirements or stayed enforcement of many laws and rules related to the provision of telemedicine, it has also still required providers to comply with state law. If the federal emergency has not ended before enforcement of state telemedicine laws and rules resumes on September 17, 2021, physicians and physician assistants who are providing medical care to a patient situated in Ohio must still comply with the Ohio laws and rules governing telemedicine.

Q10: What does it mean for the Medical Board to resume enforcement regarding the provision of telemedicine in Ohio?
A: It means that providers must follow the existing laws and rules governing in-person visits for patients. Beginning again on September 17, 2021, if a provider is licensed by the State Medical Board of Ohio and fails to follow the laws and rules governing in-person patient visits, they could be subject to a disciplinary action by the State Medical Board of Ohio. If the provider is not licensed in Ohio, that provider could be subject to civil, criminal, and/or administrative penalties for the unlicensed practice of medicine in Ohio.

Q11: Will the Medical Board discipline licensees for conduct involving failure to follow laws and rules requiring in-person patient visits for the time period between March 9, 2020 to September 17, 2021?
A: The Medical Board will not retroactively enforce these rules. However, a licensee could be disciplined for conduct involving violations of other Medical Board laws and rules during this time period.
Licensure and other general questions

Q12: To what professions do the Medical Board laws and rules requiring in-person patient visits apply?
A: The current Medical Board laws in Chapters 4730 and 4731 of the Revised Code (R.C.) and rules in Chapters 4730 and 4731 of the Ohio Administrative Code (OAC) governing in-person patient visits apply to physicians (including training certificate holders) and physician assistants licensed in Ohio.

Q13: Why do these FAQs (except those involving medical marijuana) include physician assistants in the questions and answers when the language of most of the relevant rules only states “physician”?
A: The rules are applicable to physician assistants because OAC rule 4730-1-07 states that the provisions of all rules in Chapters 4731-11 and 4731-29 of the Ohio Administrative Code are applicable to physician assistants. In addition, R.C. 4730.42 provides that a supervising physician shall not grant physician-delegated prescriptive authority to a physician assistant in a manner that exceeds the supervising physician's prescriptive authority.

Q14: Do I have to apply for a separate telemedicine license?
A: No, there is not a separate license for telemedicine in Ohio. Specific to licensees of the Medical Board, in order to practice telemedicine in Ohio, the provider must be licensed in Ohio as a physician or physician assistant.

Q15: Do I have to be physically located in Ohio at the time that I am seeing a patient located in Ohio via telemedicine?
A: If a physician or physician assistant is licensed in Ohio, that healthcare provider may provide telemedicine that is compliant with Medical Board laws and rules to a patient located in Ohio while the healthcare provider is located in another state of the United States.

Q16: I am an Ohio physician that wants to provide telemedicine to patients located in another state. What regulations does the State Medical Board of Ohio have on this out-of-state practice?
A: Because the practice of medicine is deemed to occur in the state in which the patient is located, the laws of the other state where the patient is located regulate this practice of medicine. Most states, including Ohio, require physicians to be licensed in that state to perform telemedicine. Ohio licensees who want to practice medicine via telemedicine to treat or diagnose patients located in another state should check with that other state’s licensing board for updated licensure and state law information. Information on the telemedicine laws, rules, and policies of other states may be accessed at the Federation of State Medical Boards (“FSMB”) website.

Laws and rules for telemedicine in Ohio

Q17: What are the telemedicine laws and rules that the Medical Board enforces as to its physician and physician assistant licensees?
A: To protect the health and safety of patients, the Medical Board has laws and rules that require an initial and/or periodic in-person patient visit for those medical visits involving the prescribing of drugs. Generally, there is no telemedicine for initial patient visits with a physician or physician assistant involving prescribing as OAC rule 4731-11-09 prohibits physicians from prescribing controlled substances or non-controlled substances to a person on whom the physician has never conducted a physical examination with some exceptions. In addition, visits that involve prescribing of specific types of controlled drugs also have initial and periodic in-person visit requirements. These are explained in FAQs 27, 28, and 29.
Q18: What are the laws and rules that apply to physicians and physician assistants not licensed in Ohio who want to provide telemedicine to patients located in Ohio?

A: R.C. 4731.34 provides that the practice of medicine in Ohio includes both the practice of medicine that occurs in person or “through the use of any communication, including oral, written, or electronic communication.” If a physician or physician assistant located in Ohio or in another state wants to provide medical care to patients in Ohio via telemedicine, that physician or physician assistant must obtain an Ohio physician or physician assistant license. In almost all cases, a physician or physician assistant that is not licensed in Ohio cannot provide telemedicine to a patient located in Ohio as that is the unlicensed practice of medicine prohibited by Ohio law. However, R.C. 4731.36(A) provides two limited exceptions:

“(3) A physician or surgeon in another state or territory who is a legal practitioner of medicine or surgery therein when providing consultation to an individual holding a license to practice issued under this chapter who is responsible for the examination, diagnosis, and treatment of the patient who is the subject of the consultation, if one of the following applies:
(a) The physician or surgeon does not provide consultation in this state on a regular or frequent basis.
(b) The physician or surgeon provides the consultation without compensation of any kind, direct or indirect, for the consultation.
(c) The consultation is part of the curriculum of a medical school or osteopathic medical school of this state or a program described in division (A)(2) of section 4731.291 of the Revised Code.

(4) A physician or surgeon in another state or territory who is a legal practitioner of medicine or surgery therein and provided services to a patient in that state or territory, when providing, not later than one year after the last date services were provided in another state or territory, follow-up services in person or through the use of any communication, including oral, written, or electronic communication, in this state to the patient for the same condition.”

Q19: What is the standard of care that applies to telemedicine?

A: The standard of care for telemedicine must be consistent with the standard of care for in-person medical care. A physician or physician assistant can face disciplinary action for “a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established.” R.C. 4731.22(B)(6) and R.C. 4730.25(B)(19).

Q20: For medical treatment that does not involve prescribing or one of the laws or rules discussed in the FAQs, how does the Medical Board’s resumption of enforcement of telemedicine laws and rules affect physicians, physician assistants, and patients?

A: The physician or physician assistant is responsible for communicating with the patient as to whether telemedicine is appropriate in a given situation knowing that the standard of care must be met regardless of if the medical diagnosis or treatment is given in-person or via telemedicine. This standard of care includes but is not limited to:

(1) informing patient about telemedicine services provided and obtaining informed consent from patient;
(2) compliance with federal and state laws and regulations related to the privacy of patient health information;
(3) documentation of all telemedicine services provided including:
   (a) the full name and license number of the licensee;
   (b) verification of patient identity for the appropriate provision of telemedicine;
   (c) complete medical record of telemedicine visit including but not limited to patient
history, patient exam, testing, and treatment; and
(d) referral of patients when medical services cannot be provided by telemedicine to another Ohio licensed medical provider who practices in an area of Ohio that patient can access for in-person medical services.

