Rules & Policies Agenda for Board Meeting
October 13, 2021

A. Rule Review Update
B. Telemedicine Discussion
C. Pharmacy Board Rule – Nicotine Replacement
D. Podiatric Scope of Practice
E. Appointment of IMLC Commissioners
F. Weight-Loss Rules
G. 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: September 30, 2021

Attached please find the updated rule review schedule and spreadsheet.

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

**Comment Deadline 10/8/21**
- 4731-6-05
- 4731-16-02
- 4731-16-05
- 4731-16-08
- 4731-22-07
- 4731-36-01

**Comment Deadline 10/19/20**
- 4731-11-03
- 4731-11-04
- 4731-11-04.1

### RULES AT JCARR

**Hearing Scheduled 10/29/21**
- 4730-1-07
- 4730-2-07
- 4731-35-01
- 4731-35-02

### RULES SENT FOR INITIAL CIRCULATION

**Comment Deadline 9/25/20**
- 4731-6-14

**Comment Deadline 8/30/21**
- 4731-30-04

### RULES FOR REVIEW AT MASSAGE THERAPY ADVISORY COUNCIL

**Comment Deadline 7/2/21**
- 4731-1-01
- 4731-1-02
- 4731-1-03
- 4731-1-04
- 4731-1-05
- 4731-1-07
- 4731-1-08
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- 4731-1-15
- 4731-1-16
- 4731-1-17
- 4731-1-18
- 4731-1-19

### Rules Needing Amendments Due to HB442 and HB263

The following rules need to be amended or rescinded to remove references to cosmetic therapy and oriental medicine:
- 4731-16-01 Impaired Practitioners Definitions
- 4731-16-18 Eligibility for one-bite program
- 4731-22-02 Application

The following rules need to be amended or rescinded to address changes from HB263:
- 4731-4-02 Criminal Records Checks
- 4731-12-04 Eligibility for Licensure in Podiatric Medicine and Surgery by endorsement from Another State
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<th>CSI recommendation</th>
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- Revised filings are marked with "Revised filing" and include dates for filing changes.
- Dates for current review and effective dates are provided.
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MEMORANDUM

TO: State Medical Board of Ohio Board Members

FROM: Stephanie Loucka, Executive Director

DATE: October 13, 2021

RE: Telemedicine

Background

The State Medical Board of Ohio (SMBO) has a variety of in-person patient care requirements, mostly relative to prescribing situations. Since March 2020, enforcement of those in-person requirements has been put on hold due to the ongoing pandemic.

Throughout the pandemic, telemedicine has provided a large disruption to the healthcare delivery system. It is important to note, telemedicine is a tool, not a type of healthcare. In recent months, stakeholders have been very vocal to both us and the legislature that providers would like to see telemedicine continue. Accordingly, we should assess our regulations to ensure 1) ongoing patient safety and 2) the continued evolution of healthcare tools that benefit patients.

Below, you will find information about pending legislation and potential next steps, the stakeholder engagement that board staff conducted through September, proposed policy goals to guide changes to rule and/or law (based on the stakeholder feedback), and finally, our concerns with the currently pending legislation, House Bill 122 (HB 122).

Legislative/Regulatory Steps

House Bill 122, a bill that greatly expands a provider’s ability to use telemedicine, has passed the house and is moving through the Senate. We have concerns with the bill as drafted.

Regardless of the path of legislation, we would like to pursue changes to the in-person patient care requirements in our rules. If the legislation continues to move, we will advocate for amendments that would allow those board agreed upon suggested rule changes.
Stakeholder engagement

Throughout the month of September, Board staff conducted numerous stakeholder meetings (detailed below).

Group meetings:
2 IP meetings, including:
- Cleveland Clinic
- Ohio Association of Community Health centers
- OHA
- OSMA
- Ohio Psychiatric Physicians
- Ohio Osteopathic Association
- UH Hospital System
- OSU Wexner Medical
- Ohio Academy of Pediatrics

OHA meeting, including:
- Mt. Carmel
- Cincinnati Children’s
- OhioHealth
- MetroHealth

Individual meetings:
- UH Hospital System physicians
- Ohio Association of Community Health centers
- OneFifteen- Alcohol and Drug Rehab
- OPHP Medical Director
- OSMA
- OHA
- Metro Health (two meetings)
- Cleveland Clinic

For a summary of the stakeholder feedback, please see the additional documents in the board packet. In addition to stakeholder meetings, SMBO staff solicited written responses from stakeholders. Some stakeholders provided feedback to each question, some provided answers in a summary form, others provided survey results from outreach they did independent of the board’s questions. A summary of the comments, as well as a packet of all complete responses are included.
Proposed SMBO Policy Goals

Standard of Care
The standard of care for telehealth services should be the same as the standard of care for in-person health care services. As the Board’s recent stakeholder engagement demonstrated, there is universal acceptance among health care systems, hospitals, associations, and individual providers of this seminal truth.

Continuity of care
If a health care professional determines at any time during the provision of telehealth services that the telehealth visit will not meet the in-person standard of care for the health care issue of the patient, the health care professional shall immediately schedule the patient for an in-person visit or refer the patient for an in-person visit to another health care professional that can conduct the in-person visit. It is the health care professional’s responsibility to follow measures to ensure that the patient gets the timely care that is needed.

Additionally, a health care professional who provides telehealth services to a patient for a period of twelve consecutive months without an in-person visit shall conduct an in-person visit that includes a physical examination. If the provider cannot conduct the required in-person visit, the provider must refer the patient to another health care professional or the patient’s usual source of clinical care, that is not an emergency department, to provide the in-person visit with physical examination. The in-person visit and physical exam must account for and provide the appropriate care for the patient and the condition for which the patient utilized telemedicine.

Technology
A health care professional shall use synchronous, interactive, real-time electronic communication technology comprised of both audio and video elements to provide telehealth services except when one of following exceptions is met to provide telehealth services through asynchronous technology in which only one of the audio or video components exists:

1. when a good faith attempt has been made to utilize the synchronous technology and has been documented in the medical record, but technical problems have necessitated that the telehealth service be conducted using asynchronous technology provided that the standard of care for an in-person visit can be met; or
2. when the patient does not have access to synchronous technology and the provision of telehealth services through the use of asynchronous technology is in the best interest of the patient’s health to avoid a significant compromise in the patient’s health or due to the patient’s lack of mobility and the standard of care for an in-person visit can be met.

The Board’s previous telehealth committee also discussed a technology exception for when the telehealth service provided by the health care professional to the patient is for a verbal consultation or verbal counseling and the telehealth service does not require a visual examination or visual evaluation of the patient through synchronous technology. This exception should be reexamined given the increase in technology over the last 18 months.

These reasonable exceptions provide the flexibility to continue the improved access to care, particularly as to behavioral health, realized during the pandemic, while still setting the standard of care and protecting patients from substandard care and telehealth fraud most often perpetrated through telephone-based telehealth.
Prescribing

Health care professionals that are prescribing non-controlled substances through telehealth shall follow the standard of care, continuity of care, and technology requirements outlined above. As a baseline for the prescribing of controlled substances through telehealth, health care professionals shall in addition comply with all requirements under state and federal law.

From a rule perspective, due to the ongoing opioid epidemic, for prescribing a drug that is a controlled substance used in medication assisted treatment through telehealth, a physician or physician assistant shall also:

(1) comply with the Opioid Treatment rules in OAC chapters 4731-33 or 4730-4 respectively; and

(2) conduct an in-person physical examination of the patient or refers the patient for an in-person physical examination with another physician, physician assistant, certified nurse practitioner, or federal qualified health center associated with the physician or medical practice conducting the patient’s medication assisted treatment within 90 days of the start of medication assisted treatment. The in-person visit, and physical exam must specifically account for the patient’s participation in medication assisted treatment.

For prescribing all other controlled substances through telehealth, a physician or physician assistant shall also comply with all other applicable rules in OAC chapters 4731-11 and 4731-33. This means for controlled substance prescribing other than MAT, the physician or physician assistant must conduct an in-person physical examination before initially prescribing.

Rulemaking authority for standard of care

The Medical Board should have specific statutory rulemaking authority in legislation for the Board to adopt rules regarding the standard of care for telehealth for health care professionals under its jurisdiction and any other rules necessary to implement the legislation. At least one other board currently has this authority. This would allow the Medical Board to tailor the requirements of telehealth legislation to the characteristics of its licensed professions authorized to deliver telehealth. The standard of care for telehealth would include topics such as:

(1) establishment of the patient’s identity and physical location;
(2) obtaining informed consent to telehealth treatment;
(3) compliance with privacy requirements for patients and their protected health information;
(4) obtaining consent to share records of the telehealth visit with the patient’s primary care provider and make necessary referrals;
(6) medical evaluation, diagnosis, and development of treatment plan;
(7) documentation of all pertinent requirements in the patient’s medical record;
(8) provision of appropriate follow-up care and/or recommendation or referral for that care;
(9) assurance of the availability of the medical record of the telehealth visit to the patient.

These rules would set the floor for each Medical Board licensed profession’s use of telehealth and allow the Board to respond to the evolving nature of telehealth.
SMBO Concerns with HB 122

The Board is specifically concerned with the following portions of HB 122

- **Standard of Care:** The bill proposes that the standard of care for telehealth services does not have to meet the standard of care for in-person services. Proposed 4743.09 (D) states: “When a patient has consented to receiving telehealth services, the health care professional who provides those services is not liable in damages under any claim made on the basis that the services do not meet the same standard of care that would apply if the services were provided in-person.” Further, the bill does not explicitly include board authority to adopt rules regarding the standard of care.

- **Continuity of care:** There is no requirement to ever have the patient have an in-person visit with the physician providing telemedicine, the patient’s primary care physician, or an associated PA or APRN. Theoretically under this legislation, a provider could decide to never see a patient in-person regardless of occupation or specialty. This opens up possibilities of substandard care and missed diagnoses.
  
  o The bill proposes a one size fits all approach that makes telehealth the default for initial visits without regard to the differences in the standard of care for an occupation, of a specialty practice within that occupation, or with activities within the occupation such as prescribing controlled substances. Propose 4743.09(C)(1) states: A health care professional may use synchronous or asynchronous technology to provide telehealth services to a patient during an initial visit if the appropriate standard of care for an initial visit is satisfied.

  o The bill proposes the same one size fits all approach that makes telehealth the default for an annual visit without regard to the differences in an individual patient’s needs or the standard of care for an occupation or of a specialty practice within that occupation.

- **Technology:** The bill allows a telehealth provider to use synchronous or asynchronous technology to provide telehealth if the standard of care is satisfied. The legislation does not provide any guardrails for controlled drug prescribing, nor does it acknowledge the possibility of preemptive federal requirements for an in-person visit or synchronous technology.

- **The rule making authority is unclear.**
  
  o The Board has rules around in-person visits for some prescribing that we believe we need to keep.

  o The ‘floor’ of what telemedicine should look like needs to be created.
Re: Proposed Questions to Stakeholders for Telemedicine Discussion

Dear Members and Leadership of the Ohio Medical Board,

Thank you again for your time on September 16th where we discussed the important regulatory issues regarding the use of telemedicine to treat substance use disorder patients. We greatly appreciated the opportunity to sit down and share our experience with you. We hope we provided you with helpful and insightful information as a stakeholder, and we were grateful to hear the perspectives of other stakeholders, including members of the Medical Board.

We recognize and respect your role in safeguarding patients and your desire to foster an environment of innovation. Our work is deeply rooted in patient safety and innovation.

As requested, below are answers to the Questions for Stakeholders on Ohio telemedicine rules. After you review, please feel free to reach out to either one of us to discuss further.

Martha C. Taylor, MSN
President & CEO
OneFifteen

Natalie Lester, MD, MPH, MBA
Chief Medical Officer
OneFifteen
1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?

Through its providers and partners, OneFifteen offers a full continuum of substance use disorder treatment. In March 2020, we transitioned to a telehealth platform with synchronous, audiovisual visits, and we trained our whole staff on use of this technology (not only physicians, but also nurses, therapists, peers supporters, among others). Since then, OneFifteen has performed more than 10,000 telehealth encounters using real-time, audiovisual formats. Our technology is both HIPAA and 42 CFR Part 2 compliant.

Our physicians have used this telehealth platform to conduct telemedicine visits in multiple ways:

(1) **If the patient was onsite** and the physician was off site (e.g., to decrease exposure risk to SARS-CoV-2), the patients used a tablet in our clinical setting and the physician connected through their own laptop. These visits could be of new or established patient visits, and could include visits where the patient was required to be onsite, e.g., for medication injection visits.

(2) **If the patient was located remotely**, the physician would use our telemedicine platform to invite the patient to the appointment, and the patient could connect to the visit using their own device (usually a smartphone).

The types of visits included the following:

- New patient assessments, with or without prescription of a controlled substance
- Established patient visits, with or without controlled substance prescriptions

Conditions treated included assessment and treatment of substance use disorders (SUD), including opioid, alcohol, stimulant, sedative/hypnotic, and cannabis use disorders, as well as assessment and treatment of co-occurring mental health conditions. Treatment included stabilization of conditions associated with opioid, alcohol, and sedative/hypnotic withdrawal.

**When prescribing a controlled substance, and in other cases of medical acuity**, the physician would ensure compliance with best-practices through the following:

- When there was a concern about a patient’s acuity, the patient was asked to present to our Crisis Stabilization Unit (CSU) for a nursing assessment. If the provider was located remotely, the patient would be connected to the provider through a tablet for further assessment.
- Routine urine drug screening (UDS) could be done asynchronously
- Other lab tests, including hepatitis and HIV screening, among others, could be completed asynchronously if the patient was located remotely. (Our CSU offers nursing services 24/7, enabling patients to drop in after business hours if needed.)
Use of telemedicine has enhanced our ability to reach patients “where they are” by addressing structural and attitudinal barriers to care. Some patients who received care through telemedicine may have been unable to attend appointments due to lack of transportation, need for childcare, employment schedules, concern about viral exposure risk, or concern for stigma associated with receiving SUD treatment. Use of telemedicine also helped with our own workforce limitations by giving providers the option to work remotely. Staff used this flexibility to work remotely for reasons related to the pandemic (during a COVID-19-related quarantine and while recovering from COVID-19) and for reasons unrelated to the pandemic (while caring for ill family members, picking up additional shifts from home that they would not have taken if required to be onsite). We believe use of telemedicine has helped to overcome these barriers, and it contributed to our rising numbers of patients engaged in care throughout the pandemic.

2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.

OneFifteen has deployed telemedicine within our comprehensive substance use disorder treatment program. As an “essential service,” we have maintained a physical presence and kept our doors open throughout the pandemic, and we believe it has been important to offer treatment options via telemedicine to ensure the safety of both patients and staff. We consider our program to be hybrid care, and we have provided physicians and patients the opportunity to jointly decide when to use telemedicine as an alternative to in-person care. A number of factors are considered, including the complexity of a patient’s condition, the patient’s access to technology and data (for use of telemedicine when the patient is offsite), and the patient’s comfort with and preference for telehealth.

For encounters where the patient is located remotely, using their own device, the following types of patient encounters were more likely to occur via telemedicine. (We note that not all of these examples will be impacted by enforcement of Ohio telemedicine regulations.)

- Treatment of substance use disorders and co-occurring mental health conditions for individuals who are in a maintenance phase of their illness, where medications are likely to be continued or incrementally changed.

- Rapid follow-up after initiating a new treatment protocol. For example, if a patient received initiation of buprenorphine for treatment of opioid use disorder, our team is likely to schedule a follow-up visit 2-4 days after this medication was started, and then would request that the patient return onsite approximately 7 days after medication initiation. This intermediate appointment facilitated closer follow-up for patients after initiating a new medication.

- If a patient indicated having a significant barrier to onsite treatment (for example, no transportation, lack of childcare, etc.), that visit would likely be converted to a telemedicine visit. The treatment team would work with that patient to determine parameters for future in-person and/or telemedicine visits, based on clinical judgment and best practices.
For encounters where the patient is located onsite (for example, in our CSU), and the patient is using a OneFifteen-issued tablet to see a remote physician, the following patient encounters were more likely to occur via telemedicine:

- **On weekends and after hours**, we staff our CSU with on-call physicians who are available to assess patients remotely through telemedicine. Without use of telemedicine, we would not be able to operate our CSU 24/7. Telemedicine has allowed us to build a responsive clinical staffing model, where providers are available to see patients but not required to be onsite unless there is a patient to be seen. With relatively low overnight patient volumes, this has been an attractive opportunity for our providers to work additional shifts without feeling burnt out.

3. Which practice groups or specialty types have not utilized telemedicine?

All medical providers working at OneFifteen have used telemedicine, including addiction medicine physicians, psychiatrists, family medicine physicians, and internal medicine physicians. All of our nurse practitioners have also used telemedicine. We do not employ any physician assistants. Our telehealth platform has been used not only by medical specialties but also by nurses, mental health technicians, therapists, case managers, and peer supporters. To date, **87 clinicians** have completed at least one telehealth visit using our telehealth platform. This includes **25 physicians** including resident physicians who have rotated through our clinical sites.

4. What symptoms should require in-person assessments?

For mental health and addiction services, most symptoms can be adequately assessed by telemedicine. Observing a patient through a synchronous audio/video feed is a reasonable medium for conducting the mental status exam that is performed during an in-person assessment: a physician will complete an evaluation of a patient’s mental state by observing a patient’s affect, speech, and behavior, usually without completing a more extensive physical exam, unless there is a specific reason to do so. We should note that other forms of telehealth, including telephonic assessment without video feed, provide incomplete information needed for a full assessment of the patient’s mental state, and therefore OneFifteen’s medical providers use synchronous audiovisual connection for our telemedicine care.

There are some symptoms of SUD where in-person monitoring is preferable:

- Alcohol and sedative/hypnotic withdrawal assessment; monitoring of vital signs for evidence of hemodynamic instability is indicated
- Abscesses, cellulitis, and other infections that are sequelae of injection drug use
- Signs of systemic illness (jaundice, edema, substantial weight loss, etc.)

In these instances, we have had the experience where an initial telemedicine encounter can serve as a triage point for an individual who might not have received any treatment at all. For example, if we see a...
patient in alcohol withdrawal who has a substantial tremor -- which is particularly easy to identify remotely as the patient holds their smartphone -- we use that encounter as an opportunity to educate the patient about risks of untreated alcohol withdrawal, and we coordinate transfer to an appropriate level of care, which may be an Emergency Department.

5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Our healthcare providers have routinely initiated care for new patients through telemedicine during the pandemic.

When the patient is located remotely, and using their own device:

- **Conducting an initial assessment via telemedicine has worked well when:**
  - The patient was hesitant to receive an in-person visit because they are concerned about the stigma of addiction or mental illness or the risk of contracting SARS-CoV-2.
  - The patient has faced certain structural barriers like lack of transportation and need for childcare.

- **Conducting an initial assessment via telemedicine has not worked well when:**
  - The patient does not have easy access to the technology necessary to engage in a telemedicine encounter, or has inadequate bandwidth for a real-time video and audio connection (resulting in delays in video or audio streaming).

When the patient is located onsite, and the provider is located remotely:

- **Conducting an initial assessment via telemedicine has worked well when:**
  - This almost always works well. Onsite nursing staff are able to attain information from the patient (vital signs, urine drug screen, labs) and relay that information to the offsite provider.
  - This has worked particularly well to address workforce shortages, and has enabled us to extend our current workforce to cover night and weekend hours remotely. We have also found that staff appreciate the option to work remotely, and our rate of provider absenteeism is exceptionally low.

- **Conducting an initial assessment via telemedicine has not worked well when:**
  - A new patient insists upon a face-to-face encounter with an SUD provider. We found that the majority of patients had no problem seeing a provider via a tablet, but there were a few patients who were uncomfortable with this technology and requested an in-person evaluation.
6. Has your organization completed any type of survey of the healthcare providers or patients regarding their satisfaction with telemedicine visits? Are there results you can share with the Medical Board?

We conducted a recent survey of OneFifteen clinical staff regarding their satisfaction with telemedicine visits and received responses from N=19 clinical staff, including 7 medical providers. The results show that our clinical staff find telemedicine visits to be an efficient and effective method of treatment. For example:

- When asked “How satisfied are you with telemedicine visits?,” 79% of respondents indicated “Satisfied” or “Very satisfied”
- When asked if they perceive “great value in telemedicine visits,” 79% of respondents indicated they “Agree” or “Strongly Agree”
- When asked if they “know which patients are suited to telehealth,” 76.5% of respondents indicated they “Agree” or “Strongly Agree”

As an example of strong satisfaction with telemedicine, one healthcare provider stated: “Telehealth reduces STIGMA! Patients enjoy the flexibility. Telehealth is a great option to have and offer patients who are already struggling with numerous barriers to care.”

Finally, examples of specific areas where healthcare providers found value in telemedicine visits include:

- Ease of access for patients who may struggle to attend in-person appointments
- Increase in engagement of my patients to the care program
- Flexibility to see patients if they miss their original appointment time
- Ability to have a more flexible work environment
- Ability to schedule patients for more frequent visits

While we have not systematically surveyed patients about their experiences with telemedicine, we have done a number of user experience interviews with patients about technology as an aid to their treatment. Our user experience researcher offered the following quote from one interview: “Telehealth—it has been very helpful! Before I didn’t have a car, and also I was afraid- with Covid. It was nice to get treatment without having to be physically here. 80% of my appointments are remote.” This same patient described our technology as being “easy to use.”

7. Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

In behavioral health, diagnosis is based almost entirely on clinical interview, review of information from other sources (e.g. medical records), clinical scales, and the mental status exam -- all of which can be attained through a telemedicine encounter using a synchronous audiovisual connection. Additional
information, such as the results of a urine drug screen, can supplement and enhance our confidence in a
diagnosis, though it is rare that the results of a drug screen would change a treatment plan; when there
is concern that it may, we would request testing to be done asynchronously. Thus, our confidence in the
ability to make a diagnosis during a telemedicine encounter is high because the process of coming to a
diagnosis is the same as it would be during an in-person visit.

Moreover, a substantial body of literature on the use of telehealth in the diagnosis and treatment of
behavioral health conditions has shown that it is equivalent, and at times superior, to in-person care.
SAMHSA recently published a review in their Evidence-Based Resource Guide Series titled, “Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders,” which includes a review of the research in this area.

8. What will your healthcare providers not be able to do when the in-person office visits in the
Medical Board rules are put back in place?

A return to enforcement of pre-pandemic telemedicine rules would limit the number and quality of
services that we provide in a number of ways.

(1) **We would have to close or significantly restrict our Crisis Stabilization Unit (CSU) services overnight and on the weekends.** We currently staff our CSU with a remote, on-call physician or nurse practitioner between the hours of 5pm-8am on weekdays and 24/7 on weekends. This physician or NP is available to assess individuals who walk in for treatment by using telemedicine: the remote provider sees the patient on a tablet and communicates the treatment plan with onsite nursing staff. There is insufficient demand for after hours / weekend services to staff a provider 24/7 in-house, and that would also not be a cost effective model of care. Many patients who walk in after hours will be in withdrawal from opioids, alcohol, or sedative/hypnotic agents, and our standard plan of care will be to treat the withdrawal syndrome using controlled substances (buprenorphine for treatment of opioid withdrawal, and benzodiazepines for treatment of alcohol and sedative/hypnotic withdrawal). Unless there are rule changes to telemedicine rules, we would no longer be able to continue to offer this service to the community.

(2) **We would have to halt plans to open five rural TeleHubs by the end of the year.** We have received grant funding and are in the midst of negotiations to launch partnerships with primary care clinics and other providers to provide needed SUD treatment in rural regions. One-third of Ohio counties have two or fewer DATA 2000-waivered prescribers, and ten counties lack any DATA 2000-waivered prescribers. As a result, individuals with OUD in these regions are unlikely to receive buprenorphine -- a lifesaving, FDA-approved medication indicated for the management of OUD. The intent of our Rural TeleHub Program is to address workforce shortages in rural regions by extending the geographic reach of DATA 2000-waivered prescribers through telemedicine. Our proposed model of care will include, among other services,
prescription of controlled substances by telemedicine -- specifically the prescription of buprenorphine for the treatment of OUD by a DATA 2000-waivered, addiction medicine provider using synchronous, audiovisual telemedicine technology. Under pre-pandemic Ohio regulations, the prescribing provider would need to complete a physical examination before initiation of a new controlled substance, which would not be feasible given the geographic distance between the patient and the prescriber. If Ohio resumes enforcement of telemedicine rules, we would consider moving the site of these TeleHubs to another state where the telemedicine rules would align with federal regulations, where we would be able to address the urgent need for SUD treatment in regions with poor access to care.

(3) **We would not reach some vulnerable patients during the window of opportunity when they are ready for treatment.** In 2020, over 93,000 individuals in the U.S. died from an unintentional drug overdose -- one every six minutes. Ambivalence is a part of the disease of addiction, and many individuals are highly ambivalent about entering treatment. Telemedicine is one of the tools we have to reach patients “where they are” and when they are ready for treatment. Many individuals experiencing severe opioid withdrawal will turn to high-potency opioids to alleviate their withdrawal symptoms -- and some of those individuals may die from an overdose. Our ability to reach patients via telemedicine -- whether to treat the patient in their own home, in our CSU, or at another location -- enables our physicians to offer care when patients need it most.

(4) **We anticipate that we would see lower treatment retention rates.** We evaluated time to dropout among n=891 individuals who sought treatment at OneFifteen between October 2020 and April 2021, and evaluated three groups of patients: those who received care exclusively in person (“in person” group); those who received care through a combination of telephone and in person (“phone” group; phone-based treatment has been used by therapists, but was not a mode of treatment used by the medical providers at OneFifteen); and those who received some care remotely using their own device (“telehealth” group). These three groups did not differ significantly among demographic or clinical characteristics, but we found that patients who used telehealth were 70% less likely to drop out of care compared to individuals who did not use telehealth. This is an observational, retrospective study, and the groups were not randomized, but we believe we are identifying a group of patients who both use telehealth and who have better outcomes. Restrictions that limit use of telehealth may impact retention in treatment among patients.
9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

We use an internally developed, proprietary telehealth platform that is compliant with HIPAA and 42 CFR Part 2. Our telemedicine visits include interactive, real-time electronic communication. While non-medical clinicians on our team (therapists, case managers, and peer supporters) have offered telephone-based services through the pandemic, we set the expectation in March 2020 that our medical team (physicians, nurse practitioners, and nurses) would use telemedicine with a synchronous audiovisual connection. We also have used text messaging (via SMS text or directly to the OneFifteen Patient App) to communicate asynchronously with patients, but this was not a primary means of communication for the medical team.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes, prescriptions are provided based on telemedicine visits:

- **26%** of telemedicine visits result in a prescription for controlled substances
- **39%** of telemedicine visits result in a prescription for non-controlled substances.
As an adjunct to our first telehealth study, we analyzed n=281 patients who received a first-dose of a controlled substance between October 2020 and June 2021. All of these patients received either buprenorphine for the treatment of opioid use disorder, or a benzodiazepine (lorazepam or diazepam) for the treatment of alcohol or sedative/hypnotic withdrawal. The telehealth group included individuals who were evaluated by their provider via telemedicine, regardless of whether the patient, the physician/NP, or both were located remotely (that is, some patients in this group were physically located onsite using a tablet, and others were remote and using their own device). No statistically significant differences were found between the telehealth group (n=111) and the in-person group (n=170) on demographic characteristics, clinical factors, dropout and retention rates, and duration of medication. We found similar results when stratified by substance (buprenorphine vs. benzodiazepines).

11. How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Lab tests including urine drug screening and urine pregnancy testing are a routine part of addiction medicine care. Asynchronous drug screen tests have been incorporated into our clinical workflows for patients receiving telemedicine encounters. We do not require that urine screens are collected prior to a telemedicine visit; rather, we allow physicians to make a sound clinical decision about how best to manage their patients. There are some clinical circumstances where the physician would request obtaining a urine drug screen before proceeding in care. For example, if a physician suspects that the patient is diverting a controlled substance, that physician may request that the patient come to our clinic to provide a urine drug screen before a telemedicine visit or before a prescription is e-prescribed.

Other lab tests that are part of routine treatment for SUD and co-occurring psychiatric disorders -- including hepatitis and HIV testing, drug levels, metabolic monitoring labs for a patient on an atypical antipsychotic, etc. -- are not point-of-care tests and must be sent to a lab. In these instances, we give patients the option to have laboratory testing ordered at a commercial lab (perhaps closer to their home), or the patient can come to our Crisis Stabilization Unit or Outpatient Clinic to have bloodwork done.

12. How is patient information, such as weight and temperature obtained? Does the patient self-report?

When needed, self-report is used for weight, temperature, and even measurement of other vital signs like pulse and blood pressure, which many patients are able to measure with home monitoring devices. Much of the time, these values are not needed for routine encounters via telemedicine for the treatment we are providing. In circumstances where self-monitoring is insufficient, patients are referred to one of our physical locations for continued assessment. For example, if a patient is in alcohol withdrawal with moderate or severe symptoms, it is important to assess blood pressure and heart rate, and the patient would be directed to present to our Crisis Stabilization Unit for further assessment.
It is worth noting that many patients who are referred to our physical location were unwilling to do so before the telemedicine visit. The doctor-patient interaction via telemedicine can help a patient move along the continuum of change as they learn about the medical risk of their clinical syndrome. For example, the physician may have begun a telemedicine visit anticipating that the patient would have an uncomplicated case of alcohol withdrawal, in which case a short benzodiazepine taper would be indicated. If the physician discovered that the patient has a more severe withdrawal syndrome, he or she could choose not to prescribe benzodiazepines and, instead, refer the patient to our CSU for further assessment. In this example, the physician would have been unlikely to have this telemedicine encounter under pre-pandemic telemedicine rules, because the patient would have been directed to present for in-person care. In our experience, for patients like this, who prefer an initial assessment to occur via telemedicine, it is often not the decision between telemedicine and in-person care, but between telemedicine and no care.

13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

To our knowledge, we have not seen any negative outcomes due to the use of telemedicine. Our hybrid model of care has allowed patients to receive care remotely while also, when appropriate, receiving care in person. Patients who did not wish to use telemedicine were able to receive services onsite, and physicians who were concerned about a patient’s condition could request that the patient present for an in-person visit.

As we look forward to building out more remote models of care -- for example, through our Rural TeleHub program -- we intend to maintain a “hybrid” care model, in which patients will continue to have a healthcare location identified where they can access in-person care when indicated. In this model, however, the in-person provider would not be the same individual as the addiction medicine provider; instead, this model is predicated on collaboration between local healthcare providers and remote addiction medicine physicians. We believe this model holds the promise of being able to address workforce development issues in behavioral healthcare and to deliver SUD care in regions with limited access to this care.

14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?

Providers are adept at identifying factors that would suggest the need for an in-person visit, and these signs and symptoms are the same that would prompt us, in person, to pursue a more extensive evaluation -- an abnormal mental status exam, a history that alerts us to a potentially complicated withdrawal syndrome, or a mismatch between what the patient tells us and what we observe of their mental state. Some clinical situations that arise in our patient population include moderate or severe withdrawal from alcohol or sedative/hypnotic agents, co-occurring withdrawal syndromes, methamphetamine-induced psychosis, and reports of physical complaints inconsistent with the reported
history. Suspicion of intoxication could prompt our healthcare providers to advise the patient that a urine drug screen is necessary before continued prescription of controlled substances.

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?

Because telehealth extends the availability of our treatment team, as described above, and because we reserve the right to advise the patient that a face-to-face visit is needed, we are generally able to navigate treating chronic conditions with controlled substances. The concerns for misuse, diversion, and lack of adherence, must be weighed against the known benefits of effective treatment of addiction disorders with controlled substances and in the context of the structural barriers: for some patients and some circumstances, the option is not between a telemedicine appointment and an in-person appointment; it is between a telemedicine appointment and no appointment at all, and a return to substance use.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

We believe an annual in-person visit would be a reasonable request for an individual receiving a controlled substance through telemedicine. In order to accommodate scenarios where the telemedicine provider might be located at a geographic distance from the patient, we would recommend that an annual in-person visit could be completed either by the addiction medicine provider directly, or by another healthcare provider so long as there is direct communication between the examining healthcare provider and the prescribing physician. For example, if a patient in a remote rural county receives addiction medicine care, then that individual could be assessed in-person by their primary care physician, provided that there is communication and coordination of care between those two physicians.

At OneFifteen, the frequency of telemedicine vs. in-person visits and urine drug screening depends on the phase of recovery that an individual is in. For patients who are prescribed a controlled substance, we request urine drug screens weekly for the first month and then monthly thereafter, unless there is a clinical indication to change this frequency (for example, a return to substance use). We do not require a specific frequency of in-person visits; that decision has been left to the physician’s clinical judgment. Stable patients with SUDs in long-term remission are likely candidates for ongoing telemedicine visits with infrequent in-person visits.