The medical provider is also responsible for training staff in the competent use of the appropriate telemedicine technology.

Visits involving prescribing a drug that is not a controlled substance

Q21: What are the rules for telemedicine related to a medical visit involving prescribing a drug that is not a controlled substance?

A: OAC rule 4731-11-09(B) states: Except as provided in paragraph (C) of this rule, a physician shall not prescribe, personally furnish, otherwise provide, or cause to be provided, any prescription drug that is not a controlled substance to a person on whom the physician has never conducted a physical examination. Paragraph (C) allows a physician to prescribe, personally furnish or otherwise provide a non-controlled substance prescription drug to a person on whom the physician has never conducted a physical examination and who is at a location remote from the physician if the physician complies with all of the following requirements:

(1) The physician shall establish the patient's identity and physical location;
(2) The physician shall obtain the patient's informed consent for treatment through a remote examination;
(3) The physician shall request the patient's consent and, if granted, forward the medical record to the patient's primary care provider or other health care provider, if applicable, or refer the patient to an appropriate health care provider or health care facility;
(4) The physician shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care, which may include portions of the evaluation having been conducted by other Ohio licensed healthcare providers acting within the scope of their professional license;
(5) The physician shall establish or confirm, as applicable, a diagnosis and treatment plan, which includes documentation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;
(6) The physician shall document in the patient's medical record the patient's consent to treatment through a remote evaluation, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;
(7) The physician shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the minimal standards of care;
(8) The physician shall make the medical record of the visit available to the patient;
(9) The physician shall use appropriate technology that is sufficient for the physician to conduct all steps in this paragraph as if the medical evaluation occurred in an in-person visit.

Q22: For prescribing non-controlled substance prescription drugs, does rule 4731-11-09 specify what type of telemedicine technology must be used?

A: The rule states that a physician shall "use appropriate technology that is sufficient for the physician to conduct all steps in this paragraph as if the medical evaluation occurred in an in-person visit.”
Visits involving prescribing a drug that is a controlled substance

Q23: What are the rules for telemedicine for a medical visit involving prescribing a drug that is a controlled substance?
A: The first applicable rule is OAC rule 4731-11-09(A) which states that “[e]xcept as provided in paragraph (D) of this rule, a physician shall not prescribe, personally furnish, otherwise provide, or cause to be provided, any controlled substance to a person on whom the physician has never conducted a physical examination.” There are additional rules addressed in FAQs 27, 28, and 29 regarding prescribing specific types of controlled substance prescription drugs.

Q24: What are the exceptions in which an Ohio licensed prescriber may prescribe a drug that is a controlled substance to a person on whom the physician has not conducted a physical examination and who is at a location remote from the physician?
A: Paragraph (D) of OAC rule 4731-11-09 lists the limited exceptions in which an Ohio licensed prescriber may prescribe a drug that is a controlled substance to a patient whom they have not personally physically examined and who is at a different location than the prescriber:

1. The person is an active patient of an Ohio licensed physician or other health care provider who is a colleague of the physician, and the drugs are provided pursuant to an on call or cross coverage arrangement between them and the physician complies with all steps of OAC rule 4731-11-09(C). An active patient is defined as one that within the previous twenty-four months the physician or physician assistant being cross-covered conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine.

2. The patient is physically located in a hospital or clinic registered with the U.S. drug enforcement administration (“DEA”) to personally furnish or provide controlled substances, when the patient is being treated by an Ohio licensed physician or other healthcare provider acting in the usual course of their practice and within the scope of their professional license and who is registered with the DEA to prescribe or otherwise provide controlled substances in Ohio.

3. The patient is being treated by, and in the physical presence of, an Ohio licensed physician or healthcare provider acting in the usual course of their practice and within the scope of their professional license, and who is registered with the DEA to prescribe or otherwise provide controlled substances in Ohio.

4. The physician has obtained from the administrator of the DEA a special registration to prescribe or otherwise provide controlled substances in Ohio.

5. The physician is the medical director, hospice physician, or attending physician for a hospice program licensed pursuant to Ohio Revised Code Chapter 3712 and both of the following conditions are met: (a) the controlled substance is being provided to a patient who is enrolled in that hospice program, and (b) the prescription is transmitted to the pharmacy by a means that is compliant with Ohio board of pharmacy rules.

6. The physician is the medical director of, or attending physician at, an institutional facility (as defined in OAC rule 4729-17-01) and both of the following conditions are met: (a) the controlled substance is being provided to a person who has been admitted as an inpatient to or is a resident of an institutional facility, and (b) the prescription is transmitted to the pharmacy by a means that is compliant with Ohio board of pharmacy rules.
Q25: What are the telemedicine technology requirements for a physician that prescribes a drug that is a controlled substance to a person on whom the physician has never conducted a physical examination and who is at a location remote from the physician?
A: Per federal law that has remained unchanged during the pandemic, the telemedicine communication in a patient visit involving prescribing a prescription drug that is a controlled substance must be conducted by a telecommunication system that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or physician assistant. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. R.C. 4731.74 requires that the prescribing of a prescription drug that is a controlled substance to a person on whom the physician has never conducted a physical examination and who is at a location remote from the physician must comply with federal law requirements.

Q26: In a group practice where one or more of the group practice physicians or physician assistants have examined the patient, can any of the physicians and PAs that have examined the patient within the past 24 months prescribe drugs that are controlled or non-controlled substances for the patient by telemedicine without having to follow all of the requirement of OAC rule 4731-11-09?
A: To fall outside of the requirements of OAC rule 4731-11-09, a physician or physician assistant must have sufficient familiarity with the patient such that the physician or PA must have examined the patient previously and become familiar with the patient’s specific condition for which the medication is being prescribed. If the physician or PA has examined the patient previously for a different problem or condition than the specific condition for which the medication is being prescribed, that prescriber would have to comply with the requirements of OAC rule 4731-11-09.

Q27: What are the specialized requirements for prescribing drugs that are controlled substances?
A: OAC rule 4731-11-03(B): Schedule II Controlled substance stimulants: A physician may use a schedule II controlled substance stimulant for only specified purposes in the rule if the physician performs an appropriate physical examination of the patient.

OAC rule 4731-11-14(B)(1)and (G): Prescribing for subacute and chronic pain: Before prescribing an opioid analgesic for subacute or chronic pain, the physician shall complete and document in the patient record assessment activities to assure the appropriateness and safety of the medication including a physical examination. If the treatment includes opioids at doses at or above the average of 50 MED per day, the physician shall, every three months, complete an assessment which includes a physical examination.

OAC rule 4731-29-01(E)(6)(a)(i): Standards and procedures for the operation of a pain management clinic: Patient records must contain information regarding physical examination.

OAC rule 4731-33-03(B)(1)(e): Office-based treatment for opioid addiction: Physician must perform an assessment including an appropriate physical examination. This assessment includes the following testing: urine drug screen or oral fluid drug testing; pregnancy test for women of childbearing age and ability, HIV, Hepatitis B & C tests, and consideration for screening for tuberculosis and sexually transmitted diseases in patients with known risk factors. Also, OAC rule 4731-33-01(B)(2) allows that “for other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.”

OAC rule 4730-4-03(B): Office-based treatment for opioid addiction: Rule includes the same requirements for physician assistant assessment and physical examination of patient as for physicians
Q28: What are the specialized requirements for prescribing weight loss drugs?

A: OAC rule 4731-11-04(B)(2)(b) and (C)(1): Controlled substances: Utilization of short term anorexants for weight reduction: Before initiating treatment for weight reduction utilizing schedule III or IV controlled substances, the physician shall perform an appropriate physical examination of the patient. When using schedule III or IV controlled substances, the physician shall meet face-to-face with the patient at a minimum of every thirty days.

OAC rule 4731-11-04.1(A)(1)(b) and (B)(1): Controlled substances: utilization for chronic weight management: Before initiating treatment utilizing any controlled substance anorexiant for the purposes of chronic weight management, the physician shall perform a physical examination of the patient. A physician shall meet face-to-face with the patient for the initial visit and at least every thirty days during the first three months of treatment.

Q29: What are the specialized requirements for recommending treatment with medical marijuana to a patient?

A: R.C. 4731.30 requires a physician to obtain a certificate to recommend from the Medical Board before a physician may recommend treatment with medical marijuana to a patient.

Further, R.C. 4731.30(C)(1)(b)(i) requires a physician to conduct an in-person physical examination of a patient to establish a bona fide physician-patient relationship to issue a recommendation for treatment with medical marijuana to the patient. In addition, R.C. 4731.30(D)(2) requires a physician to also conduct a physical examination for the issuance of a recommendation for treatment with medical marijuana to the patient after the expiration of the original recommendation and three renewals.

OAC rule 4731-32-03(A) and (E) Standard of Care – Medical Marijuana: The physician shall establish and maintain a bona fide physician-patient relationship with the patient for the provision of medical services that is established in an in-person visit that complies with this rule and for which there is an expectation that the physician will provide care to the patient on an ongoing basis. Physician shall be available to provide follow-up care and treatment to the patient, including physical examinations relevant to the patient’s condition to determine the efficacy of medical marijuana in treating the patient’s qualifying medical condition.

OAC rule 4731-32-03(B)(9): Standard of Care - Medical Marijuana: The physician shall create and maintain a medical record that documents the provision of medical services, including the performance of a physical examination relevant to the patient’s current medical condition.

Note: There are more situation specific FAQs regarding OAC rule 4731-11-09 here.
MEMORANDUM

TO: State Medical Board of Ohio Members
FROM: Stephanie Loucka, Executive Director
RE: Quality Assurance Committee
DATE: August 11, 2021

The Federation of State Medical Boards, in their 2020 audit of the SMBO, recommended various quality assurance steps in the handling of the board’s complaints. At the October 2020 retreat, the board decided to take two specific recommendations to a newly formed committee: the addition of a public member to the Secretary and Supervising Member process and the creation of a Quality Assurance Committee.

The newly formed ad hoc FSMB Recommendations Committee met through the first half of 2021. In addition to recommending that the board add a public member to the secretary and supervising member review of sexual misconduct complaints, the committee landed on the below recommendations for a new quality assurance process.

**Recommendations**

**Newly formed standing committee: Quality Assurance Committee**

**Purpose:** Conduct a quarterly audit of closed complaints of all types that provides reassurance to the public and an additional self-check of the board’s processes

**Committee composition:** The committee will include four physician members and one consumer member, for a total of five members. Board members may volunteer to be on the committee, with any conflicts being resolved by the Board President.

The consumer member on the committee should not be the same consumer member aiding the Secretary and Supervising Member in reviewing sexual misconduct cases.

**Process:** The committee will review 10 closed cases per month (30 per quarter) with each committee member assigned two cases for review per month (6 per quarter). Each committee member will receive two cases for review on a monthly basis.

Cases for review will be selected randomly and will exclude cases that were closed by protocol, such as complaints in which the Board lacks jurisdiction.
Any sexual misconduct complaints chosen in the random sample will be directed to the consumer member of the Committee, unless a consumer member had been involved in the initial decision to close the complaint.

If a complaint is recommended for reopen by the reviewing member, the reviewing committee member will meet with the Secretary, Supervising Member, and a consumer member to discuss the case and recommended next steps, either forwarding the matter to Enforcement or maintaining the closed status.

Additional information to review: The committee will also review quarterly metrics regarding the status of open and closed complaints.

Next Steps

Committee members: Express interest in serving to Betty Montgomery, President or Stephanie Loucka

Staffing: Board staff will be assigned to oversee the process. This will include the culling and distribution of materials, providing technical expertise, and synthesizing reviewing members comments. The assigned staff member will also facilitate the quarterly committee meeting.

System development: Salesforce will need to be configured to allow for the electronic review of the complaints by the committee members. A system like the one used by the expert reviewers in the historical case review will be deployed.

Timeline: First quarterly meeting to be held in October to further discuss and understand process; second quarterly meeting in January will include first set of case review.
Legislative Update: August 11, 2021

Bills of high interest or with significant activity since the last board meeting:

**SB 6 – Join Interstate Medical Licensure Compact (Sen. Roegner and Sen. Steve Huffman)**

*To enter into the Interstate Medical Licensure Compact*

**Areas of Interest:**
- Board staff are working through implementation
- Working groups have been assigned to

**Status:** Passed out of the legislature 6/24/2021. Signed by Governor DeWine 7/1/2021. Required to be operational by 9/28/2022.

**SB 131 – Occupational Licensing (Reciprocity) (Sen. Roegner and Sen. McColley)**

*To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.*

**Areas of Interest:**
- Requires automatic licensure of out of state applicants that meet certain criteria.

**Board Position:** Neutral

**Status:** Introduced in the Senate 3/16/2021. Third Senate committee hearing 6/9/2021.


*To make changes to the laws governing massage establishments and massage therapy.*

**Areas of Interest:**
- Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.

**Board Position:** Neutral

HB 110 – State Operating Budget (Rep. Oelslager)

*Creates appropriations for FY 2022-2023.*

**Areas of Interest:**
- The Medical Board budget request was granted in the first version of the bill and remained in the final version.
- Staff has met to discuss the completion of action items required in the budget bill.