Our process of using a tablet for a patient, located onsite, to see a remote physician has been viewed as an acceptable alternative to a face-to-face assessment because onsite nursing staff attain additional objective measures that can be shared with the physician.
17. If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

As described extensively above, we have been operating a SUD treatment program with maximal flexibility to reach as many patients as possible. Our experience is that we have been able to maintain an informed, close doctor-patient relationship with our patients, even for those individuals who have received the vast majority of their care remotely through telemedicine. Our provider team meets once per week to discuss challenging cases, and we have on occasion used that venue to discuss the appropriateness of telemedicine care for individuals who have entered a more acute phase of their SUD. We also leverage our multidisciplinary care team (offering therapy, case management, and peer support services) to keep patients engaged in care. But overall, our experience is that patients appreciate the flexibility of telemedicine, and the interpersonal engagement that occurs during a telemedicine encounter is similar to that of an in-person visit.

18. What is the percentage of your patient visits you believe could be done via telemedicine?

This depends on the type of telemedicine and the location of the patient. A platform like OneFifteen’s telehealth platform provides flexibility to offer services where the patient, the provider, or both may be located remotely.

If you include telemedicine encounters where the patient is located onsite and the provider is remote, connected via a tablet, we estimate that well over 90% of our patient visits could be done via telemedicine. This requires the presence of a facility and nursing staff to assess the patient, check vital signs, give injectable medications, etc. Through communication with the nursing team and assessment of the patient via telemedicine, the remote physician is well equipped to assess, diagnose, and treat a patient.

If you restrict the discussion of telemedicine to those encounters where the patient is located remotely and is using their own device, we estimate that approximately 50% of patient visits could be done via telemedicine. There are several reasons for this. Some of these reasons are related to clinical factors, such as assessment of withdrawal syndromes in person and need to collect urine drug screens. Some are unrelated to clinical status, for example patients need to have access to smartphone technology and data plans; the local region needs to have broadband signals; and the patient needs to agree to telehealth sessions. There are many patients for whom 100% of visits would be appropriate, provided that they could get labs done asynchronously, and especially if they have a primary care physician who is doing an annual health assessment.
19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?

(1) We urge the Medical Board to permanently waive the requirement that a physician or physician assistant must conduct an initial in-person assessment when prescribing a controlled substance for the treatment of a substance use disorder or other behavioral health condition, with the following stipulations:

○ We recommend that this requirement be waived for Schedules III-V controlled substances as classified by the U.S. DEA.

○ From our perspective, waiving the requirement for Schedule II controlled substances is more nuanced. We do not see value in waiving an in-person visit requirement for prescribing full opioid agonist medications used for pain control, but we would encourage the Board to consider waiving the in-person requirement for prescription of stimulants for the use of behavioral health conditions such as ADHD. (While this would have little impact on our program, we are aware of the workforce shortages of child psychiatrists, and believe that telemedicine may be of value in the accurate assessment and treatment of ADHD among children.)

○ We do not perceive value in waiving the requirement for Schedule I controlled substances, such as cannabis, and would recommend that the Board leave this regulation in place for Schedule I drugs.

○ We would also recommend that initiation of a controlled substance via telemedicine should only be allowed when a real-time, synchronous audiovisual technology is used. Telephonic connections and asynchronous technologies provide insufficient information for the full assessment needed to diagnose and treat an individual who would benefit from a controlled-substance prescription.

(2) For individuals prescribed a controlled substance via telemedicine, we feel it would be reasonable to require an annual in-person evaluation, which could be provided by the addiction medicine provider or another healthcare provider, so long as there is collaboration and communication between the local healthcare provider and the remote addiction medicine physician or physician assistant.

(3) As the Board continues to look at evaluating these rules, we urge the Board to revise Ohio’s Office Based Opioid Treatment (OBOT) rules. We understand the Board’s concern about patient care and safety, but we find these rules to be overly prescriptive of a physician’s actions in a way that is inconsistent with other areas of medicine, including in areas governing the prescription of full opioid agonists. We request the following rule changes:

○ Modify the requirement that a physical examination must occur prior to initiation of buprenorphine, by indicating that this examination can be completed during a telemedicine visit using a synchronous, audiovisual connection.
○ Align rules to include the updates from the American Society of Addiction Medicine National Practice Guidelines 2020 Focused Updates and the Substance Abuse and Mental Health Services Administration Treatment Improvement Protocol 63.

○ Eliminate the requirement for a plan for psychosocial treatment for physicians who are not board certified addictionologists or psychiatrists. Physicians should provide available treatment options. The necessity for treatment should be a shared decision between the patient and physician, but not required.

○ We believe there is value in establishing a treatment agreement between the physician and the patient regarding prescription of a controlled substance, and we believe this agreement can be established even when care is remote. We encourage the Board to adopt language that is permissive of electronic communication and not limited to written signatures and materials. Further, we would suggest that the Board remove the requirement that information about medications be distributed in writing, as this is not required in other areas of medicine and the patient will receive this information as an accompaniment to their prescription (the package insert).

We hope these answers to your questions have been helpful, and we would be happy to answer any additional questions that you may have. We do feel there is one last subject that needs to be explored as the Board considers revisions to telemedicine and in-person visits: the relationship between the federal rules and Ohio’s rules.

Ohio’s regulations and the Federal regulations (per the Controlled Substances Act (CSA) and as amended by Ryan Haight Act of 2008) are largely aligned, and if Ohio’s telemedicine rules are revised, providers will still need to adhere to Federal rules. Like Ohio, the federal government has suspended enforcement of telemedicine regulations during the public health emergency (PHE), and the federal PHE is not expected to expire until mid-2022. As we understand it, there are a few relevant issues to surface about the relationship between Ohio and federal rules:

1. **Relaxing Ohio’s OBOT rules would align telemedicine practice in Ohio with the federal pre-pandemic rules.** In particular, Ohio requires a physical examination to be performed before initiation of a controlled substance for the treatment of OUD. Federal rules do not include this type of OUD-specific requirement. In our experience, telemedicine encounters using synchronous, audiovisual technology provide sufficient information to diagnose OUD and start a medication like buprenorphine.

2. **Relaxing Ohio’s telemedicine rules on the prescribing of a controlled substance would align telemedicine practice in Ohio with the federal pandemic rules** -- in other words, if Ohio’s rules on first-dose prescribing are relaxed, Ohio practitioners including OneFifteen could continue to offer telemedicine as we have for the past 18 months and as described above so long as the federal PHE continues. We do not know if the current federal rules under the federal PHE will become permanent. If we return to federal rule enforcement, OneFifteen’s providers will have
to adhere to prescribing a first-dose of a controlled substance in person, although there are some exceptions, such as when the patient is located in a facility or accompanied by a provider with a DEA number. (The OBOT stipulation for a physical examination by the prescriber supersedes this exception, so without changes to the OBOT rule, we could not practice under these stated exceptions.)

3. **Amending both the OBOT and telemedicine controlled-substance regulations will set Ohio up to be at the forefront of innovation when federal rules are amended.** By making Ohio’s pandemic telemedicine flexibility permanent, practitioners in Ohio will be well positioned to be first-movers in telemedicine innovation when federal rules change.

OneFifteen hopes to develop innovative care models that others can replicate. We have been able to set the groundwork for this during the past 18 months of the pandemic: by deploying a synchronous audiovisual technology that supports telemedicine encounters where the patient and/or provider are located remotely; by using telemedicine to extend our workforce both in time (after hours coverage) and space (rural TeleHubs); and by treating patients “where they are” and using telemedicine to enhance their engagement in care.

We sincerely appreciate the opportunity to present this information to the Board.
October 4, 2021

Jill Phalen Reardon
Director of External Affairs
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215

Dear Ms. Reardon,

On behalf of the Ohio Association of Community Health Centers (OACHC), thank you for the opportunity to submit answers to the State Medical Board’s proposed questions for the ongoing discussion on telemedicine.

The OACHC supports all of Ohio’s 57 Federally Qualified Health Centers and FQHC Look-Alikes (more commonly referred to as Community Health Centers), providing care to more than 854,000 Ohioans across 452 sites throughout 74 of the 88 counties. Community Health Centers are non-profit healthcare providers with patient-majority boards that meet the specific needs of the community they serve. For more than 55 years, Community Health Centers have provided integrated whole person care, often providing medical, dental, behavioral health, pharmacy, vision, and other needed supplemental services under one roof, regardless of one’s insurance status.

Community Health Centers are required to offer comprehensive services in areas of high need and have been pioneering telehealth to address geographic, economic, transportation, and linguistic barriers to health care access. Health care leaders all across the country, including Community Health Centers, continue to incorporate and grow the use of various telehealth modalities as equity tools to overcome health disparities for underserved populations. Telehealth is providing access and the ability to deliver needed health care to patients who are unable to have an in-person visit with a provider, or plainly prefer the virtual experience and the convenience it brings.

As Ohio Community Health Centers continue to respond to the opioid epidemic, COVID-19 pandemic, and the recent Delta surge, they have greatly expanded their use of telehealth. Please see the following OACHC responses to the questions posed by the Board:

1. **How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?**
   - OACHC Answer: Increased utilization across the board, key in maintaining contact with patients and improved continuity of care. It has increased access for high-risk patients too and has been used medically and in behavioral health settings extensively. In addition to supporting
increased access to timely care for our underserved populations, Health Centers are also using these tools to overcome persistent clinical workforce shortages, decrease of “no-show” rates, maintaining provider-patient relationships and easing of language barriers.

2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.
   - OACHC Answer: Primary care and especially critical for Substance Use Disorder (SUD) and Behavioral Health (BH) patients to be able to do suboxone and psych meds by telehealth. In addition, our centers have seen a strong preference by patients for using telemedicine for short follow up appointments.

3. Which practice groups or specialty types have not utilized telemedicine?
   - OACHC Answer: None

4. What symptoms should require in-person assessments?
   - OACHC Answer: Emergency or potentially life threatening and when determined clinically necessary within organizations protocols.

5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
   - OACHC Answer: BH, Medication Assisted Treatment (MAT), primary care, COVID Care, emergency dental care

6. Has your organization completed any type of survey of the healthcare providers or patients regarding their satisfaction with telemedicine visits? Are there results you can share with the Medical Board?

7. Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
   - OACHC Answer: No

8. What will your healthcare providers not be able to do when the in-person
office visits in the Medical Board rules are put back in place?

- OACHC Answer: MAT, SUD, some BH visits w diagnosis of anxiety, anxiety of returning to medical office, some medical, dental, and services to meet the needs of mobility and other older patients challenged or fearful with being exposed to COVID or other communicable diseases. In addition, there will be compressed accessibility to same day and next day access which could result in patients deferring care to the emergency room/urgent care.

9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

- OACHC Answer: HIPAA Compliant platforms (audio video); and audio-only.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

- OACHC Answer: In general, majority of visits do not involve controlled meds. However, the controlled med visits are at times the most critical (MAT/Suboxone/MH med assessment and follow-up)

11. How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

- OACHC Answer: Both

12. How is patient information, such as weight and temperature obtained? Does the patient self-report?

- OACHC Answer: Patient reports or if clinically necessary remote patient monitoring (RPM) is deployed

13. What factors lead healthcare providers to advise the patient that an in-person visit is needed?

- OACHC Answer: clinically indicated, clinician needs labs or other elements that in-person visit needed or if the patient prefers to see their practitioner in person (may be preferred by racial, ethnic, or cultural populations).
15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?
   • OACHC Answer: No

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
   • OACHC Answer: Yes on average, patient seen in-person once every 12 months, and not initially.

17. If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
   • OACHC Answer: Telemedicine is another tool for providers that does not determine whether care is satisfactory or not, that is determined by the doctor patient relationship. If the provider had poor performance prior to telehealth, it is likely they will continue to provide poor care despite the mechanism the care is delivered.

18. What is the percentage of your patient visits you believe could be done via telemedicine? OACHC Answer: 30-40%

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?
   • OACHC Answer: Like ODM, make the Board’s emergency rules permanent, allow continuation of telephone only being acceptable in cases where the patient does not have internet or access to a computer/smartphone. The continued ability to see a patient by telehealth for MAT/controlled substances is critically needed. In addition, require on average, patient seen in-person once every 12 months, and not initially.

OACHC strongly supports the ability to use telehealth to serve Ohio’s communities and most vulnerable populations. As providers of integrated care, Community Health Centers both welcome and need consistent and standardized regulations for telehealth moving forward. We appreciate the opportunity to share our feedback on behalf of Ohio’s Community Health Centers and look forward to working with the Board on these rules. If you have any questions or would like to further discuss, please contact Julie DiRossi-King, Chief Operating Officer at (614) 884-3101 or jdirossi@ohiochc.org.

Sincerely,

Randy Runyon
President & CEO
1. **How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?**

Our healthcare providers engaged in over 400K telehealth visits in 2020 alone. These types of visits included direct-to-patient, outpatient, emergency department, inpatient, along with asynchronous visits and virtual “check-ins.” The biggest difference noted here is the drastic change in volume. In all of 2019, our enterprise conducted just over 11,000 visits, the majority of these were through a very small subset of providers via our urgent care platform. Today, nearly all of our providers have conducted at least one virtual visit, and many have adopted it as part of their standard clinic setup.

Additionally, now we see tens of thousands of patients per month via telehealth, and our providers have become more facile and accustomed to the virtual environment. Workflows have been developed and standardized on how to setup and interact with a patient via our telehealth tools. This includes educational materials and curricula that we plan to build into our telehealth credentialing process; and this is something that we aim to make mandatory on a regular basis for providers conducting telehealth visits. Recently, we have invested in a single system-wide platform partner, one which we chose after a comprehensive and wide ranging selection process drive by our providers’ opinions. This single platform will help us standardize workflows across our system when it comes to telehealth visits.

2. **Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.**

Both psychiatry and behavioral health have utilized telehealth by far the most, with 85% of their current visits virtual at this time (the vast majority are video). Psychiatry has done initial and follow up visits, counseling, psychiatry, group, and individual visits all by virtual means. As well, primary care and our family practice groups have continued to use telehealth at high levels, with some providers still seeing upward of 50% through the telehealth tool.

Providers find there are a broad range of patients and conditions that can be effectively managed via telehealth. These can include acute new patient visits for simple things like a sinus infection or urinary tract infection; as well as more complex chronic conditions such as heart failure, cystic fibrosis, and sickle cell patients that require regular checkups and medication maintenance regimens. Telehealth has improved continuity of care and access to care as we have seen a reduction in patient no-show rates by about 50%, when compared to in-person visits.

3. **Which practice groups or specialty types have not utilized telemedicine?**

Every service line and every department that is patient facing has used telemedicine in some form or fashion. Even entities such as pathology have utilized tele-consultations with colleagues to ensure accurate and prompt diagnoses, especially as staffing shortages arose.
4. **What symptoms should require in-person assessments?**

As you can see from the above answers, telehealth can be used as an effective tool to interact with patients who are at a remote location regardless of symptom profile. The key component of this is ensuring a safe and effective evaluation and treatment plan. In some circumstances this may require an in-person visit, while in many others it does not. We currently believe it would be very difficult and lacking in evidence to designate specific symptoms that require an in-person visit. Furthermore, relying solely on symptoms to direct whether a visit should be telehealth is far from foolproof. It is not a one-size fits all approach. Clinical evaluation and care requires considering a multitude of different factors ranging from symptoms, to lab work, to imaging, and even physical examination, much of which can be accomplished via telehealth.

As well, this COVID-19 pandemic has highlighted the many other factors that physicians must take into account when asking a patient to come into the office. This would include Social Determinants of Health (SDOH), including the ability of a patient to access transportation, finances, or family support (or lack thereof), and a patient’s disabilities, all of which can impact a patient’s ability to attend in-person visits. Telehealth can be a boon for patients in many of these circumstances to effectively replace in-person visits.

Just as important, we have found telehealth to be of great value in more efficiently triaging patients to be directed to the right in-person care. This has reduced hundreds of hospital-to-hospital transfers across our communities and likely saved thousands more in avoidance of acute care situations via a telehealth visit. Thus, we can safely say that determining specific symptoms of which are not appropriate for telehealth would be very difficult. It is more often the clinical condition of the patient, the many SDOH factors, and the clinician’s judgement that all rule in or rule out telehealth as an effective tool for evaluation.

5. **Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?**

Yes. All patient facing specialties across our system from general surgery, ENT, medical oncology, all the way to psychiatry have initiated new patient visits via telehealth during the last year. For psychiatry in particular, nearly all new patients in the past 18 months have been virtual, this has transformed behavioral health access for the better. Whereas our psychiatric workforce is heavily concentrated near the Cleveland Metro area, much of our catchment area as a system, including the majority of patients we serve, are at least a 45 minute drive to the nearest psychiatric provider. Our virtual population has massively changed this balance, with no clear trade-offs.

This can be said to various degrees for other specialties such as family medicine, ENT, Urology, and other subspecialty areas and in particular under certain prescribing situations. This is true for controlled prescriptions in particular, where medical and psychiatric providers want to taper people off questionable regimens and have been able to support primary care for this in new and productive ways. For example, this has proven effective when prescribing Suboxone and to get it to people with rapid access quickly where they otherwise would have struggled and also for
intellectual disabilities where patients who struggled to manage office-based visits are better able to engage by video without disruption and stress in a new environment.

Patients have been effusive about their preference for telehealth, noting that they were on the fence about getting care in the first place but agreed due to the virtual capability and the ability to get in more quickly as a result and not be forced to take additional time off work. On occasion, we have noted that we are not able to easily evaluate certain symptoms in very specific patients; in those less common cases, the clinicians have made that decision. Full evaluation of neuropsychiatric disorders at times - due to need for physical exam for instance - can be hard. Similarly, fully evaluating dementia through testing can pose some challenges outside the office.

We find some providers have had issues with patients who may have limited bandwidth or poor digital literacy, where they do not know how to attend to a live, synchronous audio-video telehealth encounter. Our hope is that by continued usage of telehealth, digital literacy improves. As well, UH has taken proactive steps to improve the digital equity of our communities in pilot projects providing free broadband, free internet connected devices, and tech support along with digital literacy training to groups of underserved patients. Audio-only telehealth has also helped to bridge any digital divide.

6. Has your organization completed any type of survey of the healthcare providers or patients regarding their satisfaction with telemedicine visits? Are there results you can share with the Medical Board?

Last year, UH sought to understand the satisfaction of both patients and providers with telehealth. We commissioned an enterprise wide survey that was sent out to our 2,633 healthcare providers. The survey asked several questions about telehealth including how providers viewed it, the platforms they used, and the reasons why they would and would not use telehealth. This survey indicated that 96% of providers showed interest in using telehealth, and over 82% of providers had significant interest in continuing to use telehealth even after the pandemic was over. The number one reason providers wanted to continue using telehealth was that it improved patient access to care. This reasoning for increased usage was consistent across various specialties and in different care settings.

Similarly, we have evaluated patient satisfaction by performing focus groups and have distributed Press-Ganey surveys to all patients when it comes to patient satisfaction with telehealth. Patients’ happiness with telehealth visits is in line with the literature, as over 90% of patients are satisfied with their telehealth experience, and approximately 70% reach the “top box” and are extremely satisfied with their experience. Specifically, according to our patient experience survey of at least 7,000 patients, 75% of our patients are “very satisfied with their overall experience” using telehealth.

7. Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
Stated simply, the diagnostic accuracy of a telehealth visit is expected to be identical to an in-person visit. Monitoring diagnostic accuracy is something that has been done even pre-pandemic in various situations. For both synchronous and asynchronous telehealth care, there is plenty of evidence in the literature supporting the diagnostic accuracy of telehealth in many different situations, from asynchronous care of dermatologic conditions, to acute upper respiratory issues, to chronic condition management\textsuperscript{1,2,3,4}.

Telehealth as a tool has continued to provide appropriate and accurate care in the correctly chosen patient. As such, there is no single telehealth modality that will provide an accurate diagnosis for all conditions, just as there is no single lab test or imaging tool that provides a diagnosis for all conditions. So, the factors that determine accuracy of a telemedicine diagnosis are again wrapped up in the providers’ selection of appropriate patients at appropriate times and for appropriate conditions, all of which may vary from visit to visit. Our goal at UH is to measure accuracy of diagnoses via telehealth just as we do for in-person visits – by continuing to hold providers to a high standard within their departments and divisions, monitoring for excessive health care utilization, including readmissions, overuse of health care resources, and undue complications. Much of this relies on provider judgement and peer to peer accountability. These are all things we do now for providers and their patients when seen in-person and will continue to do as more patients receive telehealth care.

8. **What will your healthcare providers not be able to do when the in-person office visits in the Medical Board rules are put back in place?**

Access to appropriate health care will be reduced, in some cases significantly and with severe and real-world consequences. We do not think it is an exaggeration to say that there is the potential for disastrous consequences to our communities, as morbidity and mortality will be negatively impacted. In particular, our behavioral health colleagues are very concerned because psychiatry access will be massively reduced, heavily biasing against rural areas. Specifically, for our behavioral health team, providing Suboxone access for patients in a rapid manner will be massively reduced and could worsen the narcotic-related pandemic that still exists within our communities. Patient-provider engagement will be heavily impaired as many more patients are willing to engage in visits when they did not have to carve out too much time and travel.

9. **What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?**

Our providers use a number of different technologies; however we do closely regulate the software platforms as well as hardware that is used. All platforms are required to be HIPAA compliant and ensure high levels of encryption along with confidential data transfer. This includes interactive, real time communication with both audio and video. We ask providers to use UH approved devices, typically UH laptops or computers with a video monitor and camera.

We also want to highlight the benefits of audio-only visits. These types of visits have been vital for certain patient populations who may be technologically illiterate or encounter barriers to access these technologies, including areas where there is a lack of broadband internet. This would include individuals along our East Cleveland locations and rural locations, where there is a clear disparity in digital connectivity and in digital literacy. Audio-only visits have been absolutely vital to maintain this connection to patients, often those from disadvantaged communities and vulnerable socioeconomic situations. Expanding the definition of telehealth to include an audio only interaction is very much needed.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Prescriptions are provided based on telemedicine visits. We have not seen any data to suggest that telehealth visits result in a higher number of prescriptions, including controlled substances. For psychiatry, most patients seen were prescribed medications during virtual visits, which includes around 30% of patients getting controlled prescriptions and more than 50% in child psychiatry getting controlled prescriptions. This has not resulted in any new problems. To the contrary, more children who would benefit from stimulants got them, which is a good thing. We have not encountered any abuse of prescribing from telehealth visits.

11. How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Laboratory tests can be part of a pre-visit interaction or a post-visit discussion, just as they are for in-person visits. These days, many times a full visit is not required for a follow up discussion of lab results. Providers and patients are connected through our patient portal and will often be able to communicate through this modality to save time and costs, while ensuring adherence to follow up tests, imaging, or other diagnostic or treatment recommendations. Telehealth has been of great benefit in allowing patients improved access and reducing the time they need to take for an office visit. Often, we hear from patients how this time saved in avoiding an unnecessary in-person visit allows them to obtain their diagnostic tests quicker and more efficiently.

12. How is patient information, such as weight and temperature obtained? Does the patient self-report?

How vital signs and other objective patient information are acquired will vary in different settings and among different providers. We do have “hospital-at-home” and home care programs that use Remote Patient Monitoring (RPM) devices that are often bluetooth enabled and communicate data automatically to our care teams. This includes blood pressure, weight,
temperature, heart rate, pulse oximetry, among many other patient reported outcome measures in appropriately selected patients. As well, we perform outpatient telehealth visits – where patients from rural areas present to a central clinic location with a nurse is able to acquire vital signs and document them for consideration by the provider.

We also have providers who will ask a patient to weigh themselves during the virtual visit and take a temperature during the virtual visit so they can guide the patient and visualize the results on the device through the video. Other providers will use patient reported outcomes for weight and temperature. Thus, there are a range of different ways that patient vital signs can be acquired. Again, this process relies on provider judgement to determine which patients need to have vital signs monitored and through what means.

13. **Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?**

We have not found this to be the case. In fact, many of our primary care providers have commented on how telemedicine actually improves the progress they can make when caring for patients with chronic conditions. One of the single biggest factors in prevention of chronic condition related morbidity is reliable and consistent access with a health care provider. Telehealth has improved things in this respect when compared to in-person visits.

14. **What factors lead healthcare providers to advise the patient that an in-person visit is needed?**

Very generally, when there is a degree of physical interactiveness that is a requisite to verify, diagnoses, or guide further treatment/therapy. Depending on the patient and condition, this does not need to occur during the first visit and can be required as clinicians deem appropriate for follow up visits.

15. **Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?**

Our psychiatric providers are particularly interested in this question. Our providers have indicated that no - there is no concern. Specifically around Suboxone, as it isn't distributed as widely as it should be and large scale population studies show that even diverted Suboxone improves public health measures, like spread of hepatitis and HIV. Regarding benzos and stimulants - there are no concerns different from what happens during in-patient visits. In both cases, there is potential for providers to overprescribe or prescribe inappropriately based on objective standards.

Prior to virtual visits, the opioid epidemic spread easily without virtual visits. Furthermore, lack of access to appropriate specialists leads less experienced primary care providers to have to make decisions that are less than ideal (the vast majority do the best they can under tough circumstances). Our behavioral health providers are especially impassioned to be very clear – we would strongly discourage any restrictions based on speculative concerns of what might happen before data informs us of any given concern. The current evidence tells us that the benefits of improved access far outweigh the risks of abuse.
16. **Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?**

We believe the right “mix” of in-person and telemedicine visits will vary specialty to specialty, condition to condition, and provider to provider, just as most disease states will vary in their evaluation and follow up by different specialists. There are some broad strokes that can be painted here though, to give you a sense of how our providers in different specialties are using telehealth. As previously mentioned, our behavioral health providers on one end of the spectrum utilize telehealth visits for the vast majority of their visits. The conditions encompassed in behavioral health and the patients involved are quite amenable to telehealth visits. Our behavioral health providers have commented on how they have improved access to patients, which results in better treatment of chronic conditions and reduced presentations to higher acuity situations such as the emergency department or inpatient stays.

Our primary care physicians continue to use telehealth but at a lower rate, yet this significantly increased from pre-pandemic, currently around 10% of all monthly visits on average. It must be noted though that this does vary greatly by provider. We have some primary care providers that see well over 50% of their visits via telehealth, while others see less than 1%. Part of the reason around this is comfort with the platform and knowledge of how to use them, along with expected variations in practice patterns.

17. **If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?**

Our providers hold themselves to the highest standard when it comes to patient care, whether it is in-person or telehealth. At UH, as is similar across health care, there is only one standard of care regardless of the tools used. Thus, providers are ultimately responsible for the outcomes of patient care. Many of our providers find that the continuity of care is greatly improved with telehealth. They are able to see patients more frequently as there is about half the rate of missed appointments in telehealth when compared to in-person. And, just as important, we have found that for certain specialties the rate of rescheduled visits for telehealth is 70% higher than for in-person visits. We believe that telehealth, when used appropriately, will foster a more informed and closer doctor-patient relationship.

18. **What is the percentage of your patient visits you believe could be done via telemedicine?**

Again, we believe this really varies specialty to specialty and provider to provider. Our behavioral health providers believe close to two-thirds of all visits could be done via telehealth. On average, if you include our entire health system and forecasts from others that are informed in this area, about 20% of all visits are likely to be done via telehealth in the future, presuming in-person visit requirements are permanently relaxed.

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19. **What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?**

We would like to see an elimination of the in-person visit requirement when it comes to initiating new patient visits and prescribing of controlled substances. There are plenty of relationships that providers and patients have engaged in over the last year that have been initiated and continued via telehealth to great benefit for both provider and patient. In many cases, patients never would have maintained a care bond with their provider and would be limited in their ability to continue such if in-person visits are required. We understand the concerns around fraud, waste, and abuse; we believe an appropriate “floor” for monitoring would include required credentialing, education on how to use telehealth as a tool, and even considering harnessing the improved auditability that naturally exists in telehealth visits and electronic records.

We would implore the Board to recognize telehealth not as a new specialty or category of care, but instead as a tool at the clinician’s disposal to evaluate, diagnose, and treat their patients. If we can agree on this type of definition of telehealth, then we can transition from trying to regulate the appropriateness of individual symptoms, disease states, or specialty specific use of telehealth, and instead turn toward ensuring general competency in using the tool, while having education on how to improve use and reporting when it is not being used appropriately.

In the end, it comes down to a risk versus benefit conversation. The Board is intimately aware of the risks associated with over-prescription of controlled substances and the fraudulent providers who existed before COVID. We hope that we have communicated the many benefits that exist in telehealth, especially those that have been recognized post-pandemic. Clearly, post-COVID, the conversation has become more complex. We believe one of the biggest risks is now in returning to pre-pandemic telehealth restrictions. This possibility will result in the loss of health care access for the millions of patients across the state of Ohio. These are patients who have initiated and continued a doctor-patient relationship, including controlled substance prescriptions where appropriate, via telehealth. This desire and need for providers to interact with their patients via telehealth is not going to change. We hope the Medical Board can appreciate this and will make the right decisions when it comes to telehealth regulation in the year 2021.

**Final Comments:**

Our team has had many conversations about the use of telehealth over the last year. We think that it is vital to consider the situation and circumstance of our “new normal.” COVID-19 has permanently transformed the way that patients and providers engage in their health care. In our opinion, any return to pre-COVID expectations when it comes to a “requirement” of in-office visits, would imperil hundreds of thousands of our patients’ access to care. Given the large societal changes that have occurred with concerns of transmissible disease and the acceptance of telehealth as a valid tool in improving health care access, we do not see a reason to create another barrier. This barrier lies with in-person requirements when it comes to either a new or ongoing provider-patient relationship.
Telehealth is not a new type or field of medicine, but instead is a new delivery mechanism for health care. In the future, we hope that just as “telebanking” has become banking, or “teleconferencing” has become conferencing, so will “telehealth care” become simply “health care.” It is imperative that we allow this care provision to continue so we can continue to study and evaluate the benefits of telehealth in our populations.
State Medical Board of Ohio:

Nationwide Children’s Hospital appreciates the opportunity to comment on the Board’s proposed rules related to telehealth. We welcome the Board’s collaborative approach to assessing the impact these rules will have on patient care. Please see our response to the Board’s questions below.

1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?
At the onset of the pandemic, our team of providers used telehealth to reach patients that could not otherwise be seen in person. Providers gained significant experience with telehealth across specialties and conditions. This experience helped us learn a great deal about the abilities and limitations of telehealth in caring for our pediatric patients. From these learnings, we have refined our use of telehealth. We have found telehealth may be useful, on a case-by-case basis, in the following areas:

- Behavioral health and clinical therapies
- Management of chronic conditions when combined with regular in-person care
- Medically fragile and immunocompromised patients (reduce exposure and stress of travel)

2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.
Telehealth is available across all of our ambulatory specialties (see question 3 for exceptions). Behavioral health and clinical therapies are the highest utilizers. Telehealth is primarily used to support ambulatory care for established patients (e.g., follow-ups). We have some additional programs where we utilize telehealth for group therapy, school health, and connecting care between NCH facilities.

3. Which practice groups or specialty types have not utilized telemedicine?
Dental and ophthalmology are not currently live on video telehealth. Dental will go live in Q4 2021.

We do not utilize telehealth for inpatient care.

4. What symptoms should require in-person assessments?
It would be dependent on the specialty. Generally speaking, diagnoses that are based on a physical exam are completed via in-person assessment. For example, acute otitis media when no ear drainage is present.

If, during the course of a telehealth visit, a provider feels they are unable to accurately diagnose or treat a patient, we would bring them in for an in-person visit.

5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
Early in the pandemic (Q2 2020) we used telehealth for new patient visits. We suspended new patient visits last fall. There may be very limited exceptions to this when there are case-specific extenuating circumstances.

6. Has your organization completed any type of survey of the healthcare providers or patients regarding their satisfaction with telemedicine visits? Are there results you can share with the Medical Board?

Yes, we can share summary data regarding patient and provider satisfaction. Please let us know if this would be helpful. Generally speaking, satisfaction ratings are high (+95%).

7. Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

Measuring the effectiveness of telehealth is an important area of future research. This research will help us tailor the optimal mix of in-person and telehealth care for specific patient populations.

8. What will your healthcare providers not be able to do when the in-person office visits in the Medical Board rules are put back in place?

We do not expect a significant disruption to our current practice given our internal guidelines around seeing patients in person. However, we would advocate for the following:

- Extension of the overall deadline in alignment with pandemic conditions. We have seen an increase in the number of pediatric COVID cases, and we continue to use telehealth as a tool to care for vulnerable patients. Additionally, this will allow time to adjust clinic schedules without disruption to patient care.
- For hospice, palliative care, and pain, we would advocate for an in-person visit every 12 months (or 6 months) rather than every 3 months. It has been instrumental to have the ability to do telehealth in between in-person visits so as to spare families who seek fewer hospitalizations/interventions.
- For routine refills or prescription renewals of controlled substances, we would suggest eliminating the requirement that cross-covering providers must conduct a full exam/visit in accordance with 4731-11-09(C)(1)-(9). We are able to monitor the prescription of controlled substances for chronic conditions using OARSS. Requiring additional visits reduces overall patient access in a system where demand exceeds capacity.

9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

We are leveraging our patient portal to conduct synchronous video telehealth. Patients log in to their personal health portal (MyChart) and conduct the video visit via secure video session (Zoom). If there is a technology issue (e.g., patient’s internet fails), we may resort to phone or convert to an in-person visit.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes, when clinically appropriate, prescriptions may be made. Approximately 11% of visits were associated with a prescription for a non-controlled substance and 4% were associated with a prescription for a controlled substance. This data reflects June-August 2021.