**Board Position:** Support


HB 122 – Telehealth (Rep. Fraizer)

*To establish and modify requirements regarding the provision of telehealth services.*

**Areas of Interest:**
- Permits specified health care professionals to provide telehealth services.
- Requires telehealth services provided by health care professionals to be done so according to specified conditions and standards.
- Permits certain health care licensing boards to adopt rules as necessary to carry out the bill’s provisions regarding telehealth services provided by health care professionals.

**Board Position:** Interested party

**Status:** Passed out of the House 4/15/2021. Referred to Senate Health. Awaiting first Senate hearing.

**Bills that continue to be monitored but have not seen significant activity since the last board meeting:**

SB 4 – Public Records (Sen. Roegner)

*To exempt personal info of certain persons from public records law.*

**Areas of Interest:**
- Includes emergency service telecommunicators and certain Ohio National Guard members as individuals whose residential and familial information is exempt from disclosure under the Public Records Law.

**Board Position:** Neutral

**Status:** Passed out of the Senate 2/17/2021. Senate concurred in House amendments 5/26/2021.
SB 9 – Regulations (Sen. McColley and Sen. Roegner)

To reduce regulatory restrictions in administrative rules.

Areas of Interest:

- Requires certain agencies to reduce the number of regulatory restrictions in their administrative rules.
- This applies to administrative agencies only and does not currently impact the Medical Board.

Board Position: Neutral


SB 48 – Cultural Competency (Sen. Maharath and Sen. Antonio)

To require certain health care professionals to complete instruction in cultural competency.

Areas of Interest:

- Requires certain health care professionals to complete instruction in cultural competency and provide proof of completion at initial application for licensure and at renewal.
- Includes: dentists, nurses, pharmacists, physicians, psychologists, and social workers.

Board Position: Neutral


SB 55 – Massage Therapy (Sen. Brenner) (companion bill HB 81)

To make changes to the laws governing massage establishments and massage therapy.

Areas of Interest:

- Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.

Board Position: Neutral

Status: Passed out of Senate health committee 5/19/2021. Awaiting floor vote.
SB 123 – Abortion (Sen. Roegner and Sen. O'Brien)

To enact the Human Life Protection Act to prohibit abortions based upon a condition precedent.

Areas of Interest:

- Prohibits, as the crime of criminal abortion, a person from purposely causing or inducing an abortion by using a drug or substance or an instrument or other means.
- Provides that criminal abortion is a felony of the fourth degree.
- Provides an affirmative defense to a criminal abortion charge if the physician performed or induced the abortion, or attempted to do so, under the determination that it was necessary to prevent the woman’s death or a serious risk of the substantial and irreversible impairment of a major bodily function.
- Requires the State Medical Board to revoke a physician’s license to practice if the physician is guilty of abortion manslaughter, criminal abortion, or promoting abortion.

Board Position: Neutral


SB 150 – Physician Contracts (Sen. Johnson and Sen. Williams)

To prohibit the use of noncompete provisions in physician employment contracts.

Areas of Interest:

- Would prohibit the use of noncompete provisions in physician employment contracts.

Board Position: Neutral


SB 151 – Infant Medical Treatment (Sen. Johnson)

To establish standards for the medical treatment of certain infants and to name the act Emery and Elliot’s Law.

Areas of Interest:

- Outlines medical treatment for mothers and infants in emergency situations or infants with a disability.

Board Position: Neutral

SB 157 – Attempted Abortions (Sen. Johnson and Senator Steve Huffman)

*Regards child born alive after attempted abortion.*

**Areas of Interest:**

- Requires reports to be made after a child is born alive following an abortion or attempted abortion.
- Establishes certain civil or criminal penalties for failing to preserve the health or life of such a child.

**Board Position:** Neutral

**Status:** Introduced in the Senate 4/13/2021. Third Senate government, oversight and reform committee hearing 6/16/2021.

SB 161 – Surgical Smoke (Sen. Brenner)

*Regards surgical smoke.*

**Areas of Interest:**

- Requires that not later than one year after the effective date of enactment, each ambulatory surgical facility shall adopt and implement a policy designed to prevent human exposure to surgical smoke during any planned surgical procedure that is likely to generate surgical smoke.
- The policy shall include the use of a surgical smoke evacuation system.

**Board Position:** Neutral

**Status:** Introduced in the Senate 4/15/2021.

SB 206 – Art & Music Therapists (Sen. Yuko and Sen. Brenner)

*To license and regulate art therapists and music therapists.*

**Areas of Interest:**

- Creates a new license type for music therapists to be regulated under the Medical Board

**Board Position:** Interested Party

**Status:** Introduced in the Senate 7/1/2021
HB 6 – Modify laws governing certain professions due to COVID-19 (Rep. Roemer)

To modify the laws governing certain health professionals and educator preparation programs due to COVID-19.

Areas of Interest:

- Allows pharmacists to administer immunization for influenza, COVID-19 and any other disease but only pursuant to prescription for persons seven or older.
- Allows pharmacists to administer immunizations for an disease for those 13 and older.
- Allows podiatrists to administer vaccinations for individuals seven and older for influenza and COVID-1.

Board Position: Neutral


Regards emergency prescription refills.

Areas of Interest:

- Increases from one to three the number of times that a pharmacist may dispense without a prescription certain drugs to a specific patient within a 12-month period.

Board Position: Neutral

Status: Passed out the House 5/5/2021. First Senate Health hearing 6/16/2021


To exempt certain mental health care providers' residential and familial information from disclosure under the Public Records Law.

Areas of Interest:

- Adds forensic mental health providers, mental health evaluation providers, and regional psychiatric hospital employees to the list of professions, consolidated in continuing law into the term “designated public service worker,” whose residential and familial information is exempted from disclosure under the Public Records Law.

Board Position: Neutral

HB 43– Authorize public bodies to meet via video- and teleconference (Rep. Sobecki and Rep. Hoops)

To authorize public bodies to meet via teleconference and video conference.

Areas of Interest:

- Allows public bodies to meet and hold hearings via teleconference or video conference.
- Requires public bodies to provide the public with access to meetings and hearings commensurate with the method in which the meeting is being conducted.

Board Position: Neutral


To authorize the use of medical marijuana for autism spectrum disorder.

Areas of Interest:

- Allows autism spectrum disorder to be included in qualifying conditions.

Board Position: Opposed


HB 64 – Regards fraudulent assisted reproduction (Rep. Powell)

To create the crime of fraudulent assisted reproduction and civil actions for an assisted reproduction procedure without consent.