11. How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

This is dependent on the clinical circumstance. Previously completed labs and imaging are available in our EMR and reviewed by the provider during visit. In cases where recurrent and known labs are needed, some clinicians may ask families to obtain these before the telehealth visit. Others may wait until after so they can reassess need for additional testing.

12. How is patient information, such as weight and temperature obtained? Does the patient self-report?

Patient information is maintained in the EMR. Data specific to the telehealth encounter is self-reported. We are exploring integrating biometric devices for some patient populations.
13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
We do not have population-level data on clinical outcomes at this time. Anecdotally, you can find examples on both sides. For example, with therapies, some children do better with telehealth (e.g., discussing anxiety-related issues from the comfort of home) and some children do better with in-person care (e.g., toddler unable to focus for duration of speech therapy session on an iPad).

14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?
- Clinical appropriateness and relevant standards of care
- Need for ancillary in-office procedure or testing
- Patient family barriers and preferences
- The requirements of professional licensing, regulatory, or credentialing boards

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?
After an initial in-person visit, many chronic conditions can be safely managed by providers but on a case-by-case basis. For example, if the provider is completing an assessment to a refill prescription for well-controlled ADHD, this may be appropriate. If the controlled substance is for persistent or new onset pain, an in-person exam is warranted.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
Yes, we have issued guidance regarding the minimum interval of in-person visitation. Generally, this is once per year for patients with whom we maintain an ongoing care relationship. However, this guidance may be superseded by the standard of care and/or applicable laws and regulations.

17. If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
To ensure continuity of care, all patients are provided with an after visit summary through the patient portal. This summary contains a record of the diagnosis, medications, etc. Additionally, the provider would communicate directly with the patient’s PCP or referring physician, as relevant.

18. What is the percentage of your patient visits you believe could be done via telemedicine?
This varies significantly by specialty. For medical subspecialties, it may be 10-20%. For behavioral health, it may be upwards of 50%, and clinical therapies may be 10-30%.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?
We would support a requirement that the provider must be able to offer direct in-person care should the patient need labs, imaging, or an escalation in care. This would help ensure patients are connected to appropriate local resources and promote continuity of care. In the same vein, telehealth visits (and in-person visits) should always be supported by continuity of care activities such as communication with the PCP and documentation via an after visit summary.

It would be helpful if the Medical Board offered additional guidance on patients that are traveling or temporarily out of state (e.g., college). It is our desire that we may maintain an ongoing care relationship with these patients, considering their permanent place of residence to be Ohio.

We are grateful for the Board’s continued effort to improve telehealth services and look forward to working with the Board on regulatory initiatives.

Sincerely,

Laura McLaughlin, PMP
Telehealth Program Manager
Planning and Business Development
Proposed Questions to Stakeholders for Telemedicine Discussion

The following are proposed questions for healthcare providers and organizations:

1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?

   Beyond the initial objectives to maintain social distancing, telemedicine is utilized by providers across the majority of our specialties to improve access and convenience to patients while improving provider efficiency to see patients from another virtual location.

   Neurodevelopmental science center (NDSC) providers utilize telemedicine for patients with limited mobility which ease their challenges with transportation to and from the hospital. Patients with multiple health conditions are seen by multiple specialists within the telemedicine visit to care and coordinate treatment.

   Behavioral Health providers utilize telemedicine to care for patients who may otherwise be limited in their ability for in-person visit. Speech Therapy providers utilize telemedicine to conduct group visits after school to expand access and address social distancing.

   For patients with established primary care provider or specialist it offers continuity of care where virtual follow-up care may be more accessible and timelier.

   For patients in our school-based health centers, telemedicine timely addresses the patient’s symptoms while avoiding missed school days or worsening condition.

   For hospitalized patients, telemedicine is utilized by providers for virtual consultation with specialists and virtual visitations for families.

   On-demand telemedicine services for pediatric patients with symptoms of cough, rash, fever, congestion, and sore throat.

2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.

   Highest utilization of telemedicine is with virtual visits where patient is home and connecting by MyChart. 86% of virtual visits are with established patients and 14% are with new patients. The highest utilized specialties are Psychiatry, Neurology, Developmental Behavioral Pediatrics, Pediatrics, General Surgery, Speech Therapy, Endocrinology, Psychology, Dermatology, Gastroenterology, Occupational Therapy, Physiatry.

   Top 10 specified primary diagnosis for scheduled telemedicine visits include anxiety, attention deficit hyperactivity disorder, pre-operative examinations, speech disturbance, depressive disorder, autism, diabetes, lack of coordination, mood disorder and migraine.

   On-demand pediatric care via telemedicine for majority of patients ages 0-4 years old with leading diagnosis of acute upper respiratory infection, followed by fever, rash, and cough.
3. Which practice groups or specialty types have not utilized telemedicine?

The following specialties have not utilized telemedicine: Ophthalmology, Home Health Services, Dentistry, Infusion Therapy and Craniofacial Orthodontics.

4. What symptoms should require in-person assessments?

On-demand telemedicine experience indicates that urinary tract infections, strep throat and complex cases require in-person assessments or testing. Additional symptoms requiring an in-person assessment includes:

a. Any life-threatening symptoms - difficulty breathing, chest pains
b. Asthma attack - major
c. Any numbness or tingling in extremities
d. Anaphylaxis
e. Allergic reaction that includes difficulty swallowing, facial swelling or difficulty breathing
f. Head injury
g. Traumatic injuries
h. Unexplained bleeding
i. Major burns
j. Fever for infants <3 months old

5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well?

New patients are seen via telemedicine for many conditions including:

a. Rash, eczema, dermatitis, warts, acne
b. Sinusitis
c. ADHD
d. Behavior Disorders, temper tantrums
e. Autism Spectrum Disorder
f. Sleep Disorders, snoring, insomnia
g. Anxiety, depression
h. Hypotonia
i. Developmental speech or language disorder, speech delay
j. Constipation, Encopresis, Chronic Diarrhea/ Vomiting,
k. Poor weight gain management
l. Type 1 diabetes
m. Recurrent otitis media
n. Umbilical hernia
o. GE Reflux
p. Tooth Pain
q. Pre-op exam
r. Genetic counseling
s. Supervision of high-risk pregnancy and normal pregnancy
t. Gestational diabetes
u. Frequent headaches
v. Seizures, staring episode, dizziness
w. Tic Disorders
x. Feeding problems
y. Obesity/ weight management
z. Club foot, ankle pronation
aa. Cleft lip/ palate
bb. Raynaud's
cc. Chronic pain
dd. Arthralgia

What are some examples where this has not worked well?

This is not worked well in the situations where a detailed physical exam is key to the medical decision-making process or other lab studies or radiology studies are important for care. In situations where vital signs are necessary, there are some mechanisms for home evaluation and obtaining these metrics but in many cases, this is not the case, which again makes medical decision making a challenge for providers. The situations best suited to telehealth are largely those that derive from the conversational and educational aspect of care delivery which is a significant portion of interaction between provider and patient in many cases.

6. Has your organization completed any type of survey of the healthcare providers or patients regarding their satisfaction with telemedicine visits?

Patient surveys are initiated for all completed visits including telehealth. There is an ongoing research project aimed at understanding the patient and family preferences related to telehealth and we hope to have this submitted for publication in the next 3-6 months.

A provider survey was conducted in summer 2020. The results of this study largely found that there were providers that were very comfortable utilizing telemedicine as a care platform and felt they were still able to deliver high quality care. There was a broader group that would consider using it but were uncomfortable with the limitations of the platform including the technology as well as the limitations in physical exam. There was a much smaller group that felt that telemedicine was not an appropriate platform for them to utilize to care for patients and they felt it delivered inferior quality care.

Are there results you can share with the Medical Board? Not in a more detailed fashion beyond the above.

7. Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
8. What will your healthcare providers not be able to do when the in-person office visits in the Medical Board rules are put back in place?

This will significantly limit the ability to provide patient centered care. Throughout the pandemic we have been able to reach patients where they are and where they feel safe often putting their needs first. There is significant burden placed on patients and families requiring them to be present at a facility and for lengths of time that may compromise education, wages earned and patient/family time off from work. No-show rates are decreased because the family no longer must weigh the value of missing work or the child missing school to make a health care appointment. The appointment can be scheduled at a time when the parent can be available thereby not missing work or missing a much smaller time because there is no need to travel.

In a recent study, we were able to demonstrate that least 20% of the patients would not have sought care if telemedicine services were not available. Putting in person visit requirements back in place will significantly impact that ability of some patients to seek care based on this which will further compromise their health.

As it relates to providers, there will be decreases in access to care, particularly for high demand subspecialists. Utilizing technology, we can provide greater access to a smaller group of resources than we might have otherwise. This is particularly true for those living in rural areas where there may be a limited number of specialty providers that have clinics near the family. Technology eliminates that burden and can now allow a single provider to see patients from a much wider geographic area without having to travel which cuts down on their commute time and ultimately may increase the number of patients they are able to see in a day.
9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Telehealth visits are interactive, real-time with both audio and video using Epic MyChart integrated with VidyoConnect secure HIPAA compliant platform. For patients being seen in one of our clinic locations, the telemedicine equipment has a high definition camera with tilt, pan, zoom capability to facilitate better visualization during the exam and visit. In addition, TytoCare devices have been added to the telehealth carts and in school-based health clinics. This peripheral device allows the provider to examine the patient’s heart and lungs sounds, obtain a temperature, and visualize the ears, eyes, throat, and skin.

Quick Care Online is our on-demand program utilized for common minor complaints. This program utilizes the Teladoc secure platform. Patients access this via the web or download an app to connect.

10. Are prescriptions provided based on telemedicine visits? Yes

Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances?

Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

__% Scheduled telemedicine visits resulted in prescription for controlled substance. This data is not currently available

0% of on-demand telemedicine visits resulted in prescription for controlled substance (03/01/20-09/25/21 from our Quick Care Online platform).

__% Scheduled telemedicine visits resulted in prescription for non-controlled substance. This data is not currently available

29% of on-demand telemedicine visits resulted in prescription for non-controlled substance (03/01/20-09/25/21 per Quick Care Online platform)

11. How are lab tests used and evaluated at telemedicine visits?

When appropriate, lab tests are ordered during the telehealth visit. Follow up could be via secure patient message via patient portal, phone call, or another visit if additional follow up is needed. Results are sent directly to our patient portal (MyChart) for those patients who have a MyChart account.

Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Based on the specialty and the reason for the visit, the provider may order lab tests that need to be completed prior to the visit. In other cases, the studies may be obtained following the visit and communication with the clinical staff is done with the results and recommendations as appropriate.

12. How is patient information, such as weight and temperature obtained? Does the patient self-report?
In some cases, the patient/parent does self-report. We do however have some telehealth visits where the patient would come to one of our primary care practices or Health Centers, closer to their home, and have a telehealth visit with a specialist who may be at a different location. In this case, the staff at the patient location, would obtain weight and vitals as needed.

13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

This is tracked at the individual practice level, but no safety events have been reported at the organizational level.

14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?

a. Hands on physical exam needed
b. Severity of the condition- any distress
c. Tests or procedures needed during the visit
d. Patient comfort or access to the necessary technology

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?

a. Telehealth is beneficial for medication management in particular ADHD for our organization, patients on controlled substances for ADHD require evaluation every 3 months. The provider can evaluate the effectiveness of the medications and any side effects via telehealth. Offering some of these appointments by telehealth is a patient satisfier.
b. Other controlled substances
c. Concerns?

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

Most practices are including an in-person visit at minimum yearly. Others are requiring more frequent in-person visits preferring to alternate with a telemedicine visit or using the telemedicine only for check ins that need to occur in between regular visits.

17. If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
18. What is the percentage of your patient visits you believe could be done via telemedicine?

Roughly 20%

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see

a. Parity in reimbursement
b. Clinical decision by provider determines if telehealth visit is adequate to meet the needs
c. Full reimbursement for all levels of visits including level V visit types.
d. Improved access to different clinicians, including therapists
October 6, 2021

Stephanie Loucka
Executive Director
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio, 43215

Re: Telemedicine discussion comments

Dear Director Loucka:

On behalf of over 1,500 faculty physicians and over 900 residents and fellows at The Ohio State University Wexner Medical Center (OSUWMC) and OSU Physicians, Inc., we appreciate the State Medical Board of Ohio’s attention to updating its rules and requirements related to telehealth. The COVID-19 pandemic has caused us to significantly expand our telehealth capabilities and our patients and providers would like to see this option remain as flexible as it has been under the federal and state public health emergency periods. We now do more telehealth visits on average per day than we used to do in a full year.

Our patients experience additional benefits outside of their access to health care, including missing less work time and saving money from driving fewer miles. As of September 2021, we estimate that our telehealth visits have resulted in around 26 million fewer miles being traveled, with around a reduction of 1.16 million gallons being consumed.

This reduction in gasoline consumption has a net benefit to the environment as 1.16 million gallons is equivalent to the home energy use for 27,686 homes for one year or about 28 billion smartphone charges. Overall, our telehealth visits have led to avoiding around 20 metric tons of physical waste.

With the present surge in COVID-19, we are again experiencing an increase in the number of telehealth visits. Moreover, as we schedule ahead for appointments over the coming months, people are wanting to know if they will be able to have that care as a telehealth visit.

Given that the federal government has to reauthorize its COVID-19 public health emergency (PHE) order every three months it is uncertain when it will finally come to an end. The current
surge in COVID-19, with new variants turning up on a tragically frequent basis, makes us believe that the PHE will be continued well into 2022. To that end, we strongly encourage the Medical Board to maintain all the current telehealth flexibilities for at least a minimum of three months or 90 days after the federal PHE ends versus ending them as of December 31, 2021.

We further support making these flexibilities permanent in the Medical Board’s rules.

Attached are our responses to your specific questions. We bring to our answers an extensive experience with telehealth even before the pandemic, an experience that has massively expanded as a result of the pandemic.

Our telehealth journey began back in 1995 as we began using telemedicine to increase ODRC inmate access to care. The State of Ohio found significant savings from a reduction in inmate trips to the emergency room and doctors’ offices as well as unnecessary medical tests. We have provided more than 10,000 telemedicine visits with inmates and currently offer 28 specialty clinics to 29 prison sites across the state.

In 2011, the OSUWMC Comprehensive Stroke Center began tele-stroke services across the state – offering the highest level of timely, evidence-based stroke care regardless of where someone lives.

In 2013, Ohio State psychiatrists began providing tele-behavioral health services for emergency department patients. Timely patient evaluation decreases length of stay, prevents escalation of psychiatric issues, and increases the number of patients that can be discharged home instead of being admitted to a psychiatric facility.

More recently, our primary care physicians (PCPs) began offering follow-up video visits for established patients. PCPs also began electronic consultations, keeping them as the coordinator of their patients’ care with timely access to subspecialty providers. Specialty areas utilizing telehealth include dermatology, pulmonology, gastroenterology, hepatology, congestive heart failure, and otolaryngology.

We provide telehealth care through the following means:

- Two-way interactive, audio and video visits between the clinician and the patient.
- Audio-only telephone visits between the clinician and the patient.
- Electronic visits between the clinician and the patient in which the patient completes a detailed questionnaire about their medical history and current symptoms, the provider reviews the responses and either determines a care plan or recommend a follow-up appointment.

In addition, we use eConsults between providers to help our patients, reducing the need for our patients to have to visit with another provider. For example, in our tele-stroke network the
clinician at a community facility requests a consult and the OSU physician assesses the patient together with support from the patient location. These eConsults help address health inequities by giving access to specialists to individuals who face geographic distance, transportation, or other barriers to attending in-person medical appointments.

The COVID-19 pandemic forced us, like other health systems, to significantly expand our telehealth investments. As a result, our volume of telehealth visits has expanded exponentially, increasing from 70 video and 152 telephone visits in February 2020 to 12,571 video and 6,260 telephone visits in July 2021. Our monthly telehealth visit average has decreased throughout the pandemic and is around 23,000 a month, down from a high of 60,962 telehealth visits in April 2020, with a peak of 2,898 visit per day in May 2020 and around 1,020 per day currently.

Unlike most Ohio hospitals systems, we have patients who live in all 88 Ohio counties, including a large number from Ohio's Appalachian counties. In addition, OSUWMC has an extensive Medicare and Medicaid patient population. Telehealth has improved access for those patients who live outside of Central Ohio, along with our seniors and low-income families here in Central Ohio.

Telehealth has quickly become a normal way of providing care to our patients across all types of providers and conditions – from primary care to specialty care and disease management. Telehealth services are offered in primary care and more than 60 specialties and subspecialties at 65 locations. As mentioned previously, specialty areas utilizing telehealth include dermatology, pulmonology, gastroenterology, hepatology, congestive heart failure, and otolaryngology.

One clear benefit we have witnessed from our use of telehealth has been a reduction in missed appointments. Since fiscal year 2020 to date our overall no show rate has been 9.1%: 7.0% for telehealth visits and 9.4% for in-person visits. This rate has varied among specialty grouping with the no show rate for telehealth visits compared to in-person visits being:

- 7.8% compared to 9.4% for medical specialists (overall rate of 9.1%)
- 5.9% compared to 10.2% for primary care (overall rate of 9.4%)
- 6.1% compared to 8.9% for surgical specialists (overall rate of 8.7%)

During a review of our telehealth experience between March and June 2020 we found our overall no-show rate dropped from 8.5% for in-person visits to 5.4% for telehealth visits for all patients, a 36.3% reduction. For our Medicaid patients this rate declined from 11.9% for in-person visits to 8.3% for telehealth, a 30.1% reduction for patients with Medicaid, while it dropped from 4.3% in-person to 3.4% for telehealth visits for our Medicare patients, a 20.6% reduction. This decline in missed appointments translated into an estimated 1,567 more Medicaid visits and 686 more Medicare visits during this period.
Based on all our telehealth experience we have the following recommendations for the Medical Board:

- Remove any initial in-person visit requirement;
- Limit any in-person requirement to no more than every two years, if that;
- Allow prescribing of medications, including controlled substances and medications for opioid use disorder (MOUD), via telehealth, even without an initial in-person visit; and
- Allow providers to engage in audio-only visits when two-way interactive audio and visual capacity is not viable.

We do suggest that the Medical Board require providers using telehealth services to have the capacity to provide in-person care, even on the same day, if determined to be needed upon findings from the telehealth visit.

As the Medical Board reviews its rules, policies, and procedures we also request that:

- There be no geographic restrictions on where people can access and not access telehealth services;
- Telehealth service flexibilities be available for all services that can be provided via telehealth and not just limit it to behavioral health and addiction services; and
- The Medical Board be expansive in the services it allows to be provided by telehealth, incorporating CMS’ existing list of Category 1, 2 and 3 services.

Finally, as the Medical Board considers these changes, we also request it be expansive in its support for eConsults and for the use of remote patient monitoring. These services enhance the care for patients, while minimizing the need for unnecessary visits and expediting the receipt of needed services.

In addition to thoughts and recommendations to your specific questions, are including a case example provided by our James palliative care clinic team.

We greatly appreciate the Medical Board’s focus on telehealth, applying what we all have learned from our experiences over the past year and a half to modernize your telehealth provisions. We look forward to working with you and your staff on this important work.

Sincerely,

Andrew Thomas, MD
Interim Co-Leader & Chief Clinical Officer
OSU Wexner Medical Center
Senior Associate, Vice President for Health Sciences

L. Arick Forrest, MD, MBA
Vice Dean for Clinical Affairs, OSU College of Medicine
President, OSU Physicians, Inc.
Medical Director, Ambulatory Services
Proposed State Medical Board of Ohio Questions to Stakeholders for Telemedicine Discussion

1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?

The COVID-19 pandemic forced us, like other health systems, to significantly expand our telehealth investments. Telehealth has changed the healthcare landscape. It has broken down the geographic barriers for access. Telehealth eliminates the barrier of transportation that keeps up to 3.6 million people from obtaining health care each year. As a result, our volume of telehealth visits has expanded exponentially, increasing from 70 video and 152 telephone visits in February 2020 to 12,571 video and 6,260 telephone visits in July 2021. Our monthly telehealth visit average has decreased throughout the pandemic and is around 23,000 a month, down from a high of 60,962 telehealth visits in April 2020, with a peak of 2,898 visit per day in May 2020 and around 1,020 per day currently.

Unlike most Ohio hospital systems, we have patients who live in all 88 of Ohio’s counties, including a large number from Ohio’s Appalachian counties. In addition, The Ohio State University Wexner Medical Center (OSUWMC) has an extensive Medicare and Medicaid patient population. Telehealth has improved access for those patients who live outside of Central Ohio, along with our senior and low-income families in Central Ohio. With the elimination of transportation barriers, especially for our Medicaid population, we have seen a significant decrease in the no-show rate.

Telehealth has quickly become a normal way of providing care to our patients across all types of providers and conditions – from primary care to specialty care and disease management. Telehealth services are offered in primary care and more than 60 specialties and subspecialties at 65 locations. Specialty areas utilizing telehealth include dermatology, pulmonology, gastroenterology, hepatology, congestive heart failure, and otolaryngology.
2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.

Telehealth has quickly become a normal way of providing care to our patients across all types of providers and conditions – from primary care to specialty care and disease management. Telehealth services are offered in primary care and more than 60 specialties and subspecialties at 65 locations, with more than 2,239 distinct providers (physicians, APPs, and other clinical providers) delivering care via telehealth. Specialty areas utilizing telehealth include dermatology, pulmonology, gastroenterology, hepatology, congestive heart failure, and otolaryngology.

Types of encounters where we have used telehealth include:
- initial visits without an initial in-person for:
  - behavioral health and addiction services
  - primary care
  - specialty referrals from a provider who has either had a recent in-person or telehealth visit with the patient
  - genetic counseling
  - screening for patients wondering if they may need emergency care
- visits with established patients for:
  - follow-up care
  - acute care
  - prescription management
  - palliative care

3. Which practice groups or specialty types have not utilized telemedicine?

We believe that every specialty group can use telehealth at some point in the management of the patient.

4. What symptoms should require in-person assessments?

An in-person assessment is needed when a physical exam is required for medical decision making. People experiencing severe abdominal pains, chest pains, shortness of breath, or other emergency situations should also have an in-person visit, whether the same day with their provider or in an urgent care or emergency room setting.

Telehealth is not a substitute for an in-person visit, it is a compliment to it. It can serve as a starting point or as a check-in visit between in-person visits. It is a way for patients to stay connected with their health care teams in the convenience of their homes or offices.
Patients that have cognitive impairment can pose difficulties for telehealth, but combined with home visitation programs, telehealth can be used to facilitate those visits.

5. **Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?**

Yes, we have initiated care for new patients through telemedicine. We have found that this can work well in a range of circumstances and disciplines, and especially for behavioral health and addiction concerns.

We are not aware of any circumstances where telehealth did not work well with the exception of when IT glitches would occur. There is always a learning process with the biggest thing being getting the right people/symptoms scheduled for a telehealth visit. For example, it does not make sense to schedule somebody with new onset chest pain for a telehealth visit.

6. **Has your organization completed any type of survey of the healthcare providers or patients regarding their satisfaction with telemedicine visits? Are there results you can share with the Medical Board?**

We do survey patients following telemedicine visits just as we do following in-person visits. Data is reviewed internally to help guide strategy with a focus on the patient comments which can provide actionable insights for improvement and strengths to recognize. Of the physicians surveyed, 91% had completed at least one telehealth visit. Most of the providers (88%) stated they would like to continue telehealth visits after the pandemic. A survey of 1,400 patients showed that 90% would recommend a telehealth visit and 90% stating it was easy to do. Almost all of the patients (93%) would like to continue telehealth visits after the pandemic. Demographics: 50% of our telehealth visits have been in patients 55 years of age and older with more than half of those being over 66 years of age. In our patients over the age of 65, 85% want to have telehealth as an option.

7. **Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?**

We don’t assess that on in-person visits nor are for telehealth visits. Question 7 would be very hard to measure. While we don’t directly measure accuracy of diagnosis, we are looking at quality metrics for telehealth and other markers, such as subsequent in-person visits and ED visits.
8. What will your healthcare providers not be able to do when the in-person office visits in the Medical Board rules are put back in place?

Telehealth allows for more frequent contact with patients that would improve overall health and decrease emergency room and hospital utilization. Having restrictions in place for in-person visits will decrease the availability of care. Telehealth eliminates the physical barriers/limits and expands access.

While we appreciate the importance that an in-person visit can provide for a patient and their practitioners, it is not absolutely necessary that an in-person visit come before an initial telehealth visit. Moreover, such a requirement creates a critical barrier to access to mental health services, especially during a mental health crisis or substance abuse situation.

In-Person Initial Visit for Behavioral Health and Addiction Services

Accessing mental health or substance abuse in-person is often difficult, with long waiting periods before an appointment is available. When a person is ready for mental health or substance abuse care, it is vital to see a provider quickly. If no such provider is available, the ER becomes the access point of last resort, or they go without needed care entirely.

The enforcement of rules that require an initial in-person visit for substance use disorder (SUD) care negatively impacts patient access to evidence-based interventions and ongoing efforts to address the current addiction crisis. Having operated with these telemedicine flexibilities for over 17 months, behavioral health providers across the state have experienced a positive impact on patients initiating care via telemedicine, including in cases when controlled substances are used. Telemedicine has improved access to treatment by reducing barriers to care, including stigma, fear, risk of contracting COVID, and structural barriers like transportation and childcare concerns, while increasing the geographical reach of the physician and PA workforce that have appropriate DEA certification. At The Ohio State University Wexner Medical Center (OSUWMC), we have new patients receiving treatment who have previously not been able to do so due to the structural barriers noted above and other social determinants of health. This treatment is coming at a time when opioid overdose deaths have been devastating our state at an unprecedented rate.

In addition, our experience at the Ohio State Wexner Medical Center has found that some individuals who would be unlikely to initiate care in-person in a clinic setting are willing to do so via telemedicine, including those who are concerned about the stigma of addiction or mental illness or the risk of contracting COVID, in addition to those experiencing structural barriers to treatment like transportation and child care.

Other experiences have reinforced our conviction that most behavioral health services do not need an initial in-person visit. We have not seen a decrement in our clinical care for patients who have not had an in-person visit first. For example, one of our faculty did some
outcomes analysis with our Harding Hospital's partial hospitalization and intensive outpatient (PHP/IOP) services during the entire virtual period of care and did not see any change. We also brought up a behavioral health urgent care clinic at the beginning of the pandemic, which we opened first using only telehealth services. We had not seen most of these patients before, but we were able to successfully address their needs and get them into ongoing clinical care outside of the urgent care setting.

OSUWMC further believes that practitioners can determine who they need to see in-person and when they need to see them. Therefore, we should allow practitioners this discretion and not set an arbitrary initial in-person visit requirement.

While we expect this requirement is intended to reduce bad behavior by some providers, we worry that this requirement will negatively impact needed care for patients and punish good providers for the behavior of a few. There needs to be another regulatory strategy found to address the abusive use of telehealth services.

Finally, if a patient receives a mental health or substance abuse referral from a provider, who is working in an emergency room or some other setting such as primary care, the visit with this other professional should be allowed to count as the initial in-person visit. This other provider will have done the basic physical examination and determined if there were physical health issues to address. The mental health professional should have access to that information. The need for mental health care should not be delayed by requiring yet another in-person visit before they can access needed behavioral health or substance abuse services that can be provided via telehealth.

**In-Person Initial Visit for Other Services**

We believe that our rationale for not requiring an in-person visit first for mental health care applies to other health services as well. For those services where an initial in-person visit would be most appropriate, we believe those providers will require that visit. However, even then, they may be able to do an initial screening through a telehealth visit that will avoid unnecessary care or allow for the ordering of some tests that would be beneficial at the in-person visit.

Moreover, some physicians have an established relationship with a patient that does not require a visit within the prior six months for them to render care via telehealth. We believe this is especially true for people under a long-term treatment plan that only requires periodic interactions or those with an established relationship with their primary care provider. In such a situation, many acute health events can be managed through conversation and observation without needing a recent in-person visit.
For providers treating people referred to them, an in-person visit with the referring provider should be allowed to count as the in-person visit. The referring provider could be the hospital, someone leaving the ED or an inpatient stay, or an outpatient provider. Many referrals don't require the specialist to meet with the patient to render appropriate care directly. Some examples include dermatological services, physical therapy services, medication management therapy, and dietitian services.

Finally, for group practices, an in-person visit with a partner in the group should count for the in-person visit requirement, even if the telehealth visit is provided by someone else in that practice.

9. **What types of technology are your healthcare providers using? Do you use interactive, real time electronic communication comprised of both audio and video elements?**

Our preference is to use interactive, real time electronic audio with video communication with our patients. We primarily use Updox as our telehealth vehicle. However, it is critically important that we be allowed to use audio-only calls as there are multiple reasons why an audio and visual visit cannot always happen. We believe that audio-only should be allowed for all provider and service types and not solely behavioral health.

OSUWMC’s older and lower-income patients are more likely to use audio-only communication. Many people who are elderly and those from disadvantaged backgrounds often do not have access to reliable Wi-Fi, and audio-only visits are all they can do. Sometimes a visit starts as a two-way interaction, and connection challenges result in it becoming an audio-only visit. Other times, a patient lacks the comfort and the capacity to engage in a two-way interaction, and can only manage audio visits. Finally, some patients lack the resources to access two-way interactive visits but can manage an audio-only visit. Many patients who face transportation challenges will forgo care if audio-only is not an option.

Of the patients we see through telehealth, around 20% of the visits have been audio-only, before the recent COVID surge. This percent is highest for those over 65 at 36.9% in June 2021, compared to 22.6% for people ages 60 to 64, 12.4% for those 17 to 39, and 9.4% for those less than 17. Audio-only visits are also higher for our patients on Medicaid (24.8%) and on Medicare (30.9%) compared to our patients with commercial coverage (13.8%).

In July 2021, as the COVID surge took off, the percent that was audio-only jumped for those over 65 to 46.7%. The audio-only visits jumped to 35.6% for Medicaid and 41.9% for Medicare. It also increased for the commercially-covered population to 26.0%.

10. **Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances?**
Do you have any data on the percentage of telemedicine visits that result in a prescription for noncontrolled substances?

Our providers do issue prescriptions to patients when medically necessary and clinically appropriate to prescribe based on the information available during a telehealth visit. These prescriptions can happen for patients with whom we have not yet had an in-person visit and prescribing through telemedicine visits has been especially important for starting MOUD care.

The percentage of these prescriptions that are for controlled substances vary by provider and type of services. For instance, our James Palliative Care Clinic team estimates that over ninety percent of their telemedicine visits result in an opioid prescription. This percent is no different than patients see in the clinic.

11. How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

The practice around lab tests is the same for telehealth visits as it is for in-person visits. When possible, our providers will order the lab tests needed ahead of time for a patient’s appointment and go over those results during the session. For some appointments, especially any same day visits, the type of lab tests needed for the patient’s health issue, if any, are not known until the visit itself. In these cases, needed lab tests are ordered and the results reviewed by the provider. The provider will communicate with the patient through a telephone call and/or MyChart message to inform the patient of the results and any next steps for treatment. Again, depending on the lab test, that next step could be a prescription, a follow-up telehealth or in-person visit, or a referral to a specialist or some type of therapy. These decisions are based on the medical judgement of our providers. What is the appropriate next step cannot be easily prescribed through a regulation given the wide variation in possible outcomes and appropriate clinical pathways.

12. How is patient information, such as weight and temperature obtained? Does the patient self report?

If a patient has remote monitoring equipment that measures weight and temperature then the information is usually transmitted through this means. We currently use remote monitoring devices for blood sugar levels, blood pressure, and oxygenation levels. Otherwise, the patient self-reports this information.

13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
We have not seen negative outcomes due to the use of telemedicine. We have seen negative outcomes when patients have foregone medical visits, testing, or other services because of concerns about COVID. Without telehealth these negative outcomes would be even worse.

Our experiences with telehealth demonstrate that non-face-to-face provision of care can help reduce disparities seen in underserved populations by increasing access, especially by eliminating transportation needs which is a significant barrier to care for many. In addition, for those who work, telehealth reduces absenteeism by allowing care to be provided with the patient not having to take time off of work to receive needed care, which many who are paid hourly will not do.

We have faculty conducting different outcomes analyses on the effect of telehealth visits compared to in-person. One such study which reviewed PHP/IOP services provided through Harding Hospital, our psychiatric hospital, found no negative outcomes between telehealth visits and in-person visits.

Our palliative medicine group has not seen any differences in safety events or near-events between patients with in-person and telehealth visits.

14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?

Providers escalate care when it appears that the patient’s conditions are changing and a physical exam is needed to change treatment. For new patients, if the history and telehealth exam is insufficient to achieve a treatment plan, then those visits are converted to an in-person visit.

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?

We believe that telemedicine is vitally important as a modality for treating chronic conditions with controlled substances, especially palliative care.

That said, we do think it is important that providers who are treating these conditions via telemedicine have the capacity to provide in-person health care services when and if the patient needs in-person care, preferably with the same provider.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
We believe that there is no need for a specific in-person visit frequency requirement as competent providers will know when to see a patient in-person and require such a visit. We further believe that we should not overregulate good providers to address the small set of providers who might abuse telehealth services.

Moreover, the need for in-person visits varies between providers, types of care needs, and other variables. For instance, our palliative care physicians still want to see their patients in-person every 90 days or so (60 days for someone whose care began through a telehealth visit).

Setting an arbitrary in-person visit requirement does not account for this variation and will require some patients to attend in-person visits that are not necessary. This in-person visit requirement creates access barriers for those who live far away or lack transportation. It also could increase health and safety risks for patients who are at risk for falls or experience health challenges whenever they leave their homes. For example, a patient with well-controlled chronic disease processes often needs only to be seen annually. As such, a 6-month or even one year requirement prevents making care convenient via telehealth for straightforward conditions such as poison ivy, allergies, etc.

However, if the Medical Board feels it needs to set some requirement, we recommend it be no more than once every two years.

17. If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

Changing the in-person requirement should have no negative impact on continuity of care and might even improve it. Under a world of in-person visits we have many patients who we only see episodically, when some immediate needs come up. In these cases we may not see the patient for a year or more between such visits. Allowing a telehealth visit for these cases would offer the same chance for an informed doctor-patient relationship and some patients might be more willing to connect to a physician if they don’t face all the hassles of traveling to an appointment, getting off of work, and spending time in the waiting room.

For patients who have regular interactions with their provider, telehealth can offer a similar level of connectedness for patients as their in-person visits. For some people they may even be more open in a telehealth setting. At the same time, for those who want the in-person touch they have that option. And, if our providers feel they need that in-person contact on some occasion (or frequently), then in-person visits will be sought with the patient.

In addition, all of our patients have access to their providers and their staffs through MyChart for any questions that they have.
Also, for some of our patients we would still require periodic in-person visits. For instance, our patients undergoing palliative care who have opioid treatment agreements have an in-person visit every 60 to 90 days.

Finally, our patients always have the right to request an in-person visit. If the patient no longer feels telehealth is meeting their needs, they can return to having in-person visits.

18. What is the percentage of your patient visits you believe could be done via telemedicine?

There is no magic number on the percentage of patient visits that could be done via telemedicine and these percentages will vary by different practices or for different conditions.

We know that during April and May 2020 almost all of our ambulatory visits were done via telehealth. We had a total of 60,692 telehealth visits in April 2020 and, prior to the recent COVID surge, we were averaging around 23,000 visits a month.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?

Changes to Medicaid Board rules we would like to see include:

- Removing any initial in-person requirement;
- Limiting any in-person requirement to no more than every two years, if that;
- Allowing the prescribing of medications, including controlled substances and MOUD medications, via telehealth, even without an initial in-person visit; and
- Allowing providers to engage in audio-only visits when two-way interactive audio and visual capacity is not viable.

We do suggest that the Medical Board require providers using telehealth services have the capacity to provide in-person care including on the same day, if determined needed upon findings from the telehealth visit.

As the Medical Board reviews its rules, policies, and procedures we also request that:

- There be no geographic restrictions on where people can access and not access telehealth services;
- Telehealth service flexibilities be available for all services that can be provided via telehealth and not just limit it to behavioral health and addiction services; and
- The Medical Board be expansive in the services it allows to be provided by telehealth, incorporating CMS’s existing list of Category 1, 2 and 3 services.
Finally, as the Medical Board considers these changes, we also request it be expansive in its support for eConsults and for the use of remote patient monitoring. These services enhance the care for patients, while minimizing the need for unnecessary visits and expediting the receipt of needed services.
CASE EXAMPLE ON USE AND EXPERIENCE OF TELEHEALTH: OSUWMC’S PALLIATIVE CARE MEDICINE SERVICE

October 5, 2021

Our Palliative Medicine clinics have continued to provide strong opioid stewardship—signed opioid treatment agreements, urine drug testing, review of OARRS, and NARCAN prescriptions—throughout the COVID-19 Public Health Emergency and while utilizing telemedicine. For example, if a patient is seen initially through telemedicine and started on opioids for their cancer pain, they sign a treatment agreement and receive a urine drug test on their next clinic visit.

Figure 1 shows the proportion of in-clinic vs telehealth visits over the past few years. Since the start of the COVID-19 Public Health Emergency, we have conducted slightly less than 50% of our clinics via telehealth. We rarely conduct telemedicine visits for an initial visit, but when we do, it is because a patient may be too frail to come to an appointment or in too much pain. The majority of our patients have metastatic cancer. The ability to prescribe opioids on an initial telemedicine visit is vital to providing safe and effective care for these patients. The majority of the patients we see via telemedicine are established with us. They have already been screened and evaluated for high-risk opioid behaviors and have undergone appropriate stewardship.

The COVID-19 pandemic has provided an opportunity to demonstrate that opioid therapy can be safely initiated and managed via telemedicine. We have not seen an increase in reported patient safety events in our clinic with the introduction of telemedicine.

We believe the requirement that patients need to be physically seen to initiate opioid pain management poses an undue burden on our sickest patients. We also believe that the requirement that they be physically seen every 90 days needlessly risks exposure to COVID-19—many of our patients are immunocompromised. We have continued to check OARRS for patients who are seen via telemedicine. When we feel it is medically or clinically indicated, we have patients come to clinic.

Finally, in determining telemedicine regulations we hope the State Medical Board will consider that our patients are seen within an integrated healthcare system and have many touch points. Our patients with cancer regularly see their oncologist and attend chemotherapy visits. Our patients with heart failure likewise see their cardiologists and other specialists on a regular basis. We can coordinate urine drug tests if needed during those appointments and can rely on physical exam findings, lab tests, and imaging results (in addition to our own evaluation) to make safe and effective treatment decisions. We have demonstrated this since the start of the pandemic. We hope the ability of healthcare providers to leverage an integrated, electronic medical record is considered when determining telemedicine regulations.
Some of our patients are unable to see us in clinic in a timely fashion. Perhaps because they are resource limited and cannot make excessive trips (see Figure 2 of geographic distribution of patients cared for by our clinic). Perhaps because they are in too much pain or too sick to make the trip. Telemedicine allows us to meet patients where they are at and help make the best treatment decisions for them.

**Figure 1: Proportion of in-person and telehealth encounters per year.**

- **Figure 2: Heat map of patients seen by OSUWMC-James Palliative Medicine Clinic**

**Patient Volume by Zip Code**

NOTE: Patients residing outside the State of Ohio have been excluded.
October 1, 2021

Stephanie Loucka, Executive Director
Stat Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Director Loucka,

The Ohio Hospital Association appreciates the opportunity to provide feedback to the State Medical Board of Ohio as it considers more permanent changes to its telemedicine rules.

We are grateful for the Board’s actions to extend the moratorium of enforcement of its telemedicine laws and rules that require in-person patient visits through December 31, 2021. Given that we are very much still in the midst of the COVID-19 pandemic and experiencing a surge of the highly contagious Delta variant, this flexibility is much appreciated.

We are also encouraged that Medical Board staff is engaging stakeholders as a broader proposal for Board consideration is prepared. The past 18 months have demonstrated the tremendous utility of telemedicine and the provider community has proven the safety and effectiveness of delivering care in this manner. Throughout the pandemic, telemedicine has been the sole method of receiving necessary services in many cases, and the technology has evolved quickly to connect patients to providers while increasing safety for all by minimizing in-person contact. We believe the time is right to use this experience to consider ways the current telemedicine rules can be amended to enhance the use of telemedicine while continuing to effectively regulate the practice of medicine and ensure the safety of the public.

OHA shares the following recommendations for consideration:

- **The state’s telemedicine rules should allow flexibility and provider discretion based on medical specialty and patient needs.**

- **The state’s telemedicine rules should not limit technology or platforms that can be used by providers.** As the landscape of telemedicine continues to evolve, there are many options for types of technology and platforms that can be utilized by patients and providers. Providers are in the best position to determine what modes are most appropriate based on the specific clinical situation.

- **Both video and audio-only visits can be useful and appropriate ways of delivering care.** Providers effectively use both video and audio formats for delivering care virtually, depending on the clinical specialty of the provider and clinical needs of the patient. Any changes to the state’s telemedicine rules should reflect that both modalities can be useful and appropriate. For example, audio-only appointments have proven to be very effective for patients receiving mental health services and providers have cited increased patient uptake and satisfaction at being able to have a
phone call with their provider to receive care. Further, for many vulnerable and hard-to-reach populations, audio visits can dramatically increase access to care because, for example, they may not have video technology on their phone, or their access to broadband connections may be limited.

- **Both synchronous and asynchronous technologies can be useful and appropriate ways of delivering care.** Providers effectively use both synchronous and asynchronous formats for delivering care virtually. Any changes to the state’s telemedicine rules should reflect that both modalities can be useful and appropriate. While many providers encourage more traditional synchronous visits, there are situations in which asynchronous care can be useful. For example, in many dermatological cases, reviewing a high-resolution photo may provide more utility than an examination via video. Another benefit of asynchronous care is helping to expand capacity in light of staffing shortages currently being experienced by providers.

- **Providers should ensure that virtual visits uphold the same standard of care as in-person visits.** Currently, the standard of care for telemedicine must be consistent with the standard of care for in-person medical care. This has been a requirement for virtual care since before the COVID-19 pandemic and should continue. Providers are in the best position to evaluate whether the standard of care can be upheld in a virtual visit.

- **Coordination of care is important and telemedicine delivery systems should account for this.** Whether care is provided virtually or in-person, coordination is important. Providers have put many systems into place to ensure that all a patients’ care needs are met, such as electronically sharing after-visit summaries, scheduling follow-up visits with alternative providers or specialists, or escalating care to an emergency department. Many hospitals have also implemented internal guidelines that assist providers in determining whether a patient needs to be seen in-person. However, regulations should be careful not to mandate coordination that is not required by other parts of the health care system or that is excessively burdensome. For example, care coordination is challenging when patients receive care in urgent care or retail health clinics, but we do not mandate coordination in those settings that is not reasonably attainable.

- **Prescriptions of non-controlled substances can be safely issued virtually without an in-person visit requirement.** The relaxation of the “prescribing to patients not seen” requirements during the COVID-19 pandemic have demonstrated the safety and efficacy of prescribing via a virtual visit. Providers have emphasized that for non-controlled substances, the potential for abuse is low and the potential for benefit is high.

- **Prescriptions of controlled substances can be safely issued virtually in many situations, although there may be scenarios requiring increased oversight and/or regulation.** We understand that most of Ohio’s current in-person visit requirements apply to the prescribing of controlled substances. We share the Board’s commitment to protecting patient safety and preventing fraud and abuse related to controlled substances. However, we believe it is appropriate to consider whether there may be certain scenarios that allow for the safe prescribing of controlled substances via telemedicine. For example, many pediatric providers have highlighted the benefits of being able to safely and effectively prescribe certain ADHD stimulant medications virtually. Another
compelling example was provided by a neurologist, who has had success in virtually prescribing anti-convulsant medications to certain patients.

- **Reducing barriers to telehealth will help increase access to care.** Limiting access to telehealth services may result in patients foregoing care altogether, ultimately resulting in the need for more intense and expensive care in the future when the service they could have received via telehealth is delayed. Providers have experienced this phenomenon throughout the pandemic to some extent, as patients have foregone routine care they would have ordinarily received.

- **Institutional safeguards currently exist that help protect patient health and safety.** Medical Board staff has expressed some concern that it is often difficult to monitor and regulate whether physicians are appropriately utilizing telehealth or are doing things via telehealth that jeopardize patient safety. OHA appreciates this concern, but reminds the Board that hospitals have extensive credentialing, quality control, peer review, and other processes in place that act as “self-regulating” mechanisms to ensure physicians are appropriately using telehealth. Accordingly, there may be situations where care delivered via telehealth in hospitals or hospital-affiliated entities is more appropriate than in other practice settings.

Telemedicine has long been an important care delivery method for the hospital community. Through telehealth services, Ohio hospitals have increased access to care, lowered costs, improved patient satisfaction and, most importantly, improved clinical outcomes. Furthermore, the COVID-19 pandemic has provided a unique opportunity to more broadly experience and evaluate the impact of reduced regulation and increased use of telehealth. We anticipate you will continue to receive feedback from hospitals and health systems further illustrating the positive effects of increased use and access of telemedicine.

As always, we appreciate the opportunity to collaborate with the Medical Board and staff. We welcome the opportunity to be a resource as changes to Ohio’s telemedicine rules are considered.

Thanks,

Stephanie Gilligan
Senior Director of Advocacy
Bon Secours Mercy Health (BSMH), operating as Mercy Health in Ohio, has pivoted quickly to expand telehealth services during the COVID-19 pandemic to improve access to high quality care for patients across Ohio. In the 12 months from April 2020 to March 2021, BSMH completed more than 1,000,000 virtual provider visits across all markets, and adoption remains high with BSMH performing approximately 30,000 virtual provider visits monthly. In addition, BSMH was able to leverage telehealth in the inpatient setting throughout the pandemic by allowing for physicians and nurses to visualize the patient from outside of the room, both minimizing the exposure risk for our clinicians and conserving scarce personal protective equipment (PPE).

BSMH believes telehealth services will only continue to deliver increasing value across the entire care continuum for patients, communities, and the healthcare system. BSMH’s utilization of telehealth, even prior to the pandemic, extends well beyond virtual provider visits to include remote patient monitoring at home, virtual consultations in the emergency department and inpatient setting, continuous monitoring of hospitalized patients at risk for falls, and care delivery models supported virtually by experienced nurses, pharmacists, social workers and other clinicians. BSMH has deployed various technology solutions across the system to support high quality telehealth offerings. Our providers are currently equipped and trained to deliver telehealth services through multiple technology modalities including synchronous audio/video interactions, synchronous audio interactions (telephonic), and asynchronous messaging interactions. The preferred and most common delivery model is synchronous audio/video interactions, but BSMH is delivering meaningful and effective patient care in the other modalities.

In addition, BSMH experience has highlighted the need for alternative technology approaches to ensure equitable access for all patient populations, especially in rural geographies where broadband and technology access is more limited. BSMH is supportive of legislation and programs to expand broadband access across Ohio and the U.S. to address disparities as well as continued support for telehealth services delivered via alternative technology approaches when consistent with an in-person standard of care.
Given our footprint and breadth of health care offerings across Ohio, BSMH has been uniquely positioned to observe the impact of telehealth expansion on patient access to care, as well as, provider and patient experience across varying populations of patients. Patient experience with virtual provider visits based on HCAHPS scores has indicated strong support and satisfaction with this care delivery modality, although opportunities exist for continued improvement in patient communication and education. Provider experience has also improved significantly since the start of the pandemic, manifested by continued high adoption of this care delivery modality today. BSMH is exploring continued enhancements in our processes and virtual technology platforms to enable real-time feedback on experience and improve training and education on appropriate use of telehealth for both providers and patients. BSMH maintains that access to care via telehealth has become and will continue to be an expectation of our patients and the communities we serve. BSMH also maintains that telehealth services are appropriate when they can be performed consistent with an in-person standard of care. While policies are in place to comply with state and federal law, BSMH believes our providers are best suited to determine the most appropriate care delivery modality given their relationship with the patient and commitment to ensuring safety and quality standards are maintained.

BSMH will outline specific recommendations related to the established telemedicine rules from the Ohio Board of Medicine in the following section.

**Recommended Rule Changes**

1. **Physician Patient Relationship Establishment**

   ORC Ann. 4731.74 requires the Medical Board to permit the establishment of a physician-patient relationship using appropriate technology consistent with an in-person standard of care associated with prescribing drugs that are not controlled substances.

   The Ohio statutes and Board rules do not state whether establishing a physician-patient relationship via appropriate technology consistent with an in-person standard of care is permitted in other situations (e.g. diagnosing and treating).

   BSMH requests that the Medical Board clarify within their rules that a physician-patient relationship may be established using appropriate technology consistent with an in-person standard of care without limitation.

2. **Prescribing Drugs Via Telemedicine**

   BSMH believes some of the prescribing requirements listed in OAC Ann. 4731-11-09 create unnecessary time-consuming processes and barriers to care.

   BSMH makes the following recommendations:
• “The physician shall obtain the patient’s informed consent for treatment through a remote examination... The physician shall document in the patient's medical record the patient's consent to treatment through a remote evaluation”
  ◦ Recommendation: Permit informed consent about treating through remote examination to be annually provided by the beneficiary. This will align with federal requirements related to communication technology-based services such as virtual check-ins and e-visits.
• “The physician shall request the patient’s consent and, if granted, forward the medical record to the patient’s primary care provider or refer the patient to an appropriate health care provider or health care facility”
  ◦ Recommendation: A physician should not have the affirmative duty to ask patient about providing the medical record to the patient’s primary care provider. Instead, this should follow the same standard as an in-person visit.

OAC Ann. 4731-11-09 lists several requirements for prescribing controlled substances which align with current Federal requirements. However, many of these requirements are under Federal COVID-19 related waivers and many requirements may be removed within the coming months as the Federal Government takes steps to removes barriers to care and ensure timely access to care.

BSMH requests that the language be removed and be replaced with the statutory requirement found within ORC Ann. 4731.74. Specifically, prescribing drugs that are controlled substance should meet the standards that are consistent with federal law, including any waivers thereof.

Additionally, controlled substance prescribing visit requirements (e.g. 4731-11-03, OAC rule 4731-11-14, OAC rule 4731-29-01, OAC rule 4731-11-04) related to controlled substances, weight loss drugs, opioid addiction, and pain management should align with current Federal requirements, state statutory law and an in-person standard of care.

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About Bon Secours Mercy Health

Bon Secours Mercy Health is one of the 20 largest health systems in the United States and the fifth-largest Catholic health system in the country. The ministry’s quality, compassionate care is provided by more than 60,000 associates serving communities in Florida, Kentucky, Maryland, New York, Ohio, South Carolina, and Virginia, as well as throughout Ireland. Bon Secours Mercy Health provided care for patients more than 11 million times in 2019 through its network of more than 1,000 care sites, which includes 50 hospitals, as well as home health agencies, hospice, skilled nursing, and assisted living facilities. Consistent with its commitment to serve each patient with dignity, Bon Secours Mercy Health provides more than $2 million per day in community benefit. The Mission of Bon Secours Mercy Health is to extend the compassionate ministry of Jesus by improving the health and well-being of its communities and bring good help to those in need, especially people who are poor, dying, and underserved. For more information, visit https://bsmhealth.org/.
Meeting with the Ohio Hospital Association and hospital representatives and the Medical Board

Discussion Questions:

1. How have the healthcare providers in your organization utilized telemedicine differently during the pandemic?
   - Telehealth use was expanded to all providers in the organization in every specialty.
   - Prior to COVID, utilization was limited to behavioral health, eICU, and limited number of other providers and specialties.
   - Over 1,400 providers have been trained on and performed a virtual visit at OhioHealth.
   - Over 750 providers performed a video visit in September 2021.
   - Approximately 10% of ambulatory visits have been conducted via video visit in the last quarter.
   - We have appropriately managed care using virtual health via asynchronous messaging, phone visits, and video visits.

2. When is an in-person visit necessary?
   - Our office staff screen patients for virtual visit in consultation with the providers in the practice.
   - Participation is based on patient preference, appropriateness relative to the standard of care, prior successful visits, and level of clinical need.
   - Certain patients at high risk for exposure or transmission were directed to virtual visits.
   - Based on the evaluation during the virtual visit, patients may be rescheduled for an in-person visit.

3. What will your healthcare providers not be able to do, that they are able to do today, when the in-person office visits in the Medical Board rules are put back in place?
   - We desire to maintain the current Medical Board position relative to virtual health and hope that the Medical Board would support this position going forward and with governmental and private payers.
   - We prefer video visits and, when necessary, visits via asynchronous means (due to internet and other connectivity limitations) to continue for initial and ongoing care when appropriate.
   - We have not ever used special privacy exemptions for HIPAA and maintained all interactions within a secure EMR and platform. The medical board should reinforce the physician responsibilities to maintain security, privacy and medical records integrity.
   - We will continue to maintain all documentation, consents, and ordering within the legal health record.
• Consistent with the current Board position, we have permitted controlled substance prescribing for patients via virtual health during the COVID emergency. We feel that appropriate use of medical history and narcotic registries, as well as providing virtual visits consistent with the standard of care could allow providers to continue safely prescribing controlled substances via virtual means (including at the initial visit).

4. **Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances?** Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?
   • This information is available in our registries; though, it is not actively tracked. We estimate that virtual visits account for approximately 1-2% of our Opioid prescribing.

5. **What sort of discussions are you having with your providers about ensuring standard of care either in a telemedicine visit or when deciding whether telemedicine may be appropriate for an appointment?**
   • We have developed educational training for providers called “web-side manner” that is attached. We have developed educational videos, tip sheets, and onboarding training and have provided general guidelines to our providers regarding appropriateness of video visits.

6. **What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?**
   We would like to see the following:
   • Continued support for video visits broadly and phone visits in special limited circumstances.
   • Continued allowance for controlled substance prescribing and pain management, including at initial visits.
   • Use of telehealth to close gaps in care.
   • Use of patient-reported data and biomedical data capture to complete information about the patient.
   • Allow initial visits via telehealth.
   • Maintain expectations of appropriate professional practices regarding medical records documentation maintained with or transmitted to the patient’s preferred provider, medical home, or attributed practice.
   • Maintain expectations and parity in documentation of the patient visit between video and in-person visit.
   • Maintain expectation of information of security and privacy of medical records and systems.
September 21, 2021

Jill Phalen Reardon
Director of External Affairs
State Medical Board of Ohio
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Dear Ms. Phalen Reardon,

The Lindner Center of HOPE is a psychiatric center of excellence located in Mason, Ohio. The Center offers a complete campus of mental health care to patients from all over the state of Ohio and nationally. Like many mental health providers, the Center quickly adopted telehealth during the COVIDE-19 pandemic in order to continue to provide care, especially to outpatients, amid the advice and orders to stay at home and socially distance. Telehealth proved to be a critical lifeline to many patients in need of mental health care and provided access to services for many patients who never would have sought care, even prior to the pandemic. We hope to continue to use telehealth to reach such patients long after the pandemic has ended.

We urge the State Medical Board of Ohio to consider making changes to its non-emergency telehealth regulations beginning 1/1/22. For prescribing MDs, DOs, and physicians’ assistants who are mental health providers, please consider the adverse impact of requiring that initial visits be conducted in-person as opposed to via telehealth. Psychiatric providers historically do not perform a physical examination on their patients. In most cases it is not appropriate for mental health providers to touch their patients except when there is a clinical need to obtain vital signs. In the office setting, this function is often performed by office staff using automated equipment that is easy to obtain for home use. We typically collaborate with a patient’s primary care provider regarding a patient’s physical status, including the implications of the physical exam performed in their office.

For psychiatric providers, the mental status exam is the physical examination equivalent. A complete mental status examination can be conducted via telehealth without compromising the standard of care. Requiring that first visits be conducted in person limits the scope of potential patients to those patients in close physical proximity to the treatment provider who have transportation and time to commute to and from the appointment. In many ways, this requirement defeats the purpose and utility of telehealth. Thanks to COVID-19, we now have a lot of experience conducting first visits via telehealth. They can be done without compromising the standard of care and while reaching more patients than could otherwise be reached. Psychiatric providers can continue to collaborate with primary care providers for a patient’s physical exam needs, just as they always have done.
We understand and accept that telehealth psychiatric patients may sometimes need to be seen in person for initial or subsequent visits if the same standard of care cannot be met via a telehealth visit as an in-person visit. Through the pandemic, our providers have been exercising careful clinical judgment to determine when to require in-person visits and will continue to do so in the future. However, we see that ongoing mental health telehealth care without periodic in-person visits may be completely appropriate in many cases, even when controlled substances are being prescribed and doses adjusted. Take, for example, a student on stimulants for ADHD whose weight and vital signs can be obtained remotely. Telehealth has actually made follow-up for such patients more consistent due to the convenience of remote visits compared to taking time out of a busy school schedule to attend visits in person. Monitoring is also better because of telehealth and nothing is lost in terms of quality of care.

Currently, the regulations require patients treated via telehealth to be seen in person at least every 12 months. These requirements are more restrictive when controlled substances are prescribed and adjusted. **We urge the Board to reconsider these requirements and allow, where clinically appropriate, psychiatric patients, including those being prescribed controlled substances, to be seen exclusively via telehealth as long as the standard of care is clearly being met.**

As psychiatric providers, we are excited at the opportunity that telehealth provides to reach more patients. We know that mental illness is the nation’s number one public health problem and that most people delay or never seek care due to multiple barriers. The Medical Board’s rules, as currently written, significantly undermine our ability to leverage telehealth to overcome some of these barriers. As the Board moves forward with telehealth rules, we strongly urge the members to consider not requiring in-person visits in situations where physical contact with our patients would not have occurred even prior to the pandemic. **We ask that the Board treat psychiatric care as a special exception to any in-person telehealth requirements.** Doing so will allow patients to continue to receive mental health services that fully meet the standard of care and that, otherwise, may be difficult or impossible to access.

I thank the Board their consideration in this matter. Please do not hesitate to contact me personally at (513) 536-0633 if I may be of any assistance in the Board’s deliberation.

Sincerely,

Paul R. Crosby, MD, MBA
President and CEO
Frances and Craig Lindner Professor
Associate Professor and Vice Chair, Department of Psychiatry and Behavioral Neuroscience, University of Cincinnati College of Medicine
Board Certified General and Child and Adolescent Psychiatrist

cc: The Honorable Mike DeWine, Governor of the State of Ohio
The Honorable Jon Husted, Lieutenant Governor of the State of Ohio
Subject: Follow-Up - Continuity of Care

From: Kinsey Jolliff <kjolliff@metrohealth.org>
Sent: Tuesday, September 28, 2021 11:56 AM
To: Loucka, Stephanie <Stephanie.Loucka@med.ohio.gov>; Reardon, Jill <Jill.Reardon@med.ohio.gov>; Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>; Smith, Nathan <Nathan.Smith@med.ohio.gov>
Cc: Allison Poulios <apoulios@metrohealth.org>
Subject: Follow-Up - Continuity of Care

Director,

Thank you for the meeting(s) this morning. Dr. Chehade and Dr. Bruner thought they were very well conducted and productive. Your team is clearly thinking deeply about these issues and that makes a difference with our physician leaders. We appreciate your team’s work!

As I mentioned on the call with Dr. Bruner, I’ve attempted to capture the basic framework of continuity of care after talking to physicians within MetroHealth. Below are those principles –

- The health care professional shall share data with a health information exchange within the patient's local market;
- The health care professional shall have the ability to make electronic referrals within the patient’s local market for non-telehealth services, including referrals to community-based organizations;
- The health care professional shall have the ability to direct the patient to a comprehensive set of basic health care services, as well as care coordination and care management services.
- The health care professional shall have the ability to direct the patient to a practice that meets all of the requirements of a patient centered medical home that has a physical location in the patient’s local market, including eligible federally qualified health centers and rural health clinics; and
- The health care professional shall have the ability to facilitate referrals for secondary and tertiary care in the patient’s local market.

Please let me know if you have any questions.

Thanks,
Kinsey

Kinsey Jolliff
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Proposed Questions to Stakeholders for Telemedicine Discussion
The following are proposed questions for healthcare providers and organizations:

1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?

**Via:** Telehealth utilization rapidly spanned across the continuum of care for our patients, organization, and with our collaborators in care. Using telemedicine, we were able to be innovative and provide care at multiple access points throughout the varying waves of Covid. Patients were able to connect with their Primary Care Providers for continuity during the first wave to allow for continued care which leads to better outcomes vs. not seeking care and compounding diagnoses. The difference during the pandemic was initially driven from necessity for utilization for access and is now spanning into wider consumer adoption due to awareness of ease of use and expedited access to healthcare.

**Esposito:** SBHI continued to offer services via a video platform and also began using the phone for services such as: counseling, medical/psychiatric appointments both follow up and initial assessment. We also began utilizing the phone for diagnostic evaluations for new patients. Our access has been different and barriers such as transportation have been removed and our show rate for diagnostic evaluations and psychiatric evaluations improved some.

2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.

**Via:**

**Primary Care**
By the end of March- early April 2020, telemedicine rapidly progressed through Primary Care, with all providers receiving training on telehealth platforms. Telehealth was implemented in many patient encounters with the following visit types: acute/new onset problem visit, hospital follow-up visits, routine follow-up visits, Medicare Wellness visits, and new patient visits.

**Intensivists**
Deployed a teleintensivist program for external hospitals to access a teleintensivist (24/7/365) for consultation. Intent is to keep patients in their home hospital (when appropriate) through teleintensivist support with their local provider. Started in early 2021, we've seen tremendous value in this program as we continue to navigate the ongoing surges and bed capacity challenges.

**Neurology**
TeleStroke- We have a robust TeleStroke network for several years now to provide access to Neurologists for patients who are experiencing a time sensitive neurological emergency. Deployment into rural areas and across our system to increase access for better outcomes.

**NEUROOne:** Recent growth of our NEUROOne program to provide Neurology consultants for the inpatient setting across our system and to rural hospitals. Again, keeping patients in their home hospital when appropriate.

**Merritt:** Ambulatory-Our neurologist saw an increased use in the clinic setting to accommodate the >65 y.o. patients who were hesitant to travel during the early days of the pandemic. Many of these patients continue to desire to utilize telemedicine services due to the convenience and ease of the process.

**Cardiology**
Video visits used to continue to provide continuity of care for chronic cardiac conditions such as heart failure and arrhythmia management. In addition, video visits were utilized to delivery consultation to the potential cardiac patients in another Primary Care office; expediting cardiac testing and keeping patients travel to a minimum.

**Skilled Nursing Facilities**
Recently began a program to provide access to providers during after/off hours for residents in the nursing home. This program allows bedside clinicians access to providers to seek a consult for their resident. By expediting and increasing access to a provider, the intent is to decrease unnecessary trips to the ER for
patients that are appropriate for a TeleSNF consult. This also alleviates the strain on transportation systems (private & 911) of transporting patients from and to the SNF.

**Esposito:** Our psychiatrists, NP’s and therapists. Patient encounters included counseling sessions, diagnostic evaluations, follow up counseling appointments after intake, initial psychiatric evaluations and follow up med appointments as well as some case management and care coordination appointments.

3. Which practice groups or specialty types have not utilized telemedicine?

**Esposito:** All practice groups have utilized telehealth.

**Schulze:** Telehealth was not widely used by our pediatric providers.

**Merritt:** Orthopedics, GI, and ENT did not widely use telemedicine.

**Rutledge:** Surgical and Obstetric services.

4. What symptoms should require in-person assessments?

**Esposito:** When there is a lethality level present or acutely psychotic or withdrawal symptoms.

**Schulze:** Initial patient history and illness can be completed via telemedicine. Following the telehealth visit, the provider then dictates if further in-person evaluation is needed. A few conditions in which an in-person visit may be warranted are symptoms of elevated blood pressure, respiratory distress, bleeding, and any other diagnostic procedures required to support treatment. In some cases, depending on symptomology presented, referral to the Emergency Department or higher level of care is warranted.

**Rutledge:** Acute cardiac, surgical and obstetric conditions.

5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

**Esposito:** Yes, we have. We have had success in reaching our patients and providing new services via telehealth. We have had some issues with patients doing other things while attending a telehealth appointment such as shopping, getting gas etc.

**Schulze:** Our primary care providers have provided care through telehealth services for new patients. This has worked well when needing to couple this with a hospital follow-up visit. New patient visits via telemedicine expanded our ability to support transition of care for patients who were not connected to a primary care provider and required medical attention to avoid hospitalization. The implementation of telemedicine with new patients offered a platform for patients to receive care, even with symptoms of Covid, to assist in avoiding overcrowding in the Emergency Department. There were some challenges with telemedicine options for new patients presenting with symptoms requiring a physical assessment. These symptoms include but not limited to: earache/ infections, URI’s, and some rashes.

6. Has your organization completed any type of survey of the healthcare providers or patients regarding their satisfaction with telemedicine visits? Are there results you can share with the Medical Board?

**Via:** No formal survey, anecdotally has occurred.

**Esposito:** We have not.

**Schulze:** While we have not completed a formal survey specific to telemedicine visits, we continued monitoring patient experience through our NRC ratings. Our patient satisfaction scores remained strong while patients transitioned to telehealth options.

7. Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
Via: Due to the varying usage of telemedicine across our organization, we do complete rigorous measures of data for specific programs that are tied to patient outcomes, etc.

Esposito: We have not done exact measuring, but are encouraging our patients to come in person for follow up and making any needed changes to diagnosis

8. What will your healthcare providers not be able to do when the in-person office visits in the Medical Board rules are put back in place?

Esposito: Do initial evaluations remotely and this has impact on our staffing patterns that are already strained.

Schulze: This may impact our ability to keep patient’s with Covid-like systems out of the primary care office. The risk of community acquired infection may increase because of rules around in-person visits put back into place.

9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Via: Premier uses a host of technology to support telehealth. Virtual platforms that allow for video visits, PTZ cameras, Jabra speakers, etc. We’ve built our own telehealth carts to deploy across our programs.

Esposito: SBHI utilizes TeleFirst at OneFifteen and we are implementing DoxyMe for the rest of SBHI. Both platforms will offer both video and audio components.