Areas of Interest:

- Prohibits a health care professional from purposely or knowingly using human reproductive material from a donor while performing an assisted reproduction procedure if the person receiving the procedure has not expressly consented to the use of that donor’s material.
- Creates the crime of fraudulent assisted reproduction, making it a third-degree felony and allows for civil action against a fertility doctor within ten years of the offense.

Board Position: Neutral

HB 138 – Emergency Medical Services (Rep. Baldridge)

Regarding the scope of emergency medical services provided by emergency medical service personnel.

Areas of Interest:

- Eliminates the enumeration of specific services that may be provided by emergency medical services (EMS) personnel.
- Requires the State Board of Emergency Medical, Fire, and Transportation Services to establish the scope of practice for EMS personnel through rulemaking.
- Permits EMS personnel to comply with a do-not-resuscitate order issued by a physician assistant or advanced practice registered nurse.
- Requires the medical director or cooperating physician advisory board of each EMS organization to establish protocols for EMS personnel to follow when providing services at all times.

Board Position: Neutral


HB 160 – Health Estimates (Health care price transparency) (Rep. Holmes)

Regarding the provision of health care cost estimates.

Areas of Interest:

- Authorizes the relevant regulatory boards to impose administrative remedies on a health plan issuer or health care provider who fails to comply with the bill’s health care price transparency provisions.

Board Position: Interested Party


To revise the law governing the practice of athletic training.

Areas of Interest:

- Makes changes to the law governing the practice of athletic training, including by requiring an athletic trainer to practice under a collaboration agreement with a physician or podiatrist.

Board Position: Interested Party


Regarding electronic prescriptions and schedule II controlled substances.

Areas of Interest:

- Requires that all schedule II drugs be prescribed electronically.

Board Position: Interested Party


To Regulate the practice of surgical assistants.

Areas of Interest:

- Creates a new license type for surgical assistants to be overseen by the Medical Board.

Board Position: Interested Party


HB 203 – Occupational Licenses (Rep. Powell)

To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.

Areas of Interest:

- Requires automatic licensure of out of state applicants that meet certain criteria.

Board Position: Interested Party


To modify the laws governing the practice of advanced practice registered nurses and to designate these provisions as the Better Access, Better Care Act.

Areas of Interest:

- Would allow an APRN who has completed 2,000 clinical practice hours under a standard care arrangement the option to practice without a collaboration agreement.
- Allows an APRN who has not completed the required hours to enter into a standard care arrangement with an APRN who has completed 2,000 clinical practice hours.

Board Position: Interested Party


HB 286 – Court of Common Pleas (Rep. Bill Seitz)

To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.

Areas of Interest:

- Modifies the current Administrative Procedure Act by generally providing that a party adversely affected by an order of an agency may appeal from the order to the court of common pleas of the county in which the place of business of the party is located or the county in which the party is a resident.
- Removes the current provision that any party adversely affected by an order of an agency issued pursuant to any other adjudication may appeal, with certain exceptions, to the Franklin County Court of Common Pleas.

Board Position: Interested Party


To revise the law governing the practice of anesthesiologist assistants.

Areas of Interest:

- Adds anesthesiologist assistants to the list of individuals authorized to prescribe drugs or dangerous drugs or drug therapy related devices during professional practice.
- Adds anesthesiologist assistant list of practitioners from which a respiratory care therapist may receive orders or prescriptions.

Board Position: Interested Party


To authorize a pregnant minor to consent to receive health care to maintain or improve her life or the life of the unborn child she is carrying.

Areas of Interest:

- Allows a pregnant minor to consent to receive health care, such as prenatal health care, health care during delivery, post-delivery health care, and family planning services, to maintain or improve her life or the life of the unborn child she is carrying.
- States that the bill does not remove or limit any person’s responsibility under Ohio law to report child abuse or neglect.

Board Position: Neutral


Regards drug offenses and treatment.

Areas of Interest:

- Proposes to reduce the abuse of prescription opioids, establish addiction treatment facilities, increase penalties for drug trafficking violations, modify penalties for drug possession, require an offender convicted of a drug possession or drug trafficking offense involving certain drugs to be subject to ten years of post-release control, allow a criminal defendant who has a severe substance use disorder involving certain drugs to be confined by a state detoxification provider while awaiting trial, create restitution work programs, and make an appropriation.

Board Position: Interested Party


To license and regulate art therapists and music therapists.

Areas of Interest:

- Creates a new license type for music therapists to be regulated under the Medical Board

Board Position: Interested Party

Regarding pretreatment notice about the possibility of reversing a mifepristone abortion.

Areas of Interest:

- Prohibits a physician from performing a mifepristone abortion without both informing the patient of the possibility to reverse the mifepristone abortion if she changes her mind and providing information from the Department of Health website on assistance with reversing the effects of the mifepristone abortion.
- Criminalizes violations of the previous requirements as a misdemeanor of the first degree.
- Allows a patient whom a mifepristone abortion is performed on to file a wrongful death suit against an individual who fails to inform the patient of the possibility of reversal.