Schulze: Primary Care used the EPIC Video Visit platform which incorporates interactive, real-time audio and visual components, and can be completed via computer, smart-phone, or any other smart device.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Esposito: Yes, prescriptions are provided. I do not have data readily available tracking the controlled substances prescribed versus non-controlled, but I will check with OneFifteen further to see if we do have any data on that.

Schulze: Prescriptions are provided based on outcome of the telehealth visit. We do not have any specific data related to percentages of controlled or non-controlled substances ordered.

Merritt: One of our uses for telemedicine was for routine medication refill visits. Prescriptions for routine medications were not restricted due to the use of telemedicine.

11. How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Esposito: Afterward and follow-up visit as needed.

Schulze: Utilizing the EPIC telehealth platform, all lab and test results completed for the patient, were visible to our providers. Whether or not labs and other test results are completed prior to or after the telemedicine visit is dependent on the provider preference and visit type. For example, for an acute patient visit, labs are often obtained following the visit. As it relates to well-visits, often labs are performed prior to the telemedicine encounter.

12. How is patient information, such as weight and temperature obtained? Does the patient self-report?

Esposito: Self-report and then check when in-person as well.

Schulze: Patient information may be self-reported to the provider. The provider or staff then documents patient reported information in the medical record as self-reported.
13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

Esposito: We have not seen any negative outcomes thus far.

Schulze: We do not have any specific data to suggest negative outcomes because of telemedicine. In some cases, due to inability to obtain certain patient information components, progress towards meeting quality goals could not be recorded.

Merritt: Telemedicine was actually crucial to maintaining progress towards for many patients who otherwise would not have seen a provider without telemedicine options.

Cardiology: Video visits were extremely helpful for many patients with transportation issues.

14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?

Esposito: Increase in negative symptoms, long duration between face to face visits, and patient request

Merritt: certain musculoskeletal complaints require a hands on assessment and those were scheduled as in-person visits.

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?

Esposito: None at this time.

Schulze: Monitoring patients on controlled substances via telemedicine does decrease our ability to conduct point of care testing, such as urine screening, to evaluate misuse.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

Esposito: We are asking one time per year.

Schulze: This is very specific to the individual needs and comfort of the patient and the decision making required at the provider level.

17. If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

Esposito: We have not noted any decrease in the patient/doctor relationship not being in person every visit. We would continue to require at least one time yearly at a minimum presenting in person, continuing to communicate as we are and maintain our accessibility and rapport building.

Schulze: We ensure continuity of care with our patients and providers through various forms of technology and the electronic medical record, and do not anticipate a change if the rules change. Platforms such as myChart, secure chat, and consistency in electronic health record across primary and specialty networks enhances our ability to promote continuity of care.

18. What is the percentage of your patient visits you believe could be done via telemedicine?

Esposito: Medical: 50-60% ongoing Therapy: 60+%. We still find the first-time appointment after intake to be helpful to be in person, but not a requirement to establish rapport.

Schulze: Over 25% of primary care visits could be completed via telemedicine.

Merritt: 50-60% of neurology patients could be seen via telemedicine.

Cardiology: 40% of cardiac patients could be evaluated via video visits (Heart Failure #1)

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?

Via: Ongoing support of relaxed telehealth regulations to support increased access to care and to remove geographical/timeliness barriers that allow patients to seek care that meets their needs. By engaging patients with telehealth, patients will have better outcomes due to increased time to
diagnosis and potential intervention. Telehealth is a tool in the toolbox and will never replace a provider. We can use it to allow for effective use of the providers time to focus on patients that need that expertise and time.

**Esposito:** Continue to allow first time appointments to be delivered via telehealth to provide a choice to patients. We have found having a blended schedule with both office visits and telehealth to be a good mix that reduces many barriers to treatment. We recognize it is not a perfect fit for all services, but telehealth has served us well during the pandemic.
Q1
Please provide your name and email address.

Name  Jane Balbo
Email Address  janebalbo@gmail.com

Q2
How often have you used telemedicine during the pandemic?
A great deal

Q3
How have you utilized telemedicine during the pandemic? What has been different?
phone visits at first until my health system got the video visit process figured out, then video visits. Initially most of our visits were virtual, and now a great deal still are.

Q4
Please describe the types of patient encounters where telemedicine has been used.
New patient visits, mental health visits, mild respiratory concerns that are not deemed safe to bring in to office (although we can if evaluation demonstrates need for in-person exam), other non-emergent concerns like UTIs, yeast infections, etc.

Q5
What symptoms should require in-person assessments?
Anything concerning where based on history I need to do in-person assessment to determine next steps, such as neuro exam, abdominal or pelvic exam, see a rash or skin lesion better/more clearly
Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Yes! New mental health patients in particular have been great for this format. Has not worked well with neurological complaints or others where really needs an in-person exam to suss out what may be going on.

Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Extremely Satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

I am not sure I understand this question.

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

I will need to see my patients on controlled substances for ADHD and gender-affirming care for in-person visits more often but otherwise won't affect me much because I do not prescribe other controlled substances chronically.

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Zoom healthcare version purchased by my organization

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes I prescribe in telemedicine visits. I do not have that data but my employer does. I have a few that resulted in controlled substance prescription but not many.

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

both before and after - depends on the patient, concern, and at what point in their concern I see them
Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?
sometimes (and we document "self-reported" in the vitals notes next to each vital sign point)

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
I have not. It has actually improved access and reduced no-show

Q15
What factors lead you to advise the patient that an in-person visit is needed?
If I need to do an examination beyond what I can see in video, or if they are on a controlled substance - since I learned of the SMB rule change coming, I've started instituting in-person visits for those folks.

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
Absolutely - we need their vitals. We also need to get real-time UDSs!

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
I am not sure.

Q18
If the Medical Board's rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
I am not sure. Probably the best thing for me, as a university physician, is my patients who go home over summer and winter breaks (but are still in Ohio) have continuity follow-up with me. Their care is not fragmented with going back and forth between home and school providers.

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
75% because a high number are mental health - depression anxiety ocd etc
Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.

I don't think their requirements are unreasonable.

Q21
Any other comments

No
Q1
Please provide your name and email address.

Name
Chris Lauricella

Email Address
cjlauricella@gmail.com

Q2
How often have you used telemedicine during the pandemic?
A moderate amount

Q3
How have you utilized telemedicine during the pandemic? What has been different?
Tele health visits for high risk or symptomatic patients

Q4
Please describe the types of patient encounters where telemedicine has been used.
As above, routine care apts for pts at particularly high risk for contracting Covid or acute apts for pts with symptoms which may be or are COVID

Q5
What symptoms should require in-person assessments?
Difficult question to answer - in an ideal situation an in person exam can be done. But given the pandemic any pt confessing symptoms consistent with Covid are seen via tele health or directed to local ER
Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Rarely - only in “compassionate cases” meaning I had seen family but not the particular patient and they had pressing need - ie likely had Covid and needed orders for testing etc

Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Slightly satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

Nope

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

Unclear question -

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

We have a hippa compliant suite which fully integrates with our EMR for both audio and visual and time stamps the integration with the emr.

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Nope - but as a rule I wouldn’t be comfortable providing new controlled Rx to pts via tele health. And would only do refills for same if there were no red flags and if the state requirements were met.

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Prior to visit if at all practical
Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

Self report - however if I recall correctly CMS has come out with a position that we do not record stated vitals as 'real vitals' in abstract-able fields (used for quality metrics ) so any stated vitals are recorded in subjective fields

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

Yes

Q15
What factors lead you to advise the patient that an in-person visit is needed?

Clinical acumen/

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?

Many - including state guidelines and validity of drug screens etc

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

Generally I default to in person unless there is a pressing reason not to.

Q18
If the Medical Board's rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

This would obviously depend on how the rules changed and what my employer would ask of me. Bottom line the vast majority of my pts prefer the in person visits and view any telehealth as a stop gap measure at best

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?

80%
Q20
What types of changes in the Medical Board's rules related to telemedicine or in-person visit requirements would you like to see.
None

Q21
Any other comments
Respondent skipped this question
Q1
Please provide your name and email address.

Respondent skipped this question

Q2
How often have you used telemedicine during the pandemic?

A great deal

Q3
How have you utilized telemedicine during the pandemic? What has been different?

This telemedicine completely devalues a Physicians' training and experience in the physical exam. All symptoms - including COVID-19 like-symptoms - should be IN-PERSON.

Q4
Please describe the types of patient encounters where telemedicine has been used.

We have used telemedicine on new, acute, chronic, and screening patient encounters. This telemedicine completely devalues a Physicians' training and experience in the physical exam. All symptoms - including COVID-19 like-symptoms - should be IN-PERSON.

Q5
What symptoms should require in-person assessments?

This telemedicine completely devalues a Physicians' training and experience in the physical exam. All symptoms - including COVID-19 like-symptoms - should be IN-PERSON.

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

This telemedicine completely devalues a Physicians' training and experience in the physical exam. All symptoms - including COVID-19 like-symptoms - should be IN-PERSON.
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Not at all satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

We may never know. Impossible to determine. All I can say is that when we do not see people, do not do a physical exam, then we end up overtreating.

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

Use telemedicine. Just leave the waiver in place and adjust the rules / payments to reflect the current environment and leave it alone. If you can CHANGE the rules, certainly you and LEAVE THE RULES ALONE.

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Patients mostly demand Telephone for telemedicine. Video adds little to nothing to the visit. The big organizations were pushing it because it paid more or met regulatory requirements. If you are not going to see a patient and do a robust physical exam, does hearing them versus seeing a bunch of scrambled pixels allow for a better patient evaluation? Not really.

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes. In fact, more prescriptions are provided because you have the time to be able to write them all. Only a few were for controlled, about 7-8% on average. 95-97% of the visits resulted in a non-controlled substance being prescribed. Telemedicine did give the provider time to do more medication reconciliation.

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

We do both - patients are scared due to COVID-19 to get to labs. Labs of all kinds are ordered prior to and used at telemedicine visits, as well as obtained after.
Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

Patient's try to self-report, but the State does not provide everything to the patients to do that. Likewise, it is subjective, as the patients do not have medical-grade equipment. Another reason why telemedicine is not good care.

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

Yes. People have gained weight. A1c has gone uncontrolled. People are not getting screenings. What do you expect if they are told to stay home by the government? We have had to direct to ER during COVID-19 telemedicine more than once for conditions that could be handled in the office. We have likely had 1-2 patients die because they did not have access to telemedicine and our office would not allow them to be seen due to “cold-like” symptoms that likely were CHF / COPD exacerbations. Telemedicine completely devalues the physical exam and the objective skills of physicians.

Q15
What factors lead you to advise the patient that an in-person visit is needed?

I encourage all telemedicine encounters to get into the office. That is the only way to do a proper physical exam. Phone-based video is NOT diagnostic quality for rashes, skin, heart, and lung evaluation.

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?

No. In fact, likely better to use telemedicine for controlled substance conditions.

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

The correct mix is 100% in-person visits. Do not regulate this type of absolute number. Allow freedom of choice and allow the patient to ultimately choose what is best for them with their doctor. There is need for less regulation in this area to not intrude on the freedom of care.

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

What is the need to change them? The door was opened during COVID-19 to the use of this tool - you cannot go back now. “Putting rules back in place” makes no sense, since you allowed it once, you have forever altered the market. You cannot go back on that now.
Q19
What is the percentage of your patient visits you believe could be done via telemedicine?

0.00%

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.

Leave the present state alone. Pay the same amount for telephone vs. video telemedicine, as a payment differential is discriminatory to rural and poor folks who do not have internet access - nor access to high-speed internet.

Q21
Any other comments

The State has completely devalued the physical exam and the objective observations that can be ascertained by an in-person visit. The door was opened during COVID-19 to the use of this tool - you cannot go back now. "Putting rules back in place" makes no sense, since you allowed it once, you have forever altered the market. You cannot go back on that now. Leave the present state alone. Pay the same amount for telephone vs. video telemedicine, as a payment differential is discriminatory to rural and poor folks who do not have internet access - nor access to high-speed internet.
Q1
Please provide your name and email address.

Name: Luis Perez
Email Address: LP131304@ohio.edu

Q2
How often have you used telemedicine during the pandemic?
A moderate amount

Q3
How have you utilized telemedicine during the pandemic? What has been different?
In lieu of in-person visits for those with COVID symptoms, or afraid to contract COVID if they leave the house.

Q4
Please describe the types of patient encounters where telemedicine has been used.
Acute visits for respiratory symptoms, mainly.

Q5
What symptoms should require in-person assessments?
Severe symptoms, or those that are best evaluated in person.

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
I try not to see new patients via Telehealth.
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?
Not at all satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
Respondent skipped this question

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?
Respondent skipped this question

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?
Yes, both audio/video.

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?
I do not prescribe controlled substances via Telemedicine, only exception was one occasion when patient had terminal cancer.

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?
Typically afterwards.

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?
Self-report.

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
I don't treat chronic conditions via Telemedicine, just acute.
Q15
What factors lead you to advise the patient that an in-person visit is needed?
Severity of symptoms.

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
Respondent skipped this question

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
Respondent skipped this question

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
Respondent skipped this question

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
Respondent skipped this question

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
Respondent skipped this question

Q21
Any other comments
Respondent skipped this question
Q1
Please provide your name and email address.

Name
Richard Plumb

Email Address
richard.plumb@ketteringhealth.org

Q2
How often have you used telemedicine during the pandemic?
A moderate amount

Q3
How have you utilized telemedicine during the pandemic?
What has been different?

Q4
Please describe the types of patient encounters where telemedicine has been used.

Follow up for laboratory and testing

Q5
What symptoms should require in-person assessments?

New problem

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

NO
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?
Very satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
No

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?
Nothing

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?
yes

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?
Usually refills

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?
Obtained prior to visit

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?
Self report
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
no

Q15
What factors lead you to advise the patient that an in-person visit is needed?
New problems or decline in symptoms

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
no

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
no

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
Make sure in office visits used

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
25%

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
Not sure

Q21
Any other comments
Respondent skipped this question
Name: Julie Forbush DO  
Email Address: DrJForbush@protonmail.com

Q2  
How often have you used telemedicine during the pandemic?  
A great deal

Q3  
How have you utilized telemedicine during the pandemic? What has been different?  
The ability to see my cannabis and stable primary care patients have been invaluable. I have actually been surprised how well its working for a majority of patients.

Q4  
Please describe the types of patient encounters where telemedicine has been used.  
Cannabis, routine stable chronic medication visits (ADHD, DM, etc), COVID response, also mild to moderate new mental health issues

Q5  
What symptoms should require in-person assessments?  
Breathing issues, new issues, yearly physicals to monitor stable chronic illness, ortho injuries, eye issues, osteopathic manual medicine
Q6

Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

For cannabis patients with solid medical records I have done this. If I feel like there is not enough evidence or I question the severity I bring people in (no charge). For primary care, I generally require in person for at a minimum the initial visit.

Q7

From a clinical position, what is your overall satisfaction with telemedicine visits?

Extremely Satisfied

Q8

Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

I have not bc I am either confirming records for my cannabis patients, or seeing chronic stable issues via telemedicine. Since cannabis is confirming a diagnosis and counseling — in person doesn’t seem required (like I first thought it needed to be).

Q9

What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

I will not be able to see 80%+ if strict in person rules are put back in place. I am a small micro practice so this is a practice killer at this point bc of being Immune suppressed (TNF alpha) it is not an appropriate risk.

Q10

What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

I use updox so I have fully encrypted real time audio-visual interactions.

Q11

Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Refills are generally provided. ADHD med refills in this manner have been a life saver for my patients and their families bc the burden of being off work a half day is gone. I don’t have many opiate/BZD Rx’s at baseline in my office bc I have many other techniques or the ability to provide guidance with integrative techniques.
Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Chronic illness stable or with potential concern but not threatening life or limb - the order is sent to the patient or lab at their preference to be done prior to the appointment. Then it is review and there is counseling just like an in person visit. If it is an issue that needs to be investigated and has arisen during a telemedicine visit - labs are ordered and depending on the type of issue an in person or additional telemedicine visits is planned.

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

I generally have the patient provide all the vitals they have the ability to provide. This is after confirming they can appropriately verbalize or demonstrate use of their home equipment (appropriate cuff sizes etc).

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

I actually have not, but I also have a low threshold to see someone in person if warranted or the patient requests it for technology issues or patient confidence and comfort.

Q15
What factors lead you to advise the patient that an in-person visit is needed?

If urgent or emergent they are referred to the ER, or rarely a UC. If I do not seem to have a quality therapeutic relationship then I recommend in person, if I suspect an issue that is being hidden, if there are complaints that clearly need a thorough physical exam or a new issue.

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?

The concerns are what they would be in person—that there will be a minority of prescribers that are not doing due diligence in managing and monitoring appropriately. For chronic stable pain patients or chronic ADHD patients that have showed no aberrancy - we have to use judgement but its an unlikely issue. For hospice patients it should go without saying given the lack of general availability. I do have concerns with NP and PAs having a free pass and not being held to the same standard of scrutiny as physicians.

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

My cannabis patients — I have found 90% would never need an in person visit bc of the chronic it’s and severity of their illness...it becomes an undue burden. For the primary care patients — I have been doing at least an annual in person visit if possible so I have record of VS etc. I really think stable ADHD patients could go every 2 years if after a year weight is stable and symptoms are well controlled. Chronic pain patients needing opiates and such probably could be seen annually at a minimum.
Q18
If the Medical Board's rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

I am fortunate in that I have chosen to peruse a micro practice. My patients have easy access to me directly and they are respectful of my professional boundaries. I think for those stable chronic refills even having to take off 3-4 hours every 6 months can be a true burden. I do think DM, HTN, and HLP patients should be seen annually but if we are able to give them a q6 month visits that is at their convince and they have no new issues — it helps them overall and there is less stigma for work missed.

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?

90% currently

Q20
What types of changes in the Medical Board's rules related to telemedicine or in-person visit requirements would you like to see.

End the in person cannabis visit requirement yearly AND really crack down on the Burger King shove people through in 10-15 min. My cannabis patients are sick and need guidance — my initial visits last 45-90 min, we really need to crack down on the money grubbing "pill mill" operations. Its medicine, it needs to be treated like it.

Q21
Any other comments

Thanks for listening. If i have to go back to full in person I will have to shutter my micro-practice bc currently it is not prudent for me to have that level of exposure. I live and work in an extremely vaccine hostile area where i even get push back about wearing masks. Please push to kill the "anti vaccine anti discrimination" bill. I need to know that I have coverage from the Board if I refuse to see a hostile anti-masker who isn't vaccinated without fear of being sued for a perceived "slight". I haven't had to make that distinction yet giving access to vulnerable patients who are suffering from extreme misinformation—this allows me to meet them where they are and hopefully educate them so we all have better outcomes.
Q1
Please provide your name and email address.

Name: Ray J Miller DO
Email Address: wildwood@wcnet.org

Q2
How often have you used telemedicine during the pandemic? 
A moderate amount

Q3
How have you utilized telemedicine during the pandemic? What has been different?
Routine follow up and new complaints

Q4
Please describe the types of patient encounters where telemedicine has been used.
as above

Q5
What symptoms should require in-person assessments?
Most, up to 1/2 telemedicine Dx was wrong or incomplete and the opportunity to evaluate the Whole patient was lost

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
No, my opinion is this should never be done in Family Medicine
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Slightly satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

as above

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

Nothing

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Phone call

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

as few as possible due to inherent errors

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

review of yearly health assessments and routine follow-up like refills. Labs not frequently ordered for new complaints, often referred to UC or ER

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

not done
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
Multiple times in an FP setting

Q15
What factors lead you to advise the patient that an in-person visit is needed?
For FP face to face is nearly always best.

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
Don't do controlled substances often and Neve with telemedicine

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
doing all in person again at this time

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
depends on the rule changes. In person is best for all concerned.

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
1% safely

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
Full return to In person for FP, Some specialist may be OK with Telemed like Psych FU visits for med effects etc.

Q21
Any other comments
Get back to face to face it's best for all concerned.
Q1
Please provide your name and email address.
Name: Amanda R Stover
Email Address: amandajreno@gmail.com

Q2
How often have you used telemedicine during the pandemic?
A great deal

Q3
How have you utilized telemedicine during the pandemic? What has been different?
Telemedicine allowed for me to continue to provide care for my patients when it was unsafe to see them in person. I used telemedicine to complete follow up visits for chronic conditions as well as visits for acute complaints.

Q4
Please describe the types of patient encounters where telemedicine has been used.
Follow up visits for chronic conditions, visits for acute complaints

Q5
What symptoms should require in-person assessments?
shortness of breath, chest pain, abdominal pain

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
No
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Very satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

No

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

Provide care for patients who are out of state (people who travel frequently for work, people who live in another state part of the year). It will make it more difficult to provide access for patients who need to follow up on a well controlled chronic problem (ADHD, Depression, HTN)

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Updox mostly

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes I have provided prescriptions on telemedicine visits. I have no data

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

I had labs completed both before and after visits.

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

Patients self report
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
No

Q15
What factors lead you to advise the patient that an in-person visit is needed?
Uncontrolled problem, unable to make a clear recommendation based on history and visual exam of the patient

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
I think telemedicine has a role when combined with in office visits. If unchanged then every other visit could be a telemedicine visit (since these patients have to be seen every 3 months anyways)

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
No data

Q18
If the Medical Board's rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
Continue to provide quality care, ensure that in person visits continue to happen every 6-12 months at minimum

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
45%

Q20
What types of changes in the Medical Board's rules related to telemedicine or in-person visit requirements would you like to see.
Able to prescribe controlled medications using telemedicine, patient does not have to be in state for telemedicine visit

Q21
Any other comments
Respondent skipped this question
Q1
Please provide your name and email address.
Name: Gregory Hill
Email Address: Gregory.hill3@yahoo.com

Q2
How often have you used telemedicine during the pandemic?
A moderate amount

Q3
How have you utilized telemedicine during the pandemic? What has been different?
Lack of personalized health care

Q4
Please describe the types of patient encounters where telemedicine has been used.
Some rechecks and post ops out about 4-6 weeks or longer

Q5
What symptoms should require in-person assessments?
Fracture care. Major surgery post ops. Infected wounds and unhappy clients

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
No. Most of my televisits are follow ups
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Moderately satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

No I have not

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

The question is not clear

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Yes ..Electronic communication. Txt. Phone

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

No Rx via telemedicine

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Some diagnostic results are reviewed via televist

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

Self report
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

As a surgeon it's hard for me to monitor fx healing.

Q15
What factors lead you to advise the patient that an in-person visit is needed?

The time since the last visit ... non urgent conditions.

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?

Yes bbim concerned.

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

Yes. 2-3 months.

Q18
If the Medical Board's rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

More frequent visits.

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?

10-15%.

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.

No major changes.

Q21
Any other comments

No.
Q1
Please provide your name and email address.

Name: Christina M Peters
Email Address: christinampeters@yahoo.com

Q2
How often have you used telemedicine during the pandemic?
A moderate amount

Q3
How have you utilized telemedicine during the pandemic? What has been different?
Follow ups that can be done virtually. Sick visits. Opens up more hours

Q4
Please describe the types of patient encounters where telemedicine has been used.
Depression, anxiety, medication follow up, sick visits, ER and hospital follow up

Q5
What symptoms should require in-person assessments?
Chest pain. Palpitations. Joint injuries. HTN

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
Not really
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?
Extremely Satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
Have not measured

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?
Protect my staff from illness.

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?
Yes. Integrated through our EMR

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?
No data but very few controlled rx through telemedicine

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?
Obtain afterwards

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?
Yes self report
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
Not really.

Q15
What factors lead you to advise the patient that an in-person visit is needed?
Need for physical exam and vitals, EKG

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
No

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
At least once a year

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
Respondent skipped this question

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
20

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
Capability to continue telehealth visits when appropriate

Q21
Any other comments
Respondent skipped this question
Q1
Please provide your name and email address.

Name: Katherine "Toni" Clark, DO, FAAFP
Email Address: katherine.clark@ketteringhealth.org

Q2
How often have you used telemedicine during the pandemic?
A great deal

Q3
How have you utilized telemedicine during the pandemic? What has been different?

Many elderly patients unable to get out, was able to have telemedicine encounters for patients not able to get to the office during office hours

Q4
Please describe the types of patient encounters where telemedicine has been used.

Minor acute problems, chronic illness follow-up, Medicare annual wellness visits

Q5
What symptoms should require in-person assessments?

Shortness of breath, acute chest or abdominal pain, any unstable vital signs, any complaint that might be a new onset critical of life threatening problem
Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Rarely-elderly asymptomatic patient with chronic problems who wasn’t able to schedule new patient visit before running out of medications-in person visit scheduled for shortly after televisit

Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Extremely Satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

Have not made new diagnoses generally - have not found a error yet in diagnosis of treatment due to remote visit

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

I won’t be able to provide as much care since much is after hours and on weekends-will probably increase urgent care and emergency room visits

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Yes! Face time, google duo, face book messenger-since can be used without patient needing a computer

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes, no data but most visits involve at least a refil

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Both - patients have access to results via my chart
Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?
Self report which is allowed if obtained electronically

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
No-only benefit-if patient not doing well we ask to come in (or I make a house call)

Q15
What factors lead you to advise the patient that an in-person visit is needed?
If hasn’t been seen in past 12 months, if complaint requires an exam

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
I rarely treat with scheduled medications-would want to be sure exam supports the diagnosis

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
No

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
Will be difficult due to my panel's problems with transportation and limited office hours/staffing

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
90%

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
Continue the current rules
Q21

Any other comments

None
Q1
Please provide your name and email address.
Name            Melinda Ford
Email Address   ford1@ohio.edu

Q2
How often have you used telemedicine during the pandemic?
A great deal

Q3
How have you utilized telemedicine during the pandemic? What has been different?
Both telephone and video visits

Q4
Please describe the types of patient encounters where telemedicine has been used.
Regular follow ups, acute visits, only once for a brand new patient.

Q5
What symptoms should require in-person assessments?
Many orthopedic ones that need an exam, acute changes in condition, patients who need an in office lab test

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
Only once. It went okay only because it was for a patient with an eating disorder that had already been diagnosed. I didn't need to be able to do a physical exam.
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?
Slightly satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?
No

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?
Remotely check on simple follow up visits for known problems

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?
I do when the patient can access it. We are in an area without good internet and many are unable to access this.

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?
Yes I have prescribed controlled substances from a telemedicine visit. I do not have any data but have never initiated a controlled prescription with only a telemed eval- I've only renewed them.

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?
It depends on the patient. If I know that they need labs prior to the visit I will order them ahead to have to discuss on the visit. If the visit finds something that needs labs that I didn't know about prior, I order them then and advise after they are received.

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?
The patient self reports whatever they can get at home- if they have a BP cuff, are able to check pulse, have a scale, thermometer etc then I ask them for those values
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
Loss of wellness visits and immunizations

Q15
What factors lead you to advise the patient that an in-person visit is needed?
If they need in person tests or a hands on physical exam

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
Normally no, occasionally with some patients there are times that I feel I have to see them face to face

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
I don't have any idea on this and no my organization is not requiring visits at certain times.

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
Intermittent in person visits- cannot go too long without being seen in person

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
25%

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
Not sure- need to have flexibility

Q21
Any other comments
Respondent skipped this question
Q1
Please provide your name and email address.

Name: John Biery
Email Address: sportdocc1@gmail.com

Q2
How often have you used telemedicine during the pandemic?

Rarely

Q3
How have you utilized telemedicine during the pandemic? What has been different?

not actually face to face

Q4
Please describe the types of patient encounters where telemedicine has been used.

colds nothing of major issues

Q5
What symptoms should require in-person assessments?

musculoskeletal issue, cardiac

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

no
Q7  Slightly satisfied
From a clinical position, what is your overall satisfaction with telemedicine visits?

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

no

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

nothing

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

none

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

no

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

get labs drawn before visit

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

do not
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
yes

Q15
What factors lead you to advise the patient that an in-person visit is needed?
when their complaints do not seem plausible

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
yes

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
I have no organization telling me what to do

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
just do as I have done in the past

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
3

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
none

Q21
Any other comments
no, other than the fact our patients feel like they have been lost
Q1
Please provide your name and email address.

Name: Megan Jashinski
Email Address: megan.jashinski@ohiohealth.com

Q2
How often have you used telemedicine during the pandemic?
A great deal

Q3
How have you utilized telemedicine during the pandemic? What has been different?

Better patient access

Q4
Please describe the types of patient encounters where telemedicine has been used.

New patients, chronic condition checks, behavioral health visits, sick visits, medication start follow ups, hospital follow ups.

Q5
What symptoms should require in-person assessments?

Chest pain.

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Worked well with most patient populations. Some difficulty with elderly patients who are not comfortable with technology
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Extremely Satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

No

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

Respondent skipped this question

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Yes

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Do prescriptions, typically no controlled meds.

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Mix of both

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

Self report as possible. Sometimes obtained witnessed on video.

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

No
Q15
What factors lead you to advise the patient that an in-person visit is needed?
Confusion with tech

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
Respondent skipped this question

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
Respondent skipped this question

Q18
If the Medical Board's rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
Respondent skipped this question

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
70%

Q20
What types of changes in the Medical Board's rules related to telemedicine or in-person visit requirements would you like to see?
Respondent skipped this question

Q21
Any other comments
Respondent skipped this question
Q1
Please provide your name and email address.

Name: Ed Tappel DO
Email Address: Edward.TappelJr@ohiohealth.com

Q2
How often have you used telemedicine during the pandemic?
A great deal

Q3
How have you utilized telemedicine during the pandemic? What has been different?

Different: assessing if the chief complaint and symptoms require an in-person evaluation; assessing with significantly limited physical exam. Utilization: mostly developing treatment/testing plans for patients potentially infected with COVID and not sick enough to warrant an in-person eval (this has been extensively used to siphon patients from the very busy EDs and urgent care centers).

Q4
Please describe the types of patient encounters where telemedicine has been used.

Upper respiratory, lower respiratory, N&V, diarrhea, skin lesions and rashes, vulvovaginitis.

Q5
What symptoms should require in-person assessments?

Any that are severe or cause me clinical uncertainty without a physical exam.
Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Yes. Many of my video visits are in support of our urgent care centers and unknown to me. Others are post-hospital and post-ED discharges for non-critical COVID and other conditions who have no PCP for follow-up. Worked well? Telemedicine is a compromise that eliminates the in-person physical exam; each encounter leaves me wondering if I've missed something. Not worked well: internet connections are hit and miss; much time is spent (wasted?) trying to establish the connection; this seems to be following the path of EMRs: the highest trained and paid resources (and the only ones that generate income BTW) sit and fuddle with keyboards and monitors while the patients and families are spending their also-valuable time waiting for this thing to work.

Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Moderately satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

No. In my role I have no f/u with my patients.

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

Assess minor-moderate upper and lower respiratory symptoms: we don't have the facility ability to isolate COVID symptoms from our other patients. The ill patients would then be automatically triaged to urgent care or ED; potentially the illness would be managed via phone call and generate no income (not popular with those of us who depend on RVUs).

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

Something involving the internet and satellites I'm sure. My video visits are real-time AV.

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Sometimes. No. No.
Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Testing is ordered at the time of the visit and the results are reviewed by me. I notify the patients of the results (via phone or medical system's portal) and recommend next step(s).

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

Self-reported temps, BPs, heart rate, and sometimes pulse ox.

Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

Does not apply to my practice.

Q15
What factors lead you to advise the patient that an in-person visit is needed?

Severe symptoms or uncertain diagnosis.

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?

Does not apply to my practice.

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

No. Does not apply to my practice.

Q18
If the Medical Board's rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

Does not apply to my practice.

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?

30-50%
Q20
What types of changes in the Medical Board's rules related to telemedicine or in-person visit requirements would you like to see.

Q21
Any other comments

Thanks for asking!
Q1
Please provide your name and email address.

Name: Albert Salomon
Email Address: gahannadoc@aol.com

Q2
How often have you used telemedicine during the pandemic?

A moderate amount

Q3
How have you utilized telemedicine during the pandemic? What has been different?

Video and phone visits. Can discuss problems sooner. Avoid people with symptoms of COVID congregating in the waiting room

Q4
Please describe the types of patient encounters where telemedicine has been used.

Short follow ups. COVID pts

Q5
What symptoms should require in-person assessments?

Abdominal pain. R/O MI

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Rare. Pt who had been hospitalized with DKA was ok
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Moderately satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

no

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

Less frequent uncontrolled DM f/u

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

yes

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

yes

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

request pt to go tolab

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

self report. Often I ask the pt to come in every 2-3 visits
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

no

Q15
What factors lead you to advise the patient that an in-person visit is needed?

abd pain. I had a pt who had scheduled a video visit, and had her come in the next day

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?

yes

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

no requirement

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

1. I feel that should be seen in person by either PCP or specialist

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?

30%

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.

Respondent skipped this question

Q21
Any other comments

Respondent skipped this question
Q1
Please provide your name and email address.
Name: Paul T Scheatzle
Email Address: pscheatzle@gmail.com

Q2
How often have you used telemedicine during the pandemic?
Occasionally

Q3
How have you utilized telemedicine during the pandemic? What has been different?
I did not use it before

Q4
Please describe the types of patient encounters where telemedicine has been used.
nursing home

Q5
What symptoms should require in-person assessments?
Virtually all

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
Yes. I have ordered therapy but it does not work well
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Not at all satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

No. I know it is inaccurate

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

nothing

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

yes

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

no

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

both

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

nursing home staff records
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

yes

Q15
What factors lead you to advise the patient that an in-person visit is needed?

always unless in COVID lockdown

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?

Yes. There is little Physician control

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

They have all returned to in person

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?

The Board should make in person visits mandatory

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?

zero

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.

They should dissuade Osteopathic Physicians from doing telehealth. It degrades our legitimacy

Q21
Any other comments

Telehealth should only be reimbursed at approximately 50 % of a regular visit because the Osteopathic Physical and structural exam and treatment are at least 50 % of the value of our interaction
Q1
Please provide your name and email address.

Name  Maury Witkoff
Email Address  mwitkoff@columbus.rr.com

Q2
How often have you used telemedicine during the pandemic?
Occasionally

Q3
How have you utilized telemedicine during the pandemic? What has been different?
ease of seeing patients. No waits in a waiting room

Q4
Please describe the types of patient encounters where telemedicine has been used.
urgent care

Q5
What symptoms should require in-person assessments?
varies. Chest pain cardiac needs an in-person visit. Chest pain that is musculoskeletal in a low risk patient or minor could be handled remotely.

Q6
Have you initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
urgent care
Q7
From a clinical position, what is your overall satisfaction with telemedicine visits?

Extremely Satisfied

Q8
Have you measured or are you planning to measure the accuracy of the diagnosis made via telemedicine? If yes, which mode of telemedicine provided the most accurate diagnosis? If yes, what factor or factors determined accuracy in telemedicine diagnoses?

No

Q9
What will you NOT be able to do when the in-person office visits in the Medical Board rules are put back in place?

See as many patients

Q10
What types of technology are you using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?

yes

Q11
Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Rarely controlled substances

Q12
How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

not applicable

Q13
How is patient information, such as weight and temperature obtained? Does the patient self-report?

self reported
Q14
Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
no

Q15
What factors lead you to advise the patient that an in-person visit is needed?
The same factors I would use in person for sending someone to the ED

Q16
Are there any concerns regarding the use of telemedicine when treating chronic conditions with controlled substances?
not really

Q17
Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?
Episodic care

Q18
If the Medical Board’s rules related to in-person visits change, how will you ensure continuity of care (i.e., an informed, close doctor-patient relationship) with your patients?
not applicable

Q19
What is the percentage of your patient visits you believe could be done via telemedicine?
75% of urgent care patients

Q20
What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see.
Liberal use of telemedicine. Patients have been able to avoid ED visits by telemedicine. The only issue I have is people getting ivermectin and hydroxychloriquine from Front Line physicians.
Q21

Any other comments

Telemedicine has been great for the elderly, home-bound, and immunocompromised patients especially. If it is being done safely in other states, it should be done in Ohio.
<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Comments Summarized</th>
<th>Full Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Hospitals</td>
<td>Telemedicine has been beneficial in certain prescribing situations, especially controlled substances. For example, this has proven effective when prescribing Suboxone and to get it to people with rapid access quickly where they otherwise would have struggled.</td>
<td>5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well? This is true for controlled prescriptions in particular, where medical and psychiatric providers want to taper people off questionable regimens and have been able to support primary care for this in new and productive ways. For example, this has proven effective when prescribing Suboxone and to get it to people with rapid access quickly where they otherwise would have struggled and also for intellectual disabilities where patients who struggled to manage office-based visits are better able to engage by video without disruption and stress in a new environment.</td>
</tr>
<tr>
<td>OneFifteen</td>
<td>No concerns regarding suboxone since it is not distributed as widely as should.</td>
<td>15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances? Our psychiatric providers are particularly interested in this question. Our providers have indicated that no - there is no concern. Specifically around Suboxone, as it isn't distributed as widely as it should and large scale population studies show that even diverted Suboxone improves public health measures, like spread of hepatitis and HIV. Regarding benzos and stimulants - there are no concerns different from what happens during in-patient visits. In both cases, there is potential for providers to overprescribe or prescribe inappropriately based on objective standards.</td>
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<tr>
<td>Ohio Association of Community Health Centers</td>
<td>Telemedicine has been heavily used by substance use disorder and behavioral health patients. Strong preference for telemedicine for short follow ups</td>
<td>2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used. OACHC Answer: Primary care and especially critical for Substance Use Disorder (SUD) and Behavioral Health (BH) patients to be able to do suboxone and psych meds by telehealth. In addition, our centers have seen a strong preference by patients for using telemedicine for short follow up appointments.</td>
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<tr>
<td>Ohio Association of Community Health Centers</td>
<td>MAT and SUD treatment will no longer be able to be provided via telemedicine rules suspension is lifted.</td>
<td>8. What will your healthcare providers not be able to do when the in-person office visits in the Medical Board rules are put back in place? OACHC Answer: MAT, SUD, some BH visits w diagnosis of anxiety, anxiety of returning to medical office, some medical, dental, and services to meet the needs of mobility and other older patients challenged or fearful with being exposed to COVID or other communicable diseases. In addition, there will be compressed accessibility to same day and next day access which could result in patients deferring care to the emergency room/urgent care.</td>
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<tr>
<td>Ohio Association of Community Health Centers</td>
<td>The controlled med visits are at times the most critical (MAT/Suboxone/MH med assessment and follow-up)</td>
<td>10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances? OACHC Answer: In general, majority of visits do not involve controlled meds. However, the controlled med visits are at times the most critical (MAT/Suboxone/MH med assessment and follow-up)</td>
</tr>
<tr>
<td>Ohio Association of Community Health Centers</td>
<td>OACHC would like to see the ability to see patients via telemedicine for MAT/controlled substances.</td>
<td>19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see? OACHC Answer: Like ODM, make the Board’s emergency rules permanent, allow continuation of telephone only being acceptable in cases where the patient does not have internet or access to a computer/smartphone. The continued ability to see patient by telehealth for MAT/controlled substances is critically needed. In addition, require on average, patient seen in-person once every 12 months, and not initially.</td>
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<tr>
<td>OneFifteen</td>
<td>The use of telemedicine has allowed for increased access for patients with substance use disorder.</td>
<td>1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different? Use of telemedicine has enhanced our ability to reach patients “where they are” by addressing structural and attitudinal barriers to care. Some patients who received care through telemedicine may have been unable to attend appointments due to lack of transportation, need for childcare, employment schedules, concern about viral exposure risk, or concern for stigma associated with receiving SUD treatment.</td>
</tr>
</tbody>
</table>
2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.

Treatment of substance use disorders and co-occurring mental health conditions for individuals who are in a maintenance phase of their illness, where medications are likely to be continued or incrementally changed.

Rapid follow-up after initiating a new treatment protocol. For example, if a patient received initiation of buprenorphine for treatment of opioid use disorder, our team is likely to schedule a follow-up visit 2-4 days after this medication was started, and then would request that the patient return onsite approximately 7 days after medication initiation. This intermediate appointment facilitated closer follow-up for patients after initiating a new medication.

If a patient indicated having a significant barrier to onsite treatment (for example, no transportation, lack of childcare, etc.), that visit would likely be converted to a telemedicine visit. The treatment team would work with that patient to determine parameters for future in-person and/or telemedicine visits, based on clinical judgment and best practices.

4. What symptoms should require in-person assessments?

For mental health and addiction services, most symptoms can be adequately assessed by telemedicine. Observing a patient through a synchronous audio/video feed is a reasonable medium for conducting the mental status exam that is performed during an in-person assessment: a physician will complete an evaluation of a patient’s mental state by observing a patient’s affect, speech, and behavior, usually without completing a more extensive physical exam, unless there is a specific reason to do so. We should note that other forms of telehealth, including telephonic assessment without video feed, provide incomplete information needed for a full assessment of the patient’s mental state, and therefore OneFifteen’s medical providers use synchronous audiovisual connection for our telemedicine care.

There are some symptoms of SUD where in-person monitoring is preferable:
- Alcohol and sedative/hypnotic withdrawal assessment; monitoring of vital signs for evidence of hemodynamic instability is indicated
- Abscesses, cellulitis, and other infections that are sequelae of injection drug use
- Signs of systemic illness (jaundice, edema, substantial weight loss, etc.)

In these instances, we have had the experience where an initial telemedicine encounter can serve as a triage point for an individual who might not have received any treatment at all. For example, if we see a patient in alcohol withdrawal who has a substantial tremor -- which is particularly easy to identify remotely as the patient holds their smartphone -- we use that encounter as an opportunity to educate the patient about risks of untreated alcohol withdrawal, and we coordinate transfer to an appropriate level of care, which may be an Emergency Department.
OneFifteen

If Medical Board rules are put back in place, OneFifteen would be impacted in the following ways:

1. Restriction of services in crisis stabilization units which provide 24/7 treatment for patients that come in after hours for withdrawal from opioids, alcohol, or sedative/hypnotic agents. Standard plan of care to treat the withdrawal syndrome using controlled substances (buprenorphine for treatment of opioid withdrawal, and benzodiazepines for treatment of alcohol and sedative/hypnotic withdrawal).

2. No longer able to fulfill plan to open five rural TeleHubs by the end of the year.

3. Reduced ability to reach patients in vulnerable time period when they are ready for treatment.

4. Expected lower retention rates to treatment.

8. What will your healthcare providers not be able to do when the in-person office visits in the Medical Board rules are put back in place?

A return to enforcement of pre-pandemic telemedicine rules would limit the number and quality of services that we provide in a number of ways.

1. We would have to close or significantly restrict our Crisis Stabilization Unit (CSU) services overnight and on the weekends. We currently staff our CSU with a remote, on-call physician or nurse practitioner between the hours of 5pm-8am on weekdays and 24/7 on weekends. This physician or NP is available to assess individuals who walk in for treatment by using telemedicine: the remote provider sees the patient on a tablet and communicates the treatment plan with onsite nursing staff. There is insufficient demand for after hours / weekend services to staff a provider 24/7 in-house, and that would also not be a cost-effective model of care.

Many patients who walk in after hours will be in withdrawal from opioids, alcohol, or sedative/hypnotic agents, and our standard plan of care will be to treat the withdrawal syndrome using controlled substances (buprenorphine for treatment of opioid withdrawal, and benzodiazepines for treatment of alcohol and sedative/hypnotic withdrawal). Unless there are rule changes to telemedicine rules, we would no longer be able to continue to offer this service to the community.

2. We would have to halt plans to open five rural TeleHubs by the end of the year. We have received grant funding and are in the midst of negotiations to launch partnerships with primary care clinics and other providers to provide needed SUD treatment in rural regions. One-third of Ohio counties have two or fewer DATA 2000-waivered prescribers, and ten counties lack any DATA 2000-waivered prescribers. As a result, individuals with OUD in these regions are unlikely to receive buprenorphine – a lifesaving, FDA-approved medication indicated for the management of OUD. The intent of our Rural TeleHub Program is to address workforce shortages in rural regions by extending the geographic reach of DATA 2000-waivered prescribers through telemedicine. Our proposed model of care will include, among other services, prescription of controlled substances by telemedicine – specifically the prescription of buprenorphine for the treatment of OUD by a DATA 2000-waivered, addiction medicine provider using synchronous, audiovisual telemedicine technology. Under pre-pandemic Ohio regulations, the prescribing provider would need to complete a physical examination before initiation of a new controlled substance, which would not be feasible given the geographic distance between the patient and the prescriber. If Ohio resumes enforcement of telemedicine rules, we would consider moving the site of these TeleHubs to another state where the telemedicine rules would align with federal regulations, where we would be able to address the urgent need for SUD treatment in regions with poor access to care.

3. We would not reach some vulnerable patients during the window of opportunity when they are ready for treatment. In 2020, over 93,000 individuals in the U.S. died from an unintentional drug overdose – one every six minutes. Ambivalence is a part of the disease of addiction, and many individuals are highly ambivalent about entering treatment. Telemedicine is one of the tools we have to reach patients “where they are” and when they are ready for treatment. Many individuals experiencing severe opioid withdrawal will turn to high-potency opioids to alleviate their withdrawal symptoms – and some of those individuals may die from an overdose. Our ability to reach patients via telemedicine – whether to treat the patient in their own home, in our CSU, or at another location – enables our physicians to offer care when patients need it most.

OneFifteen

Lab tests including urine drug screening and urine pregnancy testing are a routine part of addiction medicine care.

For example, if a physician suspects that the patient is diverting a controlled substance, the physician may request that the patient come to our clinic to provide a urine drug screen before a telemedicine visit or before a prescription is prescribed.

11. How are lab tests used and evaluated at telemedicine visits? Are patients required to obtain them prior to the visit or do they obtain them afterward and then have a follow-up visit?

Lab tests including urine drug screening and urine pregnancy testing are a routine part of addiction medicine care. Asynchronous drug screen tests have been incorporated into our clinical workflows for patients receiving telemedicine encounters. We do not require that urine screens are collected prior to a telemedicine visit; rather, we allow physicians to make a sound clinical decision about how best to manage their patients. There are some clinical circumstances where the physician would request obtaining a urine drug screen before proceeding in care. For example, if a physician suspects that the patient is diverting a controlled substance, that physician may request that the patient come to our clinic to provide a urine drug screen before a telemedicine visit or before a prescription is e-prescribed.

Other lab tests that are part of routine treatment for SUD and co-occurring psychiatric disorders — including hepatitis and HIV testing, drug levels, metabolic monitoring labs for a patient on an atypical antipsychotic, etc. — are not point-of-care tests and must be sent to a lab. In these instances, we give patients the option to have laboratory testing ordered at a commercial lab (perhaps closer to their home), or the patient can come to our Crisis Stabilization Unit or Outpatient Clinic to have bloodwork done.

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?

Because telehealth extends the availability of our treatment team, as described above, and because we reserve the right to advise the patient that a face-to-face visit is needed, we are generally able to navigate treating chronic conditions with controlled substances. The concerns for misuse, diversion, and lack of adherence, must be weighed against the known benefits of effective treatment of addiction disorders with controlled substances and in the context of the structural barriers: for some patients and some circumstances, the option is not between a telemedicine appointment and an in-person appointment; it is between a telemedicine appointment and no appointment at all, and a return to substance use.
OneFifteen recommends the following:

1. Waiver of initial in-person visits when prescribing controlled substances for treatment of SUD or behavioral health conditions
   Exceptions:
   - requirement should be waived for Schedules III-V controlled substances as classified by the U.S. DEA.
   - They do not see value in waiving an in-person visit requirement for prescribing full opioid agonist medications used for pain control, but they encourage the Board to consider waiving the in-person requirement for prescription of stimulants for the use of behavioral health conditions such as ADHD.
   - They do not perceive value in waiving the requirement for Schedule I controlled substances, such as cannabis, and recommend that the Board leave this regulation in place for Schedule I drugs.
   - They also recommend that initiation of a controlled substance via telemedicine should only be allowed when a real-time, synchronous audiovisual technology is used. Telephonic connections and asynchronous technologies provide insufficient information for the full assessment needed to diagnose and treat an individual who would benefit from a controlled-substance prescription.

2. Annual in-person visits for patients prescribed a controlled substance are reasonable.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?
   (1) We urge the Medical Board to permanently waive the requirement that a physician or physician assistant must conduct an initial in-person assessment when prescribing a controlled substance for the treatment of a substance use disorder or other behavioral health condition, with the following stipulations:
      ○ We recommend that this requirement be waived for Schedules III-V controlled substances as classified by the U.S. DEA.
      ○ From our perspective, waiving the requirement for Schedule II controlled substances is more nuanced. We do not see value in waiving the in-person visit requirement for prescribing full opioid agonist medications used for pain control, but we would encourage the Board to consider waiving the in-person requirement for prescription of stimulants for the use of behavioral health conditions such as ADHD. (While this would have little impact on our program, we are aware of the workforce shortages of child psychiatrists, and believe that telemedicine may be of value in the accurate assessment and treatment of ADHD among children.)
      ○ We do not perceive value in waiving the requirement for Schedule I controlled substances, such as cannabis, and would recommend that the Board leave this regulation in place for Schedule I drugs.
      ○ We would also recommend that initiation of a controlled substance via telemedicine should only be allowed when a real-time, synchronous audiovisual technology is used. Telephonic connections and asynchronous technologies provide insufficient information for the full assessment needed to diagnose and treat an individual who would benefit from a controlled-substance prescription.

(2) For individuals prescribed a controlled substance via telemedicine, we feel it would be reasonable to require an annual in-person evaluation, which could be provided by the addiction medicine provider or another healthcare provider, so long as there is collaboration and communication between the local healthcare provider and the remote addiction medicine physician or physician assistant.
OneFifteen recommends the following:
3. Revision of Ohio’s OBOT rules:
   - Modify the requirement that a physical examination must occur prior to initiation of buprenorphine, by indicating that this examination can be completed during a telemedicine visit using a synchronous, audiovisual connection.
   - Align rules to include the updates from the American Society of Addiction Medicine National Practice Guidelines 2020 Focused Updates and the Substance Abuse and Mental Health Services Administration Treatment Improvement Protocol 63.
   - Eliminate the requirement for a plan for psychosocial treatment for physicians who are not board certified addictionologists or psychiatrists. Physicians should provide available treatment options. The necessity for treatment should be a shared decision between the patient and physician, but not required.
   - They encourage the Board to adopt language that is permissive of electronic communication and not limited to written signatures and materials. Further, they suggest that the Board remove the requirement that information about medications be distributed in writing, as this is not required in other areas of medicine and the patient will receive this information as an accompaniment to their prescription.

OneFifteen
Ohio vs. Federal Rules (per the Controlled Substances Act (CSA) and as amended by Ryan Haight Act of 2008)
1. Ohio requires a physical examination to be performed before initiation of controlled substance for the treatment of OUD. Federal rules do not include this type of OUD-specific requirement.
2. Ohio practitioners including OneFifteen could continue to offer telemedicine as we have for the past 18 months and as described above so long as the federal PHE continues. We do not know if the current federal rules under the federal PHE will become permanent. They would be required to adhere to federal requirements if they were to go back into effect.
3. Ohio will be well positioned to be first-movers in telemedicine innovation when federal rules change.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?
(3) As the Board continues to look at evaluating these rules, we urge the Board to revise Ohio’s Office Based Opioid Treatment (OBOT) rules. We understand the Board’s concern about patient care and safety, but we find these rules to be overly prescriptive of a physician’s actions in a way that is inconsistent with other areas of medicine, including in areas governing the prescription of full opioid agonists. We request the following rule changes:
   - Modify the requirement that a physical examination must occur prior to initiation of buprenorphine, by indicating that this examination can be completed during a telemedicine visit using a synchronous, audiovisual connection. Align rules to include the updates from the American Society of Addiction Medicine National Practice Guidelines 2020 Focused Updates and the Substance Abuse and Mental Health Services Administration Treatment Improvement Protocol 63.
   - Eliminate the requirement for a plan for psychosocial treatment for physicians who are not board certified addictionologists or psychiatrists. Physicians should provide available treatment options. The necessity for treatment should be a shared decision between the patient and physician, but not required.
   - We believe there is value in establishing a treatment agreement between the physician and the patient regarding prescription of a controlled substance, and we believe this agreement can be established even when care is remote. We encourage the Board to adopt language that is permissive of electronic communication and not limited to written signatures and materials. Further, we would suggest that the Board remove the requirement that information about medications be distributed in writing, as this is not required in other areas of medicine and the patient will receive this information as an accompaniment to their prescription (the package insert).

1. Relaxing Ohio’s OBOT rules would align telemedicine practice in Ohio with the federal pre-pandemic rules. In particular, Ohio requires a physical examination to be performed before initiation of a controlled substance for the treatment of OUD. Federal rules do not include this type of OUD-specific requirement. In our experience, telemedicine encounters using synchronous, audiovisual technology provide sufficient information to diagnose OUD and start a medication like buprenorphine.

2. Relaxing Ohio’s telemedicine rules on the prescribing of a controlled substance would align telemedicine practice in Ohio with the federal pandemic rules -- in other words, if Ohio’s rules on first-dose prescribing are relaxed, Ohio practitioners including OneFifteen could continue to offer telemedicine as we have for the past 18 months and as described above so long as the federal PHE continues. We do not know if the current federal rules under the federal PHE will become permanent. If we return to federal rule enforcement, OneFifteen’s providers will have to adhere to prescribing a first-dose of a controlled substance in person, although there are some exceptions, such as when the patient is located in a facility or accompanied by a provider with a DEA number. (The OBOT stipulation for a physical examination by the prescriber supersedes this exception, so without changes to the OBOT rule, we could not practice under these stated exceptions.)

3. Amending both the OBOT and telemedicine controlled-substance regulations will set Ohio up to be at the forefront of innovation when federal rules are amended. By making Ohio’s pandemic telemedicine flexibility permanent, practitioners in Ohio will be well positioned to be first-movers in telemedicine innovation when federal rules change.

Topic: General Prescribing
University Hospitals
UH has not seen an increase in prescribing with the increase in the use of telemedicine. The have not encountered an abuse of prescribing from telehealth visits.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?
Prescriptions are provided based on telemedicine visits. We have not seen any data to suggest that telehealth visits result in a higher number of prescriptions, including controlled substances. For psychiatry, most patients seen were prescribed medications during virtual visits, which includes around 30% of patients getting controlled prescriptions and more than 50% in child psychiatry getting controlled prescriptions. This has not resulted in any new problems. To the contrary, more children who would benefit from stimulants got them, which is a good thing. We have not encountered any abuse of prescribing from telehealth visits.
Ohio Association of Community Health Centers

Most telemedicine visits do not involve controlled medications but the visits that do are often critical (MAT/Suboxone/MH med assessment and follow-up).

OneFifteen

Of the telemedicine visits conducted during the pandemic:

● 26% of telemedicine visits result in a prescription for controlled substances

● 39% of telemedicine visits result in a prescription for non-controlled substances.

As an adjunct to our first telehealth study, we analyzed n=281 patients who received a first-dose of a controlled substance between October 2020 and June 2021. All of these patients received either buprenorphine for the treatment of opioid use disorder, or a benzodiazepine (lorazepam or diazepam) for the treatment of alcohol or sedative/hypnotic withdrawal. The telehealth group included individuals who were evaluated by their provider via telemedicine, regardless of whether the patient, the physician/NP, or both were located remotely (that is, some patients in this group were physically located onsite using a tablet, and others were remote and using their own device). No statistically significant differences were found between the telehealth group (n=111) and the in-person group (n=170) on demographic characteristics, clinical factors, dropout and retention rates, and duration of medication.

We found similar results when stratified by substance (buprenorphine vs. benzodiazepines).

OHA

Controlled substances can be prescribed safely in many situations.

Prescriptions of controlled substances can be safely issued virtually in many situations, although there may be scenarios requiring increased oversight and/or regulation. We understand that most of Ohio’s current in-person visit requirements apply to the prescribing of controlled substances. We share the Board’s commitment to protecting patient safety and preventing fraud and abuse related to controlled substances. However, we believe it is appropriate to consider whether there may be certain scenarios that allow for the safe prescribing of controlled substances via telemedicine. For example, many pediatric providers have highlighted the benefits of being able to safely and effectively prescribe certain ADHD stimulant medications virtually. Another compelling example was provided by a neuropsychologist, who has had success in virtually prescribing anti-convulsant medications to certain patients.

OHA

Controlled substances can be prescribed safely and virtually but there may be areas that require additional oversight.

Prescriptions of controlled substances can be safely issued virtually in many situations, although there may be scenarios requiring increased oversight and/or regulation. We understand that most of Ohio’s current in-person visit requirements apply to the prescribing of controlled substances. We share the Board’s commitment to protecting patient safety and preventing fraud and abuse related to controlled substances. However, we believe it is appropriate to consider whether there may be certain scenarios that allow for the safe prescribing of controlled substances via telemedicine. For example, many pediatric providers have highlighted the benefits of being able to safely and effectively prescribe certain ADHD stimulant medications virtually. Another compelling example was provided by a neuropsychologist, who has had success in virtually prescribing anti-convulsant medications to certain patients.

Nationwide Children’s Hospital

Prescriptions are being issued where clinically appropriate.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes, prescriptions are provided based on telemedicine visits:

● 26% of telemedicine visits result in a prescription for controlled substances

● 39% of telemedicine visits result in a prescription for non-controlled substances. As an adjunct to our first telehealth study, we analyzed n=281 patients who received a first-dose of a controlled substance between October 2020 and June 2021. All of these patients received either buprenorphine for the treatment of opioid use disorder, or a benzodiazepine (lorazepam or diazepam) for the treatment of alcohol or sedative/hypnotic withdrawal. The telehealth group included individuals who were evaluated by their provider via telemedicine, regardless of whether the patient, the physician/NP, or both were located remotely (that is, some patients in this group were physically located onsite using a tablet, and others were remote and using their own device). No statistically significant differences were found between the telehealth group (n=111) and the in-person group (n=170) on demographic characteristics, clinical factors, dropout and retention rates, and duration of medication.

We found similar results when stratified by substance (buprenorphine vs. benzodiazepines).

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for non-controlled substances?

Yes, when clinically appropriate, prescriptions may be made. Approximately 11% of visits were associated with a prescription for a non-controlled substance and 4% were associated with a prescription for a controlled substance. This data reflects June-August 2021.
Bon Secours - Mercy Health  BSMH requests that informed consent regarding remote examination be obtained annually.

2. Prescribing Drugs Via Telemedicine
BSMH believes some of the prescribing requirements listed in OAC Ann. 4731-11-09 create unnecessary time-consuming processes and barriers to care.
BSMH makes the following recommendations:

- The physician shall obtain the patient’s informed consent for treatment through a remote examination. The physician shall document in the patient’s medical record the patient’s consent to treatment through a remote evaluation.

Recommendation: Permit informed consent about treating through remote examination to be annually provided by the beneficiary. This will align with federal requirements related to communication technology-based services such as virtual check-ins and e-visits.

Bon Secours - Mercy Health  BSMH requests that the duty to provide medical records to a primary care provider be the same as in-person standards.

2. Prescribing Drugs Via Telemedicine
BSMH believes some of the prescribing requirements listed in OAC Ann. 4731-11-09 create unnecessary time-consuming processes and barriers to care.
BSMH makes the following recommendations:

- The physician shall request the patient’s consent and, if granted, forward the medical record to the patient’s primary care provider or refer the patient to an appropriate health care provider or health care facility.

Recommendation: A physician should not have the affirmative duty to ask patient about providing the medical record to the patient’s primary care provider. Instead, this should follow the same standard as an in-person visit.

Bon Secours - Mercy Health  BSMH requests that rules reflect that prescribing controlled substances, weight loss drugs, opioid addiction and pain management should be consistent with federal requirements.

BSMH requests that the language be removed and be replaced with the statutory requirement found within ORC Ann. 4731.74. Specifically, prescribing drugs that are controlled substance should meet the standards that are consistent with federal law, including any waivers thereof.

Additionally, controlled substance prescribing visit requirements (e.g. 4731-11-03, OAC rule 4731-11-14, OAC rule 4731-29-01, OAC rule 4731-11-04) related to controlled substances, weight loss drugs, opioid addiction, and pain management should align with current Federal requirements, state statutory law and an in-person standard of care.

Akron Children’s Hospital  Telehealth is beneficial for medication management in particular ADHD for our organization, patients on controlled substances for ADHD require evaluation every 3 months.

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?

a. Telehealth is beneficial for medication management in particular ADHD for our organization, patients on controlled substances for ADHD require evaluation every 3 months. The provider can evaluate the effectiveness of the medications and any side effects via telehealth. Offering some of these appointments by telehealth is a patient satisfier.

OSU Wexner Medical Center  OSUWMC providers issue prescriptions where medically appropriate. The percentage of controlled substance prescriptions varies by providers and the type of service.

10. Are prescriptions provided based on telemedicine visits? Do you have any data on the percentage of telemedicine visits that result in a prescription for controlled substances? Do you have any data on the percentage of telemedicine visits that result in a prescription for noncontrolled substances?

Our providers do issue prescriptions when medically necessary and clinically appropriate to prescribe based on the information available during a telehealth visit. These prescriptions can happen for patients with whom we have not yet had an in-person visit and prescribing through telemedicine visits has been especially important for starting MOUD care. The percentage of these prescriptions that are for controlled substances vary by provider and type of services. For instance, our James Palliative Care Clinic team estimates that over ninety percent of their telemedicine visits result in an opioid prescription. This percent is no different than patients see in the clinic.

OSU Wexner Medical Center  OSUWMC believes that telemedicine is an important modality for treating chronic conditions with controlled substances. They also believe that providers need to have the capacity to provide in-person care when needed.

15. Are there any concerns regarding the use of telemedicine for providers treating chronic conditions with controlled substances?

We believe that telemedicine is vitally important as a modality for treating chronic conditions with controlled substances, especially palliative care. That said, we do think it is important that providers who are treating these conditions via telemedicine have the capacity to provide in-person health care services when and if the patient needs in-person care, preferably with the same provider.

OSU Wexner Medical Center  OSUWMC recommends that prescribing of medications, including controlled substances and MOUD medications should be allowed via telehealth even without an initial in-person visit.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?

Changes to Medicaid Board rules we would like to see include:

- Allowing the prescribing of medications, including controlled substances and MOUD medications, via telehealth, even without an initial in-person visit; and
Ohio Health believes that "that appropriate use of medical history and narcotic registries, as well as providing virtual visits consistent with the standard of care could allow providers to continue safely prescribing controlled substances via virtual means (including at the initial visit)."

3. What will your healthcare providers not be able to do, that they are able to do today, when the in-person office visits in the Medical Board rules are put back in place?
   ▪ We desire to maintain the current Medical Board position relative to virtual health and hope that the Medical Board would support this position going forward and with governmental and private payers.
   ▪ We prefer video visits and, when necessary, visits via asynchronous means (due to internet and other connectivity limitations) to continue for initial and ongoing care when appropriate.
   ▪ We have not ever used special privacy exemptions for HIPAA and maintained all interactions within a secure EMR and platform. The medical board should reinforce the physician responsibilities to maintain security, privacy and medical records integrity.
   ▪ We will continue to maintain all documentation, consents, and ordering within the legal health record.
   ▪ Consistent with the current Board position, we have permitted controlled substance prescribing for patients via virtual health during the COVID emergency. We feel that appropriate use of medical history and narcotic registries, as well as providing virtual visits consistent with the standard of care could allow providers to continue safely prescribing controlled substances via virtual means (including at the initial visit).

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<tr>
<th>Topic: Initial Visits</th>
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<td>University Hospitals</td>
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<td>Ohio Association of Community Health Centers</td>
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14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?
   Very generally, when there is a degree of physical interactiveness that is a requisite to verify, diagnoses, or guide further treatment/therapy. Depending on the patient and condition, this does not need to occur during the first visit and can be required as clinicians deem appropriate for follow up visits.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?
   We would like to see an elimination of the in-person visit requirement when it comes to initiating new patient visits and prescribing of controlled substances. There are plenty of relationships that providers and patients have engaged in over the last year that have been initiated and continued via telehealth to great benefit for both provider and patient. In many cases, patients never would have maintained a care bond with their provider and would be limited in their ability to continue such if in-person visits are required. We understand the concerns around fraud, waste, and abuse; we believe an appropriate “floor” for monitoring would include required credentialing, education on how to use telehealth as a tool, and even considering harnessing the improved auditability that naturally exists in telehealth visits and electronic records.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit ascertain intervals, such as once per year or once per two years?
   ▪ OACHC Answer: Yes on average, patient seen in-person once every 12 months, and not initially.
OneFifteen

When the patient is located remotely, the initial visits via telemedicine worked well when was hesitant to receive treatment, faced barriers to prevent an in-person visits, had concerns about the stigma of receiving addiction or mental health treatment or had concerns about contracting COVID-19.

When the patient is located remotely, the initial visit did not work well when the patient did not have adequate technology for a telemedicine visit.

When the provider was located remotely, the initial telemedicine visit almost always worked well.

When the provider was located remotely, the initial telemedicine visits did not work well when new patients insisted upon face-to-face evaluation.

5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?

Our healthcare providers have routinely initiated care for new patients through telemedicine during the pandemic.

When the patient is located remotely, and using their own device:

- Conducting an initial assessment via telemedicine has worked well when:
  - The patient was hesitant to receive an in-person visit because they are concerned about the stigma of addiction or mental illness or the risk of contracting SARS-CoV-2.
  - The patient has faced certain structural barriers like lack of transportation and need for childcare.
  - Conducting an initial assessment via telemedicine has not worked well when:
    - The patient does not have easy access to the technology necessary to engage in a telemedicine encounter, or has inadequate bandwidth for a real-time video and audio connection (resulting in delays in video or audio streaming).

When the patient is located onsite, and the provider is located remotely:

- Conducting an initial assessment via telemedicine has worked well when:
  - This almost always works well. Onsite nursing staff are able to attain information from the patient (vital signs, urine drug screen, labs) and relay that information to the offsite provider.
  - This has worked particularly well to address workforce shortages, and has enabled us to extend our current workforce to cover night and weekend hours remotely. We have also found that staff appreciate the option to work remotely, and our rate of provider absenteeism is exceptionally low.

- Conducting an initial assessment via telemedicine has not worked well when:
  - A new patient insists upon a face-to-face encounter with an SUD provider. We found that the majority of patients had no problem seeing a provider via a tablet, but there were a few patients who were uncomfortable with this technology and requested an in-person evaluation.