Board Position: Interested Party

Status: Introduced in the House 7/15/2021
<table>
<thead>
<tr>
<th>Bill Number/Link</th>
<th>Name</th>
<th>Current Bill Status</th>
<th>Committee Assignment</th>
<th>Board Position</th>
<th>Bill Sponsor(s)</th>
<th>Date Introduced</th>
<th>Areas of Interest</th>
<th>Action Taken</th>
<th>Action Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB 4</td>
<td>Public Records</td>
<td>Senate concurrence in House amendments 5/26/2021</td>
<td>House Civil Justice 2/24/2021</td>
<td>Neutral</td>
<td>Senator Kristina Roegner (R-27 Hudson)</td>
<td>1/19/2021</td>
<td>Includes emergency service telecommunicators and certain Ohio National Guard members as individuals whose residential and familial information is exempt from disclosure under the Public Records Law</td>
<td>Monitoring</td>
<td>None</td>
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<tr>
<td>SB 6</td>
<td>Enter into Interstate Medical Licensure Compact</td>
<td>Signed by Governor DeWine 6/29/2021 Effective 9/28/2021</td>
<td>House Families, Aging and Human Services 5/4/2021</td>
<td>Interested Party</td>
<td>Senator Kristina Roegner (R-27 Hudson) and Senator Steve Huffman (R-5 Tipp City)</td>
<td>1/19/2021</td>
<td>Would make Ohio a member of the Interstate Medical Licensure Compact</td>
<td>Chelsea and Stephanie attended an interested party meeting hosted by the bills sponsors. - Interested party testimony was offered at the second committee hearing - Requested amendments have been added to the bill to extend implementation and appropriation for staff. Additional meetings with the bills sponsor and health committee chair are being scheduled. Continued communication and collaboration with the IMLC to ensure successful start up.</td>
<td>Monitoring for future potential inclusion</td>
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<tr>
<td>SB 9</td>
<td>Reduce regulatory restrictions in administrative rules</td>
<td>Passed out of the Senate 3/10/2021 First House hearing 5/20/2021</td>
<td>House Government Oversight 3/16/2021</td>
<td>Neutral - does not currently impact SMBO</td>
<td>Senator Rob McColley (R-1 Napoleon) and Senator Kristina Roegner (R-27 Hudson)</td>
<td>1/21/2021</td>
<td>Requires certain agencies to reduce the number of regulatory restrictions in their administrative rules.</td>
<td>Monitoring for future potential inclusion</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>Bill</td>
<td>Title</td>
<td>Status</td>
<td>Committee</td>
<td>Pages</td>
<td>Authors</td>
<td>Introduced</td>
<td>Senate</td>
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<td>SB 48</td>
<td>Cultural Competency</td>
<td>First Senate Hearing 6/16/2021</td>
<td>Senate Health 2/10/2021</td>
<td>Neutral</td>
<td>Senator Tina Maharath (D-3 Canal Winchester) and Nickie Antonio (D-23 Lakewood)</td>
<td>2/3/2021</td>
<td>Require certain health care professionals to complete instruction in cultural competency. Includes: dentists, nurses, pharmacists, physicians, psychologists and social workers.</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>SB 55</td>
<td>Massage Therapy (companion HB 81)</td>
<td>Reported out of Senate Committee 5/19/2021</td>
<td>Senate Health 2/10/21</td>
<td>Neutral</td>
<td>Senator Andrew Brenner (R-19)</td>
<td>2/10/2021</td>
<td>Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.</td>
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<tr>
<td>SB 123</td>
<td>Enact the Human Life Protection Act</td>
<td>Introduced 3/9/2021</td>
<td>Senate Health 3/10/2021</td>
<td>Interested Party</td>
<td>Senator Kristina Roegner (R-27 Hudson) and Senator Sandra O’Brien</td>
<td>3/9/2021</td>
<td>Prohibits, as The crime of criminal abortion, a person from purposely causing or inducing an abortion by using a drug or substance or an instrument or other means. - Provides that criminal abortion is a felony of The fourth degree. - Provides an affirmative defense to a criminal abortion charge if The physician performed or induced The abortion, or attempted to do so, under The determination that it was necessary to prevent The woman’s death or a serious risk of The substantial and irreversible impairment of a major bodily function. - Requires the State Medical</td>
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<td>SB 131</td>
<td>Require occupational license if experienced in another state</td>
<td>Third Senate Hearing 6/9/2021, Workforce and Higher Education 3/17/2021</td>
<td>Interested Party</td>
<td>Senator Kristina Roegner (R-27 Hudson) and Senator Rob McColley (R-1 Napoleon)</td>
<td>3/16/2021 Requires automatic licensure of out of state applicants that meet certain criteria.</td>
<td>Monitoring</td>
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<td>SB 150</td>
<td>Physician Contracts</td>
<td>Second Senate Hearing 5/12/2021, Senate Small Business and Economic Opportunity 4/21/2021</td>
<td>Neutral</td>
<td>Sen. Terry Johnson (R-14 McDermott) and Sen. Sandra Williams (D-21 Cleveland)</td>
<td>3/31/2021 Would prohibit the use of noncompete provisions in physician employment contracts.</td>
<td>Monitoring</td>
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<td>SB 151</td>
<td>Infant Medical Treatment</td>
<td>First Senate committee hearing 6/3/2021, Senate Health 4/21/2021</td>
<td>Neutral</td>
<td>Sen. Terry Johnson (R-14 McDermott)</td>
<td>3/31/2021 Establish standards for the medical treatment of certain infants and to name the act Emery and Elliot's Law.</td>
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<tr>
<td>SB 157</td>
<td>Attempted Abortions</td>
<td>Third Senate committee hearing 6/16/2021, Government Oversight and Reform 4/21/2021</td>
<td>Neutral</td>
<td>Sen. Terry Johnson (R-14 McDermott) and Sen. Steve Huffman (R-5 Tipp City)</td>
<td>3/31/2021 to require reports to be made after a child is born alive following an abortion or attempted abortion and to establish certain civil or criminal penalties for failing to preserve the health or life of such a child.</td>
<td>Monitoring</td>
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<td>Bill</td>
<td>Description</td>
<td>Stage</td>
<td>Sponsor</td>
<td>Date</td>
<td>Details</td>
<td>Monitoring</td>
<td>Notes</td>
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<tr>
<td>SB 161</td>
<td>Surgical Smoke</td>
<td>Introduced 4/15/2021</td>
<td>Senate Health 4/21/2021</td>
<td>Neutral</td>
<td>Sen. Andrew Brenner (R-Powell) 4/15/2021 Not later than one year after the effective date of enactment, each ambulatory surgical facility shall adopt and implement a policy designed to prevent human exposure to surgical smoke during any planned surgical procedure that is likely to generate surgical smoke. The policy shall include the use of a surgical smoke evacuation system.</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>SB 206</td>
<td>Art &amp; Music Therapists</td>
<td>Introduced 7/1/2021</td>
<td>Pending</td>
<td>Neutral</td>
<td>Sen. Kenny Yuko (D-25 Richmond Heights) Sen. Andrew Brenner (R-19 Delaware) 7/1/2021 Creates a new license type for music therapists to be regulated under the Medical Board</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>HB 6</td>
<td>Modify laws governing certain professions due to COVID-19</td>
<td>Enacted 5/14/2021</td>
<td>Senate Government Oversight and Reform 3/10/2021</td>
<td>Neutral</td>
<td>Rep Bill Roemer (R-38) 2/3/2021 - allows pharmacists to administer immunization for influenza, COVID-19 and any other disease but only pursuant to prescription for persons seven or older - allows pharmacists to administer immunizations for an disease for those 13 and older - allows podiatrists to administer vaccinations for individuals seven and older for influenza and COVID-19</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>HB 37</td>
<td>Regards emergency prescription refills</td>
<td>First Senate Health Hearing 6/16/2021</td>
<td>Senate Health 5/12/2021</td>
<td>Interested Party</td>
<td>Rep. Gayle Manning (R-55 North Ridgeville)</td>
<td>2/3/2021</td>
<td>Increases from one to three the number of times that a pharmacist may dispense without a prescription certain drugs to a specific patient within a 12-month period.</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>HB 41</td>
<td>Exempt mental health care providers' info from Public Records Law</td>
<td>First Senate Health Hearing 3/24/2021</td>
<td>Senate Health 3/17/2021</td>
<td>Interested Party</td>
<td>Rep. Laura Lanese (R-23) Rep. Beth Liston (D-21)</td>
<td>2/3/2021</td>
<td>Adds forensic mental health providers, mental health evaluation providers, and regional psychiatric hospital employees to the list of professions, consolidated in continuing law into the term “designated public service worker,” whose residential and familial information is exempted from disclosure under the Public Records Law.</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
</tr>
<tr>
<td>HB 43</td>
<td>Authorize public bodies to meet via video- and teleconference</td>
<td>First House Hearing 2/11/2021</td>
<td>Government Oversight and Reform 2/4/2021</td>
<td>Neutral</td>
<td>Rep. Lisa Sobecki (R-45 Toledo) and Rep. Jim Hoops (R-81 Napoleon)</td>
<td>2/3/2021</td>
<td>Allows public bodies to meet and hold hearings via teleconference or video conference. Requires public bodies to provide the public with access to meetings and hearings commensurate with the method in which the meeting is being conducted.</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>Bill</td>
<td>Description</td>
<td>Committee</td>
<td>Hearing Date</td>
<td>Sponsor</td>
<td>Action</td>
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<tr>
<td>HB 60</td>
<td>Authorize medical marijuana for autism spectrum disorder</td>
<td>Fourth House committee</td>
<td>6/15/2021</td>
<td>Rep Juanita Brent (D-12) and Rep Bill Seitz (R-30)</td>
<td>2/3/2021</td>
<td>Adds autism spectrum disorder to qualifying conditions</td>
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<tr>
<td>HB 64</td>
<td>Regards fraudulent assisted reproduction</td>
<td>Second House hearing</td>
<td>3/17/2021</td>
<td>Rep. Jena Powell (R-80)</td>
<td>2/3/2021</td>
<td>Prohibits a health care professional from purposely or knowingly using human reproductive material from a donor while performing an assisted reproduction procedure if the person receiving the procedure has not expressly consented to the use of that donor’s material</td>
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<tr>
<td>HB 81</td>
<td>Revise laws governing massage establishments / massage therapy (Companion SB 55)</td>
<td>Passed out of the House</td>
<td>6/24/2021</td>
<td>Rep. Phil Plummer (R-40) and Rep. Susan Manchester (R-84)</td>
<td>2/9/2021</td>
<td>Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.</td>
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<tr>
<td>HB 110</td>
<td>State Budget</td>
<td>Signed by Governor DeWine</td>
<td>6/30/2021</td>
<td>Rep. Scott Oelslager (R-48)</td>
<td>2/16/2021</td>
<td>State operating budget - Medical Board request was granted in the first version - Hospital licensure (R.C. 3722.02 (primary), 3722.01 to 3722.14, and 3722.99; conforming changes in numerous other R.C. sections)</td>
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</table>

The policy team will continue to monitor this bill as it progresses through the legislative process.
<p>| <strong>HB 122</strong> | <strong>Telehealth</strong> | Passed out of the House 4/15/2021 | Senate Health 4/21/2021 | Interested Party | Rep. Mark Fraizer (R-71) and Rep Adam Holmes (R-97) | 2/16/2021 | Permits specified health care professionals to provide telehealth services. Requires telehealth services provided by health care professionals to be done so according to specified conditions and standards. Permits certain health care licensing boards to adopt rules as necessary to carry out the bill’s provisions regarding telehealth services provided by health care professionals. | Monitoring | The policy team will continue to monitor this bill as it progresses through the legislative process. |
| <strong>HB 138</strong> | Regards the scope of emergency medical services | Passed out of the House 6/16/2021 | Senate Health 6/23/2021 | Neutral | Rep. Brian Baldridge (R-90 Winchester) | 2/18/2021 | Eliminates the enumeration of specific services that may be provided by emergency medical services (EMS) personnel. - Requires The State Board of emergency medical, Fire, and Transportation services to establish The scope of practice for EMS personnel through rulemaking. - Permits EMS personnel to comply with a do-not-resuscitate order issued by a physician assistant or advanced practice registered nurse. - Requires The medical director or cooperating physician advisory Board of each EMS organization to establish protocols for EMS | Monitoring | The policy team will continue to monitor this bill as it progresses through the legislative process. |</p>
<table>
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<tr>
<th>Bill</th>
<th>Description</th>
<th>Status</th>
<th>Next Dates</th>
<th>Interested Party</th>
<th>Action</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>HB 160</td>
<td>Regards the provision of health care cost estimates (health care price transparency)</td>
<td>Passed out of the House</td>
<td>5/5/2021</td>
<td>Rep. Adam Holmes (R-97 Nashport)</td>
<td>3/3/2021</td>
<td>Monitoring</td>
</tr>
<tr>
<td>HB 176</td>
<td>Revise the Athletic Training Law</td>
<td>Passed out of the House</td>
<td>5/28/2021</td>
<td>Rep. Rick Carfagna (R-68 Genoa Township) and Rep. Thomas Hall (R-53 Madison Township)</td>
<td>3/4/2021</td>
<td>Monitoring</td>
</tr>
<tr>
<td>HB 193</td>
<td>Regards electronic prescriptions</td>
<td>Passed out of the House</td>
<td>6/23/2021</td>
<td>Rep. Al Cutrona (R-59 Canfield) and Rep. Gail Pavliga (R - 75 Atwater)</td>
<td>3/9/2021</td>
<td>Monitoring</td>
</tr>
<tr>
<td>HB 196</td>
<td>Regulate the practice of surgical assistants</td>
<td>Passed out of the House</td>
<td>5/11/2021</td>
<td>Rep. Brigid Kelly (D-31 Cincinnati) and Rep. Sara Carruthers (R-51 Hamilton)</td>
<td>3/9/2021</td>
<td>Monitoring</td>
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<tr>
<td>Bill</td>
<td>Summary</td>
<td>Introduced</td>
<td>Committee</td>
<td>Interested Party</td>
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<tr>
<td>HB 203</td>
<td>Require occupational license if experienced in another state</td>
<td>3/16/2021</td>
<td>State and Local Government</td>
<td>Rep. Jena Powell (R-80)</td>
<td>Requires automatic licensure of out of state applicants that meet certain criteria.</td>
<td>Monitoring: The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
</tr>
<tr>
<td>HB 221</td>
<td>To modify the laws governing the practice of advanced practice registered nurses and to designate these provisions as the Better Access, Better Care Act.</td>
<td>3/17/2021</td>
<td>House Health</td>
<td>Rep. Tom Brinkman (R-27 Mt. Lookout) and Rep. Jennifer Gross (R-52 West Chester)</td>
<td>Would allow an APRN who has completed 2,000 clinical practice hours under a standard care arrangement the option to practice without a collaboration agreement. Allows an APRN who has not completed the required hours to enter into a standard care arrangement with an APRN who has completed 2,000 clinical practice hours.</td>
<td>Monitoring: The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
</tr>
<tr>
<td>HB 318</td>
<td>Anesthesiologist Assistants</td>
<td>5/19/2021</td>
<td>House Health</td>
<td>Rep. DJ Swearingen (R-89 Huron) and Rep. Phil Plummer (R-40 Dayton)</td>
<td>Revises the law governing the practice of anesthesiologist assistants.</td>
<td>Monitoring: The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
</tr>
<tr>
<td>HB 286</td>
<td>Court of Common Pleas</td>
<td>5/4/2021</td>
<td>House Civil Justice</td>
<td>Rep. Bill Seitz (R-Cincinnati)</td>
<td>Modifies the current Administrative Procedure Act by generally providing that a party adversely affected by an order of an agency may appeal from the order to the court of common pleas of the county in which the place of business of the party is located or the county in which the party is a resident.</td>
<td>Monitoring: The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td>Bill</td>
<td>Description</td>
<td>Introduced</td>
<td>Introduced by</td>
<td>Status</td>
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<td>Introduced by</td>
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<td>HB 355</td>
<td>Authorize a pregnant minor to consent to receive health care</td>
<td>5/19/2021</td>
<td>House Health</td>
<td>Neutral - does not currently impact SMBO</td>
<td>Rep. Kristen Boggs (D-18 Columbus) and Rep. Paula Hicks-Hudson (D-44 Toledo)</td>
<td>5/19/2021</td>
</tr>
<tr>
<td>HB 356</td>
<td>Regards drug offenses and treatment</td>
<td>6/21/2021</td>
<td>House Criminal Justice</td>
<td>Interested Party</td>
<td>Rep. Mike Loychik (R-63 Bazetta) and Rep. Adam C. Bird (R-66 New Richmond)</td>
<td>6/21/2021</td>
</tr>
<tr>
<td>HB 359</td>
<td>Art &amp; Music Therapists</td>
<td>6/24/2021</td>
<td>House Primary and Secondary Education</td>
<td>Neutral</td>
<td>Rep. Allison Russo (D-24 Upper Arlington) and Rep. Jamie Callender (R-61 Concord)</td>
<td>6/24/2021</td>
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### HB 378  
**Abortion Reversal**