Nationwide Children’s Hospital

After an initial in-person visit, many chronic conditions can be safely managed by providers but on a case-by-case basis.

OSU Wexner Medical Center

OSUWMC suggests that in-person initial visits should be left to the discretion of the practitioner for all health services.

OSUWMC further believes that practitioners can determine who they need to see in-person and when they need to see them. Therefore, we should allow practitioners this discretion and not set an arbitrary initial in-person visit requirement.

We believe that our rationale for not requiring an in-person visit first for mental health care applies to other health services as well. For those services where an initial in-person visit would be most appropriate, we believe those providers will require that visit. However, even then, they may be able to do an initial screening through a telehealth visit that will avoid unnecessary care or allow for the ordering of some tests that would be beneficial at the in-person visit.

OSU Wexner Medical Center

OSUWMC recommends that the Medical Board remove initial in-person visits from rule.

University of Cincinnati - Lindner Center of HOPE

UC Lindner Center of HOPE recommends that rules allow patients to meet with providers exclusively via telehealth where appropriate.

We urge the State Medical Board of Ohio to consider making changes to its non-emergency telehealth regulations beginning 1/1/22. For prescribing MDs, Dos, and physicians' assistants who are mental health providers, please consider the adverse impact of requiring that initial visits be conducted in-person as opposed to via telehealth. Psychiatric providers historically do not perform a physical examination on their patients. In most cases it is not appropriate for mental health providers to touch their patients except when there is a clinical need to obtain vital signs. In the office setting, this function is often performed by office staff using automated equipment that is easy to obtain for home use. We typically collaborate with a patient’s primary care provider regarding the patient’s physical status, including the implications of the physical exam performed in their office.

Currently, the regulations require patients treated via telehealth to be seen in person at least every 12 months. These requirements are more restrictive when controlled substances are prescribed and adjusted. We urge the Board to reconsider these requirements and allow, where clinically appropriate, psychiatric patients, including those being prescribed controlled substances, to be seen exclusively via telehealth as long as the standard of care is clearly being met.
<table>
<thead>
<tr>
<th>Ohio Health</th>
<th>Ohio Health prefers that initial visits be allowed via telehealth.</th>
</tr>
</thead>
</table>

6. **What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?**

We would like to see the following:
- Continued support for video visits broadly and phone visits in special limited circumstances.
- Continued allowance for controlled substance prescribing and pain management, including at initial visits.
- Use of telehealth to close gaps in care.
- Use of patient-reported data and biomedical data capture to complete information about the patient.
- Allow initial visits via telehealth.
- Maintain expectations of appropriate professional practices regarding medical records documentation maintained with or transmitted to the patient’s preferred provider, medical home, or attributed practice.
- Maintain expectations and parity in documentation of the patient visit between video and in-person visit.
- Maintain expectation of information of security and privacy of medical records and systems.

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**Topic: In-person Visits**

<table>
<thead>
<tr>
<th>University Hospitals</th>
<th>The need for regular in-person visits vary based on specialty and conditions.</th>
</tr>
</thead>
</table>

16. **Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?**

We believe the right “mix” of in-person and telemedicine visits will vary by specialty, condition to condition, and provider to provider; just as most disease states will vary in their evaluation and follow up by different specialists. There are some broad strokes that can be painted here though, to give you a sense of how our providers in different specialties are using telehealth. As previously mentioned, our behavioral health providers on one end of the spectrum utilize telehealth visits for the vast majority of their visits. The conditions encompassed in behavioral health and the patients involved are quite amenable to telehealth visits. Our behavioral health providers have commented on how they have improved access to patients, which results in better treatment of chronic conditions and reduced presentations to higher acuity situations such as the emergency department or inpatient stays.

Our primary care physicians continue to use telehealth but at a lower rate, yet this significantly increased from pre-pandemic, currently around 10% of all monthly visits on average. It must be noted though that this does vary greatly by provider. We have some primary care providers that see well over 50% of their visits via telehealth, while others see less than 1%. Part of the reason around this is comfort with the platform and knowledge of how to use them, along with expected variations in practice patterns.

<table>
<thead>
<tr>
<th>Ohio Association of Community Health Centers</th>
<th>In-person assessments are necessary in emergency situations and when deemed clinically appropriate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ohio Association of Community Health Centers</td>
<td>In-person visits are needed when clinically indicated, other elements indicate the need or when the patient prefers in-person visits.</td>
</tr>
<tr>
<td>OneFifteen</td>
<td>In-person visits are needed when identifying factors suggest the need.</td>
</tr>
</tbody>
</table>

4. **What symptoms should require in-person assessments?**

- OACHC Answer: Emergency or potentially life threatening and when determined clinically necessary within organizations protocols.

13. **What factors lead healthcare providers to advise the patient that an in-person visit is needed?**

- OACHC Answer: Clinically indicated, clinician needs labs or other elements that in-person visit needed or if the patient prefers to see their practitioner in person (may be preferred by racial, ethnic, or cultural populations).

14. **What factors lead healthcare providers to advise the patient that an in-person visit is needed?**

Providers are adept at identifying factors that would suggest the need for an in-person visit, and these signs and symptoms are the same that would prompt us, in person, to pursue a more extensive evaluation -- an abnormal mental status exam, a history that alerts us to a potentially complicated withdrawal syndrome, or a mismatch between what the patient tells us and what we observe of their mental state. Some clinical situations that arise in our patient population include moderate or severe withdrawal from alcohol or sedative/hypnotic agents, co-occurring withdrawal syndromes, methamphetamine-induced psychosis, and reports of physical complaints inconsistent with the reported history. Suspicion of intoxication could prompt our healthcare providers to advise the patient that a urine drug screen is necessary before continued prescription of controlled substances.
The frequency of telemedicine vs. in-person visits and urine drug screening depends on the phase of recovery that an individual is in.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

We believe an annual in-person visit would be a reasonable request for an individual receiving a controlled substance through telemedicine. In order to accommodate scenarios where the telemedicine provider might be located at a geographic distance from the patient, we would recommend that an annual in-person visit could be completed either by the addiction medicine provider directly, or by another healthcare provider so long as there is direct communication between the examining healthcare provider and the prescribing physician. For example, if a patient in a remote rural county receives addiction medicine care, then that individual could be assessed in-person by their primary care physician, provided that there is communication and coordination of care between those two physicians. At OneFifteen, the frequency of telemedicine vs. in-person visits and urine drug screening depends on the phase of recovery that an individual is in. For patients who are prescribed a controlled substance, we request urine drug screens weekly for the first month and then monthly thereafter, unless there is a clinical indication to change this frequency (for example, a return to substance use). We do not require a specific frequency of in-person visits; that decision has been left to the physician’s clinical judgment. Stable patients with SUDs in long-term remission are likely candidates for ongoing telemedicine visits with infrequent in-person visits. Our process of using a tablet for a patient, located onsite, to see a remote physician has been viewed as an acceptable alternative to a face-to-face assessment because onsite nursing staff attain additional objective measures that can be shared with the physician.

In-person visits are dependent on specialty and based on provider determination.

4. What symptoms should require in-person assessments?

It would be dependent on the specialty. Generally speaking, diagnoses that are based on a physical exam are completed via in-person assessment. For example, acute otitis media when no ear drainage is present. If, during the course of a telehealth visit, a provider feels they are unable to accurately diagnose or treat a patient, we would bring them in for an in-person visit.

In-person visits are needed based on clinical appropriateness, need for in-office procedures or testing, patient preference/barriers and when required by regulatory entities.

14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?

- Clinical appropriateness and relevant standards of care
- Need for ancillary in-office procedure or testing
- Patient family barriers and preferences
- The requirements of professional licensing, regulatory, or credentialing boards

In-person visits should occur once per year for patients that maintain an on-going relationship.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?

Yes, we have issued guidance regarding the minimum interval of in-person visitation. Generally, this is once per year for patients with whom we maintain an ongoing care relationship. However, this guidance may be superseded by the standard of care and/or applicable laws and regulations.

Akon Children’s suggests that in-person assessment should be required in the following situations:

- urinary tract infections
- strep throat
- complex cases
- Any life-threatening symptoms - difficulty breathing, chest pains
- Asthma attack - major
- Any number of tingling in extremities
- Anaphylaxis
- Allergic reaction that includes difficulty swallowing, facial swelling or difficulty breathing
- Head injury
- Traumatic injuries
- Unexplained bleeding
- Major burns
- Fever for infants <3 months old

Most practices are including an annual in-person minimum requirement.

4. What symptoms should require in-person assessments?

On-demand telemedicine experience indicates that urinary tract infections, strep throat and complex cases require in-person assessments or testing. Additional symptoms requiring an in-person assessment includes:

a. Any life-threatening symptoms - difficulty breathing, chest pains
b. Asthma attack - major
c. Any numbness or tingling in extremities
d. Anaphylaxis
e. Allergic reaction that includes difficulty swallowing, facial swelling or difficulty breathing
f. Head injury
g. Traumatic injuries
h. Unexplained bleeding
i. Major burns
j. Fever for infants <3 months old
4. What symptoms should require in-person assessments?  
An in-person assessment is needed when a physical exam is required for medical decision making. People experiencing severe abdominal pains, chest pains, shortness of breath, or other emergency situations should also have an in-person visit, whether the same day with their provider or in an urgent care or emergency room setting. Telehealth is not a substitute for an in-person visit, it is a compliment to it. It can serve as a starting point or as a check-in visit between in-person visits. It is a way for patients to stay connected with their health care teams in the convenience of their homes or offices.

OSU Wexner Medical Center  
In person visits are required when a physical exam is necessary for medical decision making. Telehealth is not a substitute for an in-person visit, it is a compliment to it. Telehealth may be used for check-in visits between in-person visits. It is a way for patients to stay connected with their health care providers.

OSU Wexner Medical Center  
Providers determine if an in-person visit is necessary based on the patient’s condition and history.

OSU Wexner Medical Center  
OSUWMC believes that in-person visits should be determined by a provider based on types of care and other variables. They recommend that if the Medical Board sets a requirement for in-person visits, they should be no more than once every two years.

OSU Wexner Medical Center  
OSUWMC recommends that in-person visits should be required for no more than once every two years.

Ohio Health  
In-person visits are based on patient preference, appropriateness relative to standard of care, level of clinical need and after virtual evaluation.

14. What factors lead healthcare providers to advise the patient that an in-person visit is needed?  
Providers escalate care when it appears that the patient’s conditions are changing and a physical exam is needed to change treatment. For new patients, if the history and telehealth exam is insufficient to achieve a treatment plan, then those visits are converted to an in-person visit.

16. Do you have information regarding the right mix of in-person and telemedicine visits? Is your organization requiring an in-person visit at certain intervals, such as once per year or once per two years?  
We believe that there is no need for a specific in-person visit frequency requirement as competent providers will know when to see a patient in-person and require such a visit. We further believe that we should not overregulate good providers to address the small set of providers who might abuse telehealth services. Moreover, the need for in-person visits varies between providers, types of care needs, and other variables. For instance, our palliative care physicians still want to see their patients in-person every 90 days or so (60 days for someone whose care began through a telehealth visit). Setting an arbitrary in-person visit requirement does not account for this variation and will require some patients to attend in-person visits that are not necessary. This in-person visit requirement creates access barriers for those who live far away or lack transportation. It also could increase health and safety risks for patients who are at risk for falls or experience health challenges whenever they leave their homes. For example, a patient with well-controlled chronic disease processes often needs only to be seen annually. As such, a 6-month or even one year requirement prevents making care convenient via telehealth for straightforward conditions such as poison ivy, allergies, etc. However, if the Medical Board feels it needs to set some requirement, we recommend it be no more than once every two years.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see?  
Changes to Medicaid Board rules we would like to see include:  
• Limiting any in-person requirement to no more than every two years, if that;  
• Our office staff screen patients for virtual visit in consultation with the providers in the practice.  
• Participation is based on patient preference, appropriateness relative to the standard of care, prior successful visits, and level of clinical need.  
• Certain patients at high risk for exposure or transmission were directed to virtual visits.  
• Based on the evaluation during the virtual visit, patients may be rescheduled for an in-person visit.

University Hospitals  
UH uses a number of different technologies via regulated software programs in addition to the hardware that is sued. They require that all platforms be HIPAA compliant.

Visits include interactive, real-time communication with both audio and video using UH approved devices.

UH sees benefit in audio-only visits as well to access areas lacking broadband and for patients with limited technological ability. Audio-only visits have been absolutely vital to maintain this connection to patients, often those from disadvantaged communities and vulnerable socioeconomic situations. Expanding the definition of telehealth to include an audio only interaction is very much needed.

9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?  
Our providers use a number of different technologies; however we do closely regulate the software platforms as well as hardware that is used. All platforms are required to be HIPAA compliant and ensure high levels of encryption along with confidential data transfer. This includes interactive, real time communication with both audio and video. We ask providers to use UH approved devices, typically UH laptops or computers with a video monitor and camera. We also want to highlight the benefits of audio-only visits. These types of visits have been vital for certain patient populations who may be technologically illiterate or encounter barriers to access these technologies, including areas where there is a lack of broadband internet. This would include individuals along our East Cleveland locations and rural locations, where there is a clear disparity in digital connectivity and in digital literacy. Audio-only visits have been absolutely vital to maintain this connection to patients, often those from disadvantaged communities and vulnerable socioeconomic situations. Expanding the definition of telehealth to include an audio only interaction is very much needed.
<table>
<thead>
<tr>
<th>Organization</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Ohio Association of Community Health Centers | OACHC has used HIPAA compliant platforms and audio only.                                                                                     | 9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?  
OACHC Answer: HIPAA Compliant platforms (audio video); and audio-only. |
| OneFifteen                          | OneFifteen telemedicine visits include interactive, real-time electronic communication, telephone and text message. They use an internally developed, proprietary telehealth platform that is compliant with HIPAA and 42 CFR Part 2. | 9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?  
We use an internally developed, proprietary telehealth platform that is compliant with HIPAA and 42 CFR Part 2. Our telemedicine visits include interactive, real-time electronic communication. While non-medical clinicians on our team (therapists, case managers, and peer supporters) have offered telephone-based services through the pandemic, we set the expectation in March 2020 that our medical team (physicians, nurse practitioners, and nurses) would use telemedicine with a synchronous audiovisual connection. We also have used text messaging (via SMS text or directly to the OneFifteen Patient App) to communicate asynchronously with patients, but this was not a primary means of communication for the medical team. |
| OHA                                 | SMBO rules should not limit technology or platforms to provide telemedicine. Providers are in the best position to determine what modes are most appropriate based on the specific clinical situation.                        | The state’s telemedicine rules should not limit technology or platforms that can be used by providers. As the landscape of telemedicine continues to evolve, there are many options for types of technology and platforms that can be utilized by patients and providers. Providers are in the best position to determine what modes are most appropriate based on the specific clinical situation. |
| OHA                                 | Both audio and video visits can be useful and increase patient access to care.                                                                   | Both video and audio-only visits can be useful and appropriate ways of delivering care. Providers effectively use both video and audio formats for delivering care virtually, depending on the clinical specialty of the provider and clinical needs of the patient. Any changes to the state’s telemedicine rules should reflect that both modalities can be useful and appropriate. For example, audio-only appointments have proven to be very effective for patients receiving mental health services and providers have cited increased patient uptake and satisfaction at being able to have a phone call with their provider to receive care. Further, for many vulnerable and hard-to-reach populations, audio visits can dramatically increase access to care because, for example, they may not have video technology on their phone, or their access to broadband connections may be limited. |
| OHA                                 | Both synchronous and asynchronous technologies can be useful tools and increase patient access to care.                                              | Both synchronous and asynchronous technologies can be useful and appropriate ways of delivering care. Providers effectively use both synchronous and asynchronous formats for delivering care virtually. Any changes to the state’s telemedicine rules should reflect that both modalities can be useful and appropriate. While many providers encourage more traditional synchronous visits, there are situations in which asynchronous care can be useful. For example, in many dermatological cases, reviewing a high-resolution photo may provide more utility than an examination via video. Another benefit of asynchronous care is helping to expand capacity in light of staffing shortages currently being experienced by providers. |
| Nationwide Children’s Hospital       | Nationwide Children’s is using synchronous video telehealth via a patient portal. When there is a technology fail, phone or in-person methods are used.                                                      | 9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?  
We are leveraging our patient portal to conduct synchronous video telehealth. Patients log in to their personal health portal (MyChart) and conduct the video visit via secure video session (Zoom). If there is a technology issue (e.g., patient’s internet fails), we may resort to phone or convert to an in-person visit. |
| Bon Secours - Mercy Health           | BSMH requests that rules be clarified that allow a physician-patient relationship to be established via telemedicine using appropriate technology to meet the standard of care.          | 1. Physician Patient Relationship Establishment  
ORC Ann. 4731.74 requires the Medical Board to permit the establishment of a physician-patient relationship using appropriate technology consistent with an in-person standard of care associated with prescribing drugs that are not controlled substances.  
The Ohio statutes and Board rules do not state whether establishing a physician-patient relationship via appropriate technology consistent with an in-person standard of care is permitted in other situations (e.g., diagnosing and treating).  
BSMH requests that the Medical Board clarify within their rules that a physician-patient relationship may be established using appropriate technology consistent with an in-person standard of care without limitation. |
| Akron Children’s Hospital            | Telehealth visits are interactive, real-time with both audio and video using HIPAA compliant patient portal.                                          | 9. What types of technology are your healthcare providers using? Do you use interactive, real-time electronic communication comprised of both audio and video elements?  
Telehealth visits are interactive, real-time with both audio and video using Epic MyChart integrated with VidsyConnect secure HIPAA compliant platform. For patients being seen in one of our clinic locations, the telemedicine equipment has a high definition camera with tilt, pan, zoom capability to facilitate better visualization during the exam and visit. In addition, TytoCare devices have been added to the telehealth carts and in school-based health clinics. This peripheral device allows the provider to examine the patient’s heart and lungs sounds, obtain a temperature, and visualize the ears, eyes, throat, and skin.  
Quick Care Online is our on-demand program utilized for common minor complaints. This program utilizes the Teladoc secure platform. Patients access this via the web or download an app to connect. |
OSU Wexner Medical Center

OSUWMC prefers interactive, real-time technology with audio and video but also believes that audio only calls should remain as an option.

9. What types of technology are your healthcare providers using? Do you use interactive, real time electronic communication comprised of both audio and video elements?

Our preference is to use interactive, real time electronic audio with video communication with our patients. We primarily use Updox as our telehealth vehicle. However, it is critically important that we be allowed to use audio-only calls as there are multiple reasons why an audio and visual visit cannot always happen. We believe that audio-only should be allowed for all provider and service types and not solely behavioral health.

OSUWMC's older and lower-income patients are more likely to use audio-only communication. Many people who are elderly and those from disadvantaged backgrounds often do not have access to reliable Wi-Fi, and audio-only visits are all they can do. Sometimes a visit starts as a two-way interaction, and connection challenges result in it becoming an audio-only visit. Other times, a patient lacks the comfort and the capacity to engage in a two-way interaction, and can only manage audio visits. Finally, some patients lack the resources to access two-way interactive visits but can manage an audio-only visit. Many patients who face transportation challenges will forgo care if audio-only is not an option.

Of the patients we see through telehealth, around 20% of the visits have been audio-only, before the recent COVID surge. This percent is highest for those over 65 at 36.9% in June 2021, compared to 22.6% for people ages 60 to 64, 12.4% for those 17 to 39, and 9.4% for those less than 17. Audio-only visits are also higher for our patients on Medicaid (24.8%) and on Medicare (30.9%) compared to our patients with commercial coverage (13.8%)

In July 2021, as the COVID surge took off, the percent that was audio-only jumped for those over 65 to 46.7%. The audio-only visits jumped to 35.6% for Medicaid and 41.9% for Medicare. It also increased for the commercially-covered population to 26.0%.

Ohio Health

Ohio Health prefers video visits and, when necessary, visits via asynchronous means (due to internet and other connectivity limitations) to continue for initial and ongoing care when appropriate.

19. What types of changes in the Medical Board’s rules related to telemedicine or in-person visit requirements would you like to see? Changes to Medicaid Board rules we would like to see include:

• Allowing providers to engage in audio-only visits when two-way interactive audio and visual capacity is not viable.

13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

We have not found this to be the case. In fact, many of our primary care providers have commented on how telemedicine actually improves the progress they can make when caring for patients with chronic conditions. One of the single biggest factors in prevention of chronic condition related morbidity is reliable and consistent access with a health care provider. Telehealth has improved things in this respect when compared to in-person visits.

University Hospitals

No perceived negatives.

13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

To our knowledge, we have not seen any negative outcomes due to the use of telemedicine. Our hybrid model of care has allowed patients to receive care remotely while also, when appropriate, receiving care in person. Patients who did not wish to use telemedicine were able to receive services onsite, and physicians who were concerned about a patient’s condition could request that the patient present for an in-person visit.

As we took forward to building out more remote models of care -- for example, through our Rural TeleHub program -- we intend to maintain a “hybrid” care model, in which patients will continue to have a healthcare location identified where they can access in-person care when indicated. In this model, however, the in-person provider would not be the same individual as the addiction medicine provider; instead, this model is predicated on collaboration between local healthcare providers and remote addiction medicine physicians. We believe this model holds the promise of being able to address workforce development issues in behavioral healthcare and to deliver SUD care in regions with limited access to this care.

OneFifteen

No perceived negatives.

13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?

To our knowledge, we have not seen any negative outcomes due to the use of telemedicine. Our hybrid model of care has allowed patients to receive care remotely while also, when appropriate, receiving care in person. Patients who did not wish to use telemedicine were able to receive services onsite, and physicians who were concerned about a patient’s condition could request that the patient present for an in-person visit.
13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
We do not have population-level data on clinical outcomes at this time. Anecdotally, you can find examples on both sides. For example, with therapies, some children do better with telehealth (e.g., discussing anxiety-related issues from the comfort of home) and some children do better with in-person care (e.g., toddler unable to focus for duration of speech therapy session on an iPad).

13. Have you seen any negative outcomes due to the use of telemedicine, such as loss of progress on chronic conditions?
This is not worked well in the situations where a detailed physical exam is key to the medical decision-making process or other lab studies or radiology studies are important for care. In situations where vital signs are necessary, there are some mechanisms for home evaluation and obtaining these metrics but in many cases, this is not the case, which again makes medical decision making a challenge for providers. The situations best suited to telehealth are largely those that derive from the conversational and educational aspect of care which is a significant portion of interaction between provider and patient in many cases.

5. Have your healthcare providers initiated care for new patients through telemedicine? What are some examples where this has worked well? What are some examples where this has not worked well?
Yes, we have initiated care for new patients through telemedicine. We have found that this can work well in a range of circumstances and disciplines, and especially for behavioral health and addiction concerns.
We are not aware of any circumstances where telehealth did not work well with the exception of when IT glitches would occur. There is always a learning process with the biggest thing being getting the right people/symptoms scheduled for a telehealth visit. For example, it does not make sense to schedule somebody with new onset chest pain for a telehealth visit.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nationwide Children’s Hospital</td>
<td>No data but anecdotal evidence of positive and negative outcomes. Depending on the patient/condition.</td>
</tr>
<tr>
<td>Akron Children’s Hospital</td>
<td>Telemedicine has not worked well where detailed physical exam is required to make a diagnosis, labs are needed, or radiological studies are needed.</td>
</tr>
<tr>
<td>Akron Children’s Hospital</td>
<td>No reported negatives.</td>
</tr>
<tr>
<td>OSU Wexner Medical Center</td>
<td>Only perceived negatives were technology related.</td>
</tr>
</tbody>
</table>

**Topic: Stakeholder Perceived Positives**

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Hospitals</td>
<td>UH has seen a drastic change in volume and is now seeing tens of thousands of patients per month via telehealth.</td>
</tr>
<tr>
<td>University Hospitals</td>
<td>85% of psychiatry and behavioral health visits are currently being conducted virtually. They have seen a reduction in no-show rates of about 50%</td>
</tr>
<tr>
<td>Ohio Association of Community Health Centers</td>
<td>OACHC has seen increased access and improved continuity of care with the increased utilization of telemedicine.</td>
</tr>
</tbody>
</table>

1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?
Our healthcare providers engaged in over 400K telehealth visits in 2020 alone. These types of visits included direct-to-patient, outpatient, emergency department, inpatient, along with asynchronous visits and virtual “check-ins.” The biggest difference noted here is the drastic change in volume. In all of 2019, our enterprise conducted just over 11,000 visits, the majority of these were through a very small subset of providers via our urgent care platform. Today, nearly all of our providers have conducted at least one virtual visit, and many have adopted it as part of their standard clinic setup. Additionally, now we see tens of thousands of patients per month via telehealth, and our providers have become more facile and accustomed to the virtual environment.

2. Which practice groups or specialty types have utilized telemedicine the most? Please describe the types of patient encounters where telemedicine has been used.
Both psychiatry and behavioral health have utilized telehealth by far the most, with 85% of their current visits virtual at this time (the vast majority are video). Psychiatry has done initial and follow-up visits, counseling, psychiatry, group, and individual visits all by virtual means. As well, primary care and our family practice groups have continued to use telehealth at high levels, with some providers still seeing upward of 50% through the telehealth tool.

Providers find there are a broad range of patients and conditions that can be effectively managed via telehealth. These can include acute new patient visits for simple things like a sinus infection or urinary tract infection; as well as more complex chronic conditions such as heart failure, cystic fibrosis, and sickle cell patients that require regular checkups and medication maintenance regimens. Telehealth has improved continuity of care and access to care as we have seen a reduction in patient no-show rates by about 50%, when compared to in-person visits.

1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?
"OACHC Answer: Increased utilization across the board, key in maintaining contact with patients and improved continuity of care. It has increased access for high-risk patients too and has been used medically and in behavioral health settings extensively. In addition to supporting increased access to timely care for our underserved populations, Health Centers are also using these tools to overcome persistent clinical workforce shortages, decrease of "no-show" rates, maintaining provider-patient relationships and easing of language barriers."

15
1. How have the healthcare providers in your organization utilized telemedicine during the pandemic? What has been different?

At the onset of the pandemic, our team of providers used telehealth to reach patients that could not otherwise be seen in person. Providers gained significant experience with telehealth across specialties and conditions. This experience helped us learn a great deal about the abilities and limitations of telehealth in caring for our pediatric patients. From these learnings, we have refined our use of telehealth. We have found telehealth may be useful, on a case-by-case basis, in the following areas:

- Behavioral health and clinical therapies
- Management of chronic conditions when combined with regular in-person care
- Medically fragile and immunocompromised patients (reduce exposure and stress of travel)

** Nationally, Children’s Hospital Nationwide has found that telemedicine may be useful in behavioral health, management of chronic condition in addition to regular in-person care and for patients that are medically fragile or immunocompromised.

** Bon Secours - Mercy Health

BSMH has increased access to patients and completed more than 1,000,000 virtual visits between April 2020 and March 2021.

Bon Secours Mercy Health (BSMH), operating as Mercy Health in Ohio, has pivoted quickly to expand telehealth services during the COVID-19 pandemic to improve access to high quality care for patients across Ohio. In the 12 months from April 2020 to March 2021, BSMH completed more than 1,000,000 virtual provider visits across all markets, and adoption remains high with BSMH performing approximately 30,000 virtual provider visits monthly. In addition, BSMH was able to leverage telehealth in the inpatient setting throughout the pandemic by allowing for physicians and nurses to visualize the patient from outside of the room, both minimizing the exposure risk for our clinicians and conserving scarce personal protective equipment (PPE).

** OSU Wexner Medical Center

OSUWMC has been able to expand and increase healthcare access through telemedicine to patients in rural areas, seniors and low income families. The use of telemedicine has also improved the no-show rate.

OSUWMC has been able to expand and increase healthcare access through telemedicine to patients in rural areas, seniors and low income families. The use of telemedicine has also improved the no-show rate.

Telehealth has changed the healthcare landscape. It has broken down the geographic barriers for access. Telehealth eliminates the barrier of transportation that keeps up to 3.6 million people from obtaining health care each year. As a result, our volume of telehealth visits has expanded exponentially, increasing from 70 video and 152 telephone visits in February 2020 to 12,571 video and 6,260 telephone visits in July 2021. Our monthly telehealth visit average has decreased throughout the pandemic and is around 23,000 a month, down from a high of 60,962 telehealth visits in April 2020, with a peak of 2,898 visit per day in May 2020 and around 1,020 per day currently.

Unlike most Ohio hospital systems, we have patients who live in all 88 of Ohio’s counties, including a large number from Ohio's Appalachian counties. In addition, The Ohio State University Wexner Medical Center (OSUWMC) has an extensive Medicare and Medicaid patient population. Telehealth has improved access for those patients who live outside of Central Ohio, along with our senior and low-income families in Central Ohio. With the elimination of transportation barriers, especially for our Medicaid population, we have seen a significant decrease in the no-show rate.

* Comments were also received from Premier Health, Metro Health and the Ohio Osteopathic Association
MEMORANDUM

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

FROM:     Kimberly C. Anderson, Chief Legal Counsel

RE:       Consultation on Board of Pharmacy Rules for Pharmacists Dispensing Nicotine Replacement

DATE:     September 30, 2021

Section 4729.284 of the Revised Code, effective September 30, 2021, allows pharmacists to dispense nicotine replacement therapy if the pharmacist successfully completes a course on nicotine replacement therapy and practices in accordance with a protocol developed by an Ohio licensed physician. The Board of Pharmacy is authorized to promulgate rules provided that it consults with the State Medical Board and The Ohio Department of Health prior to adopting the rules.

Attached you will find proposed rule 4729:1-3-07, which has been filed with the Common Sense Initiative. Any comments from the Medical Board are due no later than October 22, 2021. I have reviewed the statute and proposed rules and do not have any concerns.

Requested Action: Determine whether there are comments or questions to be shared with the Ohio Board of Pharmacy.
The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rule.

**New:**

- 4729:1-3-07 - Provides the standards for dispensing nicotine replacement therapy by pharmacists as authorized by HB 110 (134th General Assembly) – ORC 4729.284

Comments on the proposed rule will be accepted until close of business on October 7, 2021. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov
## Business Impact Analysis

<table>
<thead>
<tr>
<th>Agency, Board, or Commission Name: State of Ohio Board of Pharmacy</th>
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<tbody>
<tr>
<td>Rule Contact Name and Contact Information: Cameron McNamee <a href="mailto:Cameron.mcnamee@pharmacy.ohio.gov">Cameron.mcnamee@pharmacy.ohio.gov</a></td>
</tr>
<tr>
<td>Regulation/Package Title (a general description of the rules’ substantive content):</td>
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<tr>
<td>Dispensing nicotine replacement therapy by pharmacists</td>
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<tr>
<td>Rule Number(s): 4729:1-3-07</td>
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<tr>
<td>Date of Submission for CSI Review: 9/23/21</td>
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<td>Public Comment Period End Date: 10/7/21</td>
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<th>Rule Type/Number of Rules:</th>
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The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness,
predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

**Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

a. ☐ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.

b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
   - Violation of this rule may result in administrative licensure discipline for licensee. Discipline might include reprimand, continuing education, suspension of a license, denial of a license, monetary fine and/or revocation of a license.

c. ☒ Requires specific expenditures or the report of information as a condition of compliance.
   - Requires notification of patient’s primary care provider, if known (note: this is also a requirement of the statute).

d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

**Regulatory Intent**

2. Please briefly describe the draft regulation in plain language.  
   *Please include the key provisions of the regulation as well as any proposed amendments.*
New:

- 4729:1-3-07 - Provides the standards for dispensing nicotine replacement therapy by pharmacists as authorized by HB 110 (134th General Assembly) – ORC 4729.284

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rule is authorized by sections 4729.26, and 4729.284 of the Ohio Revised Code.

4. Does the regulation implement a federal requirement?  Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?
   *If yes, please briefly explain the source and substance of the federal requirement.*

No.

5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

This rule package exceeds federal requirements as this rule is required by ORC 4729.284.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the distribution of dangerous drugs and the practice of pharmacy.

Section 4729.284 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules to implement nicotine replacement therapy dispensing by pharmacists via physician protocol.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of the regulations will be measured by having the rule written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

**Development of the Regulation**

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

   *If applicable, please include the date and medium by which the stakeholders were initially contacted.*

   This rule package was sent to the Ohio Department of Health’s Tobacco Use Prevention and Cessation Program for initial review.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

   Comments from the Ohio Department of Health that were incorporated into the rule include:
   
   - Clarifies that nicotine replacement therapy can be dispensed for e-cigarette use.
   - Added details to follow-up care plan requirements recommended by ODH.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

   Scientific data was not used to develop or review this rule.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives?

   As the regulations are essential to protecting the public’s safety by ensuring uniform standards for dispensing nicotine replacement therapy by pharmacists, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. Did the Agency specifically consider a performance-based regulation? Please explain.

   *Performance-based regulations define the required outcome, but don’t dictate the process the regulated stakeholders must use to achieve compliance.*
The agency did not consider a performance-based regulation for this rule package. It is the Board’s responsibility to ensure uniform pharmacist practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to a performance-based regulations.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy’s Director of Policy and Communications reviewed the proposed rule to ensure that the regulation does not duplicate another State of Ohio Board of Pharmacy regulation.