**Introduced**  
7/15/2021  
Pending  
Neutral  


**7/15/2021**  
Prohibits a physician from performing a mifepristone abortion without both informing the patient of the possibility to reverse the mifepristone abortion if she changes her mind and providing information from the Department of Health website on assistance with reversing the effects of the mifepristone abortion. Criminalizes violations of the previous requirements as a misdemeanor of the first degree. Allows a patient whom a mifepristone abortion is performed on or induced to file a wrongful death suit against an individual who fails to inform the patient of the possibility of reversal.

**Monitoring**  
The policy team will continue to monitor this bill as it progresses through the legislative process.

<p>| <strong>Federal Legislation</strong> | <strong>S. 168 / H.R. 708</strong> | <strong>Temporary Reciprocity to Ensure Equal Access to Treatment “TREAT” Act</strong> | <strong>Referred to Senate Committee on Health, Education, Labor and Pensions</strong> | <strong>Neutral</strong> | <strong>Senate Bill - Sen. Christopher Murphy (D-CT) and Sen. Roy Blunt (R-MO) House Resolution - Rep Bob Latta (R-OH) and Rep. Debbie Dingell (D-MI)</strong> | <strong>2/2/2021</strong> | <strong>Would allow health care professionals to practice across state lines in-person or via telehealth services during COVID-19 or a future public health emergency.</strong> | <strong>Monitoring</strong> | <strong>The policy team will continue to monitor this bill as it progresses through the legislative process.</strong> |</p>
<table>
<thead>
<tr>
<th><strong>S. 155 / H.R. 688</strong></th>
<th><strong>Equal Access to Care Act</strong></th>
<th>Referred to Senate Committee 2/2/2021</th>
<th>Committee on Health, Education, Labor and Pensions</th>
<th>Neutral</th>
<th>Sen. Ted Cruz (R-TX)</th>
<th>2/2/2021</th>
<th>Would allow health care providers licensed in one jurisdiction to provide telemedicine to patients in another in which they are unlicensed during the COVID-19 public health emergency and for 180 days after the pandemic has ended.</th>
<th>Monitoring</th>
<th>The policy team will continue to monitor this bill as it progresses through the legislative process.</th>
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<tr>
<td><strong>H.R. 341</strong></td>
<td><strong>Ensuring Telehealth Expansion Act</strong></td>
<td>Referred to House Committee 1/15/2021</td>
<td>Committee on Energy and Commerce</td>
<td>Neutral</td>
<td>Rep. Roger Williams (R-TX)</td>
<td>1/15/2021</td>
<td>Would extend telehealth provisions from the CARES Act through 2025, including eliminating originating site restrictions, implementing payment parity</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
</tr>
<tr>
<td><strong>H.R. 366</strong></td>
<td><strong>Protecting Access to Post-COVID–19 Telehealth Act of 2021</strong></td>
<td>Referred to House Committee 1/19/2021</td>
<td>Committee on Energy and Commerce</td>
<td>Neutral</td>
<td>Rep. Mike Thompson (D-CA) and Rep. David Schweikert (R-AZ)</td>
<td>1/19/2021</td>
<td>Would eliminate most geographic and originating site restrictions in Medicare, establish the patient’s home as an eligible telehealth site, continue CMS telehealth reimbursement for 90 days beyond the end of the public health emergency (PHE), make permanent disaster waiver authority, and require a study on the use of telehealth during COVID, including telehealth utilization rates across state lines.</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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<tr>
<td><strong>H.R. 596 / S. 57</strong></td>
<td><strong>ACCESS Act</strong></td>
<td>Referred to House Committee 1/28/2021</td>
<td>House Appropriations; Energy and Commerce</td>
<td>Neutral</td>
<td>House Resolution - Rep. Janice Schakowsky (D-IL) and Rep. Gus Bilirakis (R-FL) Senate Bill - Sen. Amy Klobuchar (D-MN) and Sen. Bob Casey (D-PA)</td>
<td>1/28/2021</td>
<td>Would authorize $50 million for the HHS' Telehealth Resource Center to assist nursing facilities to expand the use of telehealth and establish a grant program to support virtual visits in nursing homes during the pandemic.</td>
<td>Monitoring</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process.</td>
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