15. Please describe the Agency’s plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rule will be posted on the Board of Pharmacy’s web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rule package. In addition, the Board’s compliance staff are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, regular field staff meetings featuring a regulatory update, mandatory law reviews for new employees, email updates, webinars from the Director of Policy and Communications and feedback from the Board’s legal department for every citation submitted.

**Adverse Impact to Business**

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:
   a. Identify the scope of the impacted business community; and
   b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance); and
   c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

New:

- 4729:1-3-07 - Provides the standards for dispensing nicotine replacement therapy by pharmacists as authorized by HB 110 (134th General Assembly) – ORC 4729.284. A pharmacy may experience increased administrative costs to develop and implement a physician authorized protocol and follow-up care plan. Pharmacists may also experience increased demands to meet the training requirements, the requirements of the protocol, and provide notice to a patient’s primary care provider (NOTE: These requirements are mandated by the statute).

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for pharmacist dispensing nicotine replacement therapy in accordance with the provisions of ORC 4729.284.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

This rule package does not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?
Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.
OAC 4729:1-3-07 – Dispensing nicotine replacement therapy by pharmacists. (NEW)

(A) As used in this rule, "nicotine replacement therapy" means a drug, including a dangerous drug, that delivers small doses of nicotine to an individual for the purpose of aiding in tobacco cessation or smoking cessation including for the cessation of alternative nicotine delivery systems, such as e-cigarettes.

(B) A pharmacist may dispense nicotine replacement therapy to individuals who are eighteen years old or older and seeking to quit using tobacco-containing products in accordance with paragraph (C) of this rule.

(C) For a pharmacist to be authorized to dispense nicotine replacement therapy under this rule, the pharmacist shall do both of the following:

1. Successfully complete a course on nicotine replacement therapy that is taught by a provider that is accredited by the accreditation council for pharmacy education, or another provider approved by the state board of pharmacy, and that meets requirements established in paragraph (H) of this rule; and

2. Practice in accordance with a physician-authorized protocol that meets the requirements of paragraph (D) of this rule.

(D) All of the following apply with respect to the protocol required by this rule:

1. The protocol shall be established by a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

2. The protocol shall specify a definitive set of treatment guidelines and the locations at which a pharmacist may dispense nicotine replacement therapy under this rule.

3. The protocol shall specify the types of nicotine replacement therapy that may be dispensed.

4. The protocol shall include provisions for implementation of the following requirements:

   a. Use by the pharmacist of a screening procedure, recommended by the United States centers for disease control and prevention or another organization approved by the board, to determine if an individual is a good candidate to receive nicotine replacement therapy dispensed as authorized by this rule;

   b. A requirement that the pharmacist refer high-risk individuals or individuals with contraindications to a primary care provider or, as appropriate, to another type of provider;

   c. A requirement that the pharmacist develop and implement a follow-up care plan in accordance with paragraph (D)(5) of this rule, including a recommendation by the pharmacist that the individual seek
additional assistance with behavior change, including assistance from the Ohio tobacco quit line made available by the department of health.

(5) A follow-up care plan shall include all the following:

(a) A recommendation that the individual notify their provider that they have initiated a quit attempt;

(b) A plan to deal with the psychological aspects of tobacco addiction, including information regarding how to seek services from the Ohio Tobacco Quit Line;

(c) A plan for how to deal with possible side effects;

(d) Instructions regarding how, when, and how many times to refill the medication;

(e) Instructions regarding how, when, and how many times to refill the medication;

(f) Follow-up with patient within fourteen days of initiation of the nicotine replacement therapy;

(g) How and when to stop using nicotine replacement therapy;

(h) Instructions to seek assistance from the pharmacist or provider before continuing to use the medication if a relapse occurs and tobacco use is reinitiated;

(i) If a patient returns to the pharmacy to report a relapse, the follow-up care plan should include efforts to identify smoking cues and triggers and decide upon alternative coping strategies before a follow-up attempt to quit tobacco.

(6) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(a) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(b) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector, or employee of the state board of pharmacy.

(E)

(1) Documentation related to screening, dispensing, and follow-up care plans shall be maintained in the records of the terminal distributor of dangerous drugs where the pharmacist practices for at least three
years. Dispensing of nicotine replacement therapy may be documented on a prescription form, and the form may be assigned a number for recordkeeping purposes.

(2) Not later than seventy-two hours after a screening is conducted under this rule, the pharmacist shall provide notice to the individual's primary care provider, if known, or to the individual if the primary care provider is unknown. The notice shall include results of the screening, and if applicable, the dispensing record and follow-up care plan. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(3) A copy of the documentation identified in paragraph (E)(1) of this rule shall also be provided to the individual or the individual's primary care provider on request.

(F) This rule does not affect the authority of a pharmacist to do any of the following:

(1) Fill or refill prescriptions for nicotine replacement therapy;

(2) Sell nicotine replacement therapy that does not require a prescription.

(G) A provider who is not accredited by the accreditation council for pharmacy education may petition the board for approval of a course in accordance with division (C) of section 4729.284 of the Revised Code. The board shall develop and post a petition application on its website providing the criteria for approval.

(H) No pharmacist shall do either of the following:

(1) Dispense nicotine replacement therapy in accordance with a protocol unless the requirements of paragraph (C) of this rule have been met;
(2) Delegate to any person the pharmacist's authority to engage in or supervise the dispensing of nicotine replacement therapy.

(I) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense nicotine replacement therapy pursuant to this rule have completed the requirements set forth in paragraph (C) of this rule.

(J) A terminal distributor of dangerous drugs dispensing nicotine replacement therapy in accordance with this rule shall also comply with the record keeping provisions of the applicable chapters of the Administrative Code: 4729:5-5, 4729:5-8, or 4729:5-9.
Memorandum

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

From: Kimberly C. Anderson, Chief Legal Counsel

Re: Podiatric Scope of Practice

Date: October 6, 2021

For purposes of research for the rule-making process, Jill Reardon and I have reached out to hospitals to determine how they credential the two procedures at issue, supramalleolar osteotomy of the tibia and fibula and harvest of bone marrow aspirate from the proximal tibia.

We had a discussion with Craig Frey, DPM, System Director of Podiatric Medicine and Surgery for University Hospitals in Cleveland. Dr. Frey provided a letter outlining his statements and several articles, which are attached for your review. Podiatrists with appropriate education and training are credentialed to perform these procedures at University Hospitals and Dr. Frey’s letter provides a lot of detail.

Ohio Health also provided information regarding the credentialing of podiatrists to perform the two procedures. Ohio Health indicates that the majority of its hospitals credential podiatrists to perform supramalleolar osteotomy of the tibia or fibula to correct a deformity and that some of its hospitals credential podiatrists to perform the harvest of bone marrow aspirate from the proximal tibia for foot or ankle surgery.

Jill and I have a virtual meeting scheduled with representatives of the Cleveland Clinic on October 28, 2021.

Requested Action: No action requested.
13 September, 2021

Dear Ohio Medical Board:

I am writing this letter in response to the two items of discussion in regards to Podiatric scope of practice in the State of Ohio.

**Topic A**: Harvest of bone marrow aspirate from the proximal tibia.

**Topic B**: Ability to perform a supramalleolar osteotomy for correction of pathology related to the foot/ankle

Topic A: As this topic is best addressed from a scientific standpoint, please see attached evidence based medicine documentation in support of harvesting bone marrow aspirate from the proximal tibia as both a safe and optimal procedure for foot and ankle procedures. Of note, this procedure is done in conjunction with a procedure related to the foot and ankle, it is not an “isolated” procedure.

Harvesting of bone marrow aspirate is essential for many foot and ankle procedures. This procedure is often used to augment an arthrodesis (fusion) of a joint within the foot and ankle. Though we do have the capability to harvest bone marrow aspirate from the calcaneus, there is both a scientific and practical approach in favor of the tibia over the calcaneus in many instances. In brief, the tibia has more viable osteoprogenitor cells, easier access through less soft tissue, less vacuum pressure induced lysis of cells, and no more complications than other harvesting sites in the body. The practical approach for justification of proximal tibial harvesting is that many of these patients may have comorbidities of diabetes, peripheral vascular disease, venous insufficiency, etc. It is known that tissue closer to the core of the body as opposed to the far periphery of the lower extremity, will offer a larger quantity and quality of viable tissue. Furthermore, when performing certain fusions like a subtalar fusion, calcaneocuboid fusion, tibiotalar-calcaneal fusion, violating and compromising the calcaneus to harvest bone marrow aspirate will de-vascularize a bone that we are attempting to fuse, which would be contrary to basic principles of arthrodesis and jeopardize patient safety and outcomes.

There were concerns of a podiatrist’s ability to handle complications that occur from this procedure. As noted, this procedure is very safe with no increase in complications from other harvesting sites. In fact there are noted less complications than the iliac crest. Podiatrists are trained and qualified to use external fixation using wires and half pins (much larger than a bone
marrow aspirate trochar) in the tibia. Podiatrists are more than capable to handle complications arising from this procedure that fall under their scope of practice. Any complication that does not fall under podiatric scope of practice, would require consultation with a separate specialist. This is no different than the numerous patients that orthopedic surgeons that treat trauma and/or perform reconstruction that develop post op soft tissue complications that they refer to podiatry and/or plastic surgery for assistance. There is no surgical procedure that is performed by a surgeon that does not have the potential to yield a complication that may fall out of the scope of practice of that surgeon and would require consultation. All this being said, as noted, this procedure is listed as very safe with very little risk of complications.

Topic B: I believe there is a universal confusion as to the purpose and need for this procedure to be performed by podiatry. This is done for correction of foot and ankle pathology and is done in conjunction with other procedures. A common example of the need for this procedure is a patient with ankle varus or valgus undergoing an ankle fusion or tibiotalar-calcaneal fusion. In order to obtain the appropriate alignment for the fusion, a supramalleolar osteotomy may be necessary, which is done just above the malleoli. The exact location at which this osteotomy is done is based off a measurement known as CORA (center of rotation of angulation). This is taught in depth in school and residency. If this CORA measurement is determined to be more proximal, beyond a “supra-malleolar” osteotomy, then it would fall out of the scope of podiatry. Perhaps, further defining what level a supra-malleolar osteotomy may be performed by podiatry would be helpful.

Concerns about adequate training of the lower extremity are simply inaccurate as our education and training is not isolated to the foot and ankle. Podiatric medical students spend their first 2 years covering the same topics/courses as traditional DO and MD medical schools. In fact, numerous podiatry school programs are placed in the same courses with the DO or MD medical students at their respective university. Furthermore, there is further dedication to the lower extremity from year 3 in school throughout residency. Our residents, as well as the vast majority of other residency programs, rotate with orthopedic surgery and cover and perform procedures or the foot and ankle, as well as proximal to the foot and ankle. The residents must pass this rotation for graduation, therefore our orthopedic colleagues are confirming these residents are capable of performing these procedures, which is in great contrast to the suggestions that podiatry is not appropriate trained to operate on these specific pathologies.

In certain patients with complex comorbidities (such as charcot foot/ankle), orthopedic surgeons often refer to treatment of these patients. Preventing podiatry from performing this procedure would severely compromise quality of care as well as access for these patients. Charcot deformity in itself is a major precursor to amputation. The number one cause (by a large amount) of charcot is preceded by diabetes. Should a patient go on to an amputation, they statistically have a 5 year survival rate of about 50%, which is well documented in the literature. Again, eliminating this procedure will have a large and devastating impact on patient care and access.
Additionally, certain procedures require a supramalleolar osteotomy in order to perform appropriately by surgical technique. Two of these common procedures are repair of an osteochondral defect (OCD) of the posterior or central medial talar dome as well as a specific total ankle replacement device. In order to effectively access a cartilaginous defect via an open procedure a medial supramalleolar osteotomy must be done. For certain ankle implants, specifically the Zimmer Total Ankle implant, a lateral approach with a supramalleolar fibular osteotomy is required per manufacturer protocol/technique. As podiatry has the privileges to perform both of these aforementioned procedures within the Ohio State law, eliminating supramalleolar osteotomies would require the surgeon to alter their treatment of this patient to a potentially less effective technique, system, or implant that would absolutely compromise patient care.

If you have any additional questions or require further explanation, please do not hesitate to contact me directly with any questions. Thank you for your time and consideration of this matter.

Craig B. Frey DPM, AACFAS

*University Hospitals Health System Podiatric Medicine and Surgery, System Director*

*University Hospitals Advanced Limb Salvage and Reconstruction, Fellowship Director*

*University Hospitals Podiatric Medicine and Surgery, Residency Director*

*Foot & Ankle Associates of Cleveland, Owner and Foot and Ankle Physician/Surgeon*

*Kent State University, Adjunct Professor and Clinical/Surgical Faculty*

33790 Bainbridge Rd. Suite#201

Solon, OH 44139

(P) 440-903-1041

(F) 440-600-2327
BMA from Tibia vs. Calcaneus:

The surgical use of bone marrow aspirate (BMA) is a common practice for many podiatric surgeons as a tool to improve outcomes in what are often high-risk procedures in a high risk population. Podiatric procedures often have higher risk of incomplete fusion and soft tissue graft integration due to lifestyle and health issues such as diabetes and CVD, smoking, high BMI and non-compliance.

As of now, Podiatric Surgeons in Ohio have the capability of aspirating bone marrow from the tibia or the calcaneus. Ensuring that this option remains as a means to accessing the best quality BMA in terms of concentrations of viable cells, growth factors and signaling proteins while mindfully controlling for risk reduction is vital to best medical practice for these surgeons. Tibial aspirations provide many benefits over the calcaneus including:

- **Ease of Aspiration:**
  - Simple access to a quality BMA via an unloaded tissue bed proximal to the compromised area
  - Easier Aspiration in a less sensitive region and access to higher volumes reducing cellular stress during aspiration i.e. less potential for lysis of cells
  - Less clotting (due to easier aspiration and less fat content) leading to greater preservation of platelets and their respective growth factors

- **Less Pain/Morbidity for Patients:**
  - Data that shows BM aspiration from all sites is safe with little to no morbidity associated
  - Data that shows BM aspiration from the tibia is less painful for the patient

- **Better BMA Quality:**
  - Data that shows BM aspirate from the tibia has higher concentrations of progenitor cells with more differentiation potential than that of the calcaneus
  - Data that shows higher numbers of Progenitor Cells are better for healing

**Summary of Data:**

1) **Tibial aspiration is less painful than calcaneal aspiration.**
   a. VAS scores significantly lower in Tibia vs Calcaneus in 40 patients with multiple site aspirations from the Anterior Iliac Crest (AIC), Distal Tibia (DT) and Calcaneus (CALC). No significant difference between the Tibia and Iliac Crest.
      - Daigre, et al. 2015 in F&A Specialists: Assessment of BMA Site Pain in Foot and Ankle Surgery.

2) **Tibial aspirate is better quality than calcaneal aspirate.**
   a. The following studies all support the notion that BMA done more proximally to the center core of the body produces higher volumes of bone marrow, greater numbers of progenitor cells, higher self-renewal, and greater osteogenic differentiation potential.
      - Hyer, et al. 2013, JBJS. *Quantitative Assessment of the Yield of Osteoblastic Connective Tissue Progenitors in Bone Marrow from the Iliac Crest, Tibia and Calcaneus.*
      - Marx, et al 2011, Oral & Craniofacial Tis Eng. *A Qualitative and Quantitative Analysis of Autologous Human Multipotent Adult Stem Cells Derived from Three Anatomic Areas by Bone Marrow Aspiration: Tibia, Anterior Ilium, Posterior Ilium.*
      - Narbona-Carceles et al. 2014, Injury, Int. J. Care Injured. *Bone Marrow MSC aspirates from alternate sources: is the knee as good as the IC?*

3) **Higher concentrations of Progenitor Cells in BMA leads to higher rates of healing.**


4) Safety of Bone Marrow Aspiration from multiple sites.

a. The two publications support the very low complication rates of bone marrow aspiration in general as well as in lower extremity procedures (performed by DPMs, MDs & DOs). Roukis et al. reported no complications in 548 lower extremity aspirations including the tibia. Hernigou et al showed a complication risk of only 3% (16 in 523) of aspirations from the iliac crest, a site with inherently more potential for complication than the tibia. Together these papers support the minimal invasiveness and low risk nature of bone marrow aspiration.


Complications Associated with Autogenous Bone Marrow Aspirate Harvest from the Lower Extremity: An Observational Cohort Study

Thomas S. Roukis, DPM, PhD, FACFAS,1 Christopher F. Hyer, DPM, FACFAS,2 Terrance M. Philbin, DO,3 Gregory C. Berlet, MD,4 and Thomas H. Lee, MD5

The purpose of this article is to report the complications associated with autogenous bone marrow aspirate harvested from the lower extremity (i.e., tibia and/or calcaneus) for soft tissue and/or osseous healing augmentation. This is a multi-site, multisurgeon, observational cohort study involving retrospective review of prospectively collected data of 548 autogenous bone marrow aspirate harvests from the lower extremity of 350 consecutive patients between August 2000 and March 2009. Each patient underwent autogenous bone marrow aspirate harvest from the proximal medial tibial metaphysis, distal medial tibial metaphysis, distal tibia, lateral calcaneus, medial calcaneus, or a combination of both the proximal tibial metaphysis and lateral calcaneus for application to split-thickness skin graft application sites or for mixture with allogeneic bone graft material for osseous defects or arthrodesis. Patients were kept non-weight bearing based on the index procedure and followed until clinical healing occurred or failure was declared. There were 324 female and 206 male patients with a mean age of 54.7 ± 14.1 years (range: 14 to 84 years). There were 276 left feet/ankles and 272 right feet/ankles undergoing operative interventions with 18 harvests occurring from the proximal medial tibial metaphysis, 183 from the distal medial tibial metaphysis, 11 from the tibial malleolus, 325 from the lateral calcaneus, 3 from the medial calcaneus, and 6 from both the proximal tibial metaphysis and lateral calcaneus. All procedures were deemed successful with no nerve-related injury, infection, wound-healing complications, or iatrogenic fracture occurring. When properly performed, autogenous bone marrow aspirate harvest from various locations about the lower extremity as described here represent safe and minimally invasive techniques useful for soft tissue and osseous healing augmentation. Level of Evidence: 4 (Case Series; Therapeutic Study) (The Journal of Foot & Ankle Surgery 48(6):668-671, 2009)

Key Words: bone healing, platelet-rich plasma, skin graft, foot and ankle surgery, wound.

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Autogenous bone marrow aspirate is a useful adjuvant to enhance soft tissue and osseous healing because it contains hematopoietic cells that differentiate into red and white blood cells, platelets, and macrophages, and mesenchymal cells. Mesenchymal cells are multipotent and can evolve into several cell types involved in tissue repair depending on the environment they are transferred to and include osteoblasts, chondrocytes, fibroblasts, and myogenic cells (1-4). Bone marrow is also the primary source of mesenchymal cells (1-4). Harvest of autogenous bone marrow aspirate can be performed rapidly, is simple to perform, easily reproduced, and is associated with low financial cost (5, 6). However, the safety of autogenous bone marrow aspirate harvest from the lower extremity has not been studied. Therefore, the purpose of this study was to report the complications associated with autogenous bone marrow aspirate harvested from the ipsilateral lower extremity (i.e., proximal medial tibial metaphysis, distal medial tibial metaphysis, tibial malleolus, lateral calcaneus, and medial calcaneus) for soft
TABLE 1  Study patient population data

<table>
<thead>
<tr>
<th>Harvest Location</th>
<th>Procedures</th>
<th>Patients</th>
<th>Age, y Mean ± SD (Range)</th>
<th>Sex Male/Female</th>
<th>Foot/Ankle Right/Left</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal medial tibial metaphysis</td>
<td>18</td>
<td>18</td>
<td>54.7 ± 10.6 (21-89)</td>
<td>11:05</td>
<td>7:11</td>
<td>Bone graft/Arthrodesis: 14</td>
</tr>
<tr>
<td>Distal medial tibial metaphysis</td>
<td>183</td>
<td>178</td>
<td>54.3 ± 13.1 (20-84)</td>
<td>70:108</td>
<td>96:87</td>
<td>Skin graft: 4, 4</td>
</tr>
<tr>
<td>Medial malleolus</td>
<td>11</td>
<td>11</td>
<td>59.2 ± 9.8 (28-64)</td>
<td>7:04</td>
<td>3:08</td>
<td>Bone graft/Arthrodesis: 11</td>
</tr>
<tr>
<td>Lateral calcaneus</td>
<td>325</td>
<td>314</td>
<td>54.1 ± 14.9 (14-84)</td>
<td>111:203</td>
<td>161:164</td>
<td>Skin graft: 0, 319</td>
</tr>
<tr>
<td>Medial calcaneus</td>
<td>3</td>
<td>3</td>
<td>41.7 ± 24.3 (20-88)</td>
<td>1:02</td>
<td>1:02</td>
<td>Bone graft/Arthrodesis: 3</td>
</tr>
<tr>
<td>Both proximal medial tibial metaphysis and lateral calcaneus</td>
<td>8</td>
<td>8</td>
<td>55.4 ± 20.4 (21-83)</td>
<td>6:02</td>
<td>4:04</td>
<td>Bone graft/Arthrodesis: 0</td>
</tr>
<tr>
<td>Total</td>
<td>548</td>
<td>530</td>
<td>54.7 ± 14.1 (14-84)</td>
<td>206:324</td>
<td>272:276</td>
<td>Skin graft: 8, 538</td>
</tr>
</tbody>
</table>

Results

Autogenous bone marrow aspirate was harvested a total of 570 times during the study period; however, 21 involved the iliac crest and 1 involved the fibula and were therefore excluded from analysis. For the procedures that met inclusion criteria, there were 324 female and 206 male patients with a mean age of 54.7 ± 14.1 years (range: 14–84 years) (Table 1). There were 276 (50.4%) left feet/ankles and 272 (49.6%) right feet/ankles involved with 18 (3.3%) harvests occurring from the proximal medial tibial metaphysis, 183 (33.4%) from the distal medial tibial metaphysis, 11 (2%) from the medial malleolus, 325 (59.3%) from the lateral calcaneus, 3 (0.3%) from the medial calcaneus, and 8 (1.5%) from both the proximal tibial metaphysis and lateral calcaneus. Three hundred (56.8%) of the 530 patients had no risk factors for poor soft tissue or osseous healing. In these patients, the autogenous bone marrow aspirate was used to enhance soft tissue and osseous healing. Two hundred thirty (43.4%) of the 330 patients had risk factors for poor soft tissue and/or osseous healing, including 94 (40.9%) active tobacco users; 74 (32.2%) with diabetes mellitus; 32 (13.9%) nonunions; 27 (11.7%) actively using immunosuppressive medications; and 3 (1.3%) with hostile soft tissues. One patient had bone marrow harvesting a total of 3 separate times and 16 patients had it performed 2 separate times. All procedures were deemed successful with no nerve injury, infection, wound-healing complications, or intraoperative fracture occurring at the autogenous bone marrow aspirate harvest sites.

Discussion

Traditionally, autogenous bone marrow aspirate has been harvested from the iliac crest (1-4). Alternative sites include...
the sternum and proximal ends of long bones, which also contain red marrow (2), although no studies have evaluated the relative concentration of stem cells in these locations in comparison with the iliac crest. For foot and ankle surgeons, the tibia and calcaneus offer convenient harvest sites through which a significant amount of aspirate can be obtained using a percutaneous approach that is simple to perform and easily reproduced, with low morbidity and minimal cost (5, 6). The potential to provide more rapid healing of soft tissue and bone in complex reconstruction of the foot and ankle, especially medically compromised patients, is advantageous. Complications associated with the harvest of autogenous bone marrow aspirate from the lower extremity have not been previously evaluated. The sample size for the lateral calcaneus was far in excess of the amount necessary to compare our data with historical bone graft harvest controls. The sample size for the proximal tibial metaphysis, including those patients who underwent combined harvest from the proximal tibial metaphysis and lateral calcaneus, was very close to the minimum amount needed at a 12% complication rate and, therefore, although we did not encounter any complications, we are cautious to make any definitive statement regarding lack of complications. Unfortunately no historical bone graft harvest control data exist for the distal tibial metaphysis, medial malleolus, and medial calcaneus to compare our results to. Furthermore, although we did not encounter any complications, the numbers we collected for the medial malleolus and medial calcaneus were too small to make any definitive statement regarding lack of complications for the reasons stated previously.

A weakness of this study is that it involved multiple physicians from different institutions who performed the procedure over more than 8 years’ time with different equipment. However, the fact that no complications were encountered despite these variables infers the overall benign nature of harvesting autogenous bone marrow aspirate from various locations about the tibia and calcaneus. Another weakness is that the data involved a retrospective analysis of prospectively collected data with no minimum follow-up period identified. However, as the data were collected in prospective fashion and the patients were followed until their soft tissue and/or osseous healing was complete, the potential to miss a significant incidence of complications is minimized.

Whether autogenous bone marrow aspirate harvested from the proximal tibial metaphysis, distal tibial metaphysis, medial malleolus, or calcaneus is as efficacious as that obtained from the iliac crest has yet to be determined. However, it is interesting to note that 3 of the authors of this article are orthopedic surgeons and can therefore harvest autogenous bone marrow aspirate from the iliac crest, yet only 21 (3.7%) of a total of 570 procedures included for review in this article involved harvesting autogenous bone marrow aspirate from the iliac crest instead of the lower extremity. Although numerous factors may exist that could explain this preference including preferential use of regional anes-

References


Percutaneous Autologous Bone-Marrow Grafting for Nonunions. Influence of the Number and Concentration of Progenitor Cells

Ph. Hernigou, A. Poignard, F. Beaujean and H. Rouard


This information is current as of July 25, 2005

Supplementary material
Commentary and Perspective, data tables, additional images, video clips and/or translated abstracts are available for this article. This information can be accessed at http://www.ejbjs.org/cgi/content/full/87/7/1430/DCl

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Percutaneous Autologous Bone-Marrow Grafting for Nonunions

INFLUENCE OF THE NUMBER AND CONCENTRATION OF PROGENITOR CELLS

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Investigation performed at the Service de Chirurgie Orthopédique, Hôpital Henri Mondor, Creteil, France

Background: Bone marrow aspirated from the iliac crest contains progenitor cells that can be used to obtain bone-healing of nonunions. However, there is little available information regarding the number and concentration of these cells that are necessary to obtain bone repair. The purpose of this study was to evaluate the number and concentration of progenitor cells that were transplanted for the treatment of nonunion, the callus volume obtained after the transplantation, and the clinical healing rate.

Methods: Marrow was aspirated from both anterior iliac crests, concentrated on a cell separator, and then injected into eighty noninfected atrophic nonunions of the tibia. Each nonunion received a relatively constant volume of 20 cm³ of concentrated bone marrow. The number of progenitor cells that was transplanted was estimated by counting the fibroblast colony-forming units. The volume of mineralized bone formation was determined by comparing preoperative computerized tomography scans with scans performed four months following the injection.

Results: The aspirates contained an average (and standard deviation) of 612 ± 134 progenitors/cm³ (range, 12 to 1224 progenitors/cm³) before concentration and an average of 2579 ± 1121 progenitors/cm³ (range, 60 to 6120 progenitors/cm³) after concentration. An average total of 51 ± 10³ fibroblast colony-forming units was injected into each nonunion. Bone union was obtained in fifty-three patients, and the bone marrow that had been injected into the nonunions of those patients contained >1500 progenitors/cm³ and an average total of 54,962 ± 17,431 progenitors. The concentration (634 ± 187 progenitors/cm³) and the total number (19,324 ± 6843) of progenitors injected into the nonunion sites of the seven patients in whom bone union was not obtained were both significantly lower (p = 0.001 and p < 0.01, respectively) than those in the patients who obtained bone union. The volume of the mineralized callus measured at four months on the computerized tomography scans of the patients who had union ranged from 0.8 to 5.3 cm³ (mean, 3.1 cm³). There was a positive correlation between the volume of mineralized callus at four months and the number (p = 0.04) and concentration (p = 0.01) of fibroblast colony-forming units in the graft. There was a negative correlation between the time needed to obtain union and the concentration of fibroblast colony-forming units in the graft (p = 0.04).

Conclusions: Percutaneous autologous bone-marrow grafting is an effective and safe method for the treatment of an atrophic tibial diaphyseal nonunion. However, its efficacy appears to be related to the number of progenitors in the graft, and the number of progenitors available in bone marrow aspirated from the iliac crest appears to be less than optimal in the absence of concentration.

Level of Evidence: Therapeutic Level III. See Instructions to Authors for a complete description of levels of evidence.

The osteogenic capacity of bone marrow was first demonstrated in rabbits as early as 1869 by Goujon. Since the 1960s, some authors have shown that osteogenic stem cells in bone marrow are responsible for the biological efficacy of cancellous bone. This capacity has already been exploited, by several investigators, to reinforce the osteogenic properties of bone allograft by mixing the graft with bone marrow removed during surgery. In animal experiments, Connolly et al. demonstrated a positive correlation between bone-marrow osteogenic capacity and cell concentration, and nonunions have been treated successfully clinically with autologous bone-marrow grafting alone. However, the authors of
the clinical studies did not report the number of connective-tissue progenitor cells that were transplanted, and we are not aware of any study indicating the number of progenitor cells required to obtain bone-healing in the treatment of nonunions in humans. Furthermore, only limited clinical experience with the use of intraoperative centrifugation of marrow for bone-grafting has been reported.

The purpose of the present study was to evaluate the number and concentration of progenitor cells that were transplanted for the treatment of fracture nonunions, the callus volume after transplantation of the concentrated bone marrow, and the rate of clinical union.

Materials and Methods
Operative Technique
Marrow Aspiration
Marrow was aspirated from the two anterior iliac crests with the patient under general anesthesia. After deep insertion of a beveled needle (5 to 8 cm in length and 1.5 mm in internal diameter) into spongy bone, the marrow was aspirated into a 10-ml plastic syringe. At a given depth, the needle was turned 45° to reorient the bevel during successive aspirations, so that the largest possible space was aspirated. After one full turn, the needle was moved 1 cm toward the surface through the same insertion site, and aspirations were again performed, with the needle always turned 45° after each aspiration. The marrow was aspirated in small fractions (4 ml) to reduce the degree of dilution by peripheral blood. Three, four, or five perforations were made, through the same skin opening, into the iliac crest, with the perforations spaced approximately 2 cm from each other to avoid dilution by aspiration in the previous hole. All aspirates were pooled in plastic bags containing an anticoagulant solution (citric acid, sodium citrate, and dextrose). Pooled aspirates were then filtered to separate cellular aggregates and fat (Hemoest NSR LF, B-Braun, Bethlehem, Pennsylvania).

Concentration
Concentrated buffy coat was obtained after a five-minute centrifugation at 1200 g on a cell separator (Cobe 2991, Gambro BCT, Lakewood, Colorado). This centrifugation forces the polynuclear cell layer, which is heavier because of the volume of its nuclei, to the periphery, where it can be collected and separated from the remainder. The lighter layer with anuclear red cells is found in the center and is also removed. The buffy coat contains progenitor cells but also other mononuclear cells, and some of these other cells may be a source of angiogenic or osteogenic cytokines with a clinical effect. This centrifugation method reduces a 300-ml bone-marrow aspirate to a concentrated buffy coat of about 50 ml, which is poured into a syringe for injection.

Intraosseous Reinjection
A trocar identical to that used to aspirate the marrow was placed both in the nonunion gap and around the bone ends. The tip of the trocar was positioned with use of an image inten-

sifier (Fig. 1). The fibrous tissue of the nonunion site was not removed or disturbed. The marrow was injected slowly at a rate of about 20 ml/min. After injection, the trocar, with the styllet in place, was gradually withdrawn with small oscillating motions (backward and forward) to fill in the path of the trocar.

Patient Demographics
Sixty patients with an established nonunion of the tibial shaft were treated with this technique at the same center between 1990 and 2000. Thirty-eight patients were male. Twenty-eight patients had comorbidities: fifteen had a history of tobacco use, eight had a history of alcohol abuse, three had diabetes, and two had used a pharmaceutical agent affecting bone marrow physiology. Seventeen fractures were in the proximal part of the tibia, twelve were in the distal part of the tibia, and thirty-one were in the midpart of the tibial shaft. The patients ranged in age from eighteen to seventy-eight years, with a mean age of forty years. There were twelve isolated, closed, low-energy fractures of the tibial shaft, which had been treated nonoperatively with a plaster-of-Paris cast. There were forty-eight open fractures, which had been treated with external fixation (a monolateral frame was used for four cases and a bimanual frame, for forty-four). The majority (fifty-seven) of the patients underwent definitive fracture fixation with external fixation or a cast immediately (within twenty-four hours) after the injury. Three patients underwent changes in the external fixation during the first week. All patients with an open
fracture received routine soft-tissue management, including débridement, irrigation, and definitive wound closure, immediately or within three days. According to the Gustilo-Anderson classification of open injuries, thirty-six fractures were type I, eight were type II, two were type IIIA, one was type IIIB, and one was type IIIC. The type-IIIB open fracture required flap coverage, and the type-IIIC open fracture required a vascular repair. Of the forty-eight open fractures, seven (five type I, one type II, and one type IIIA) had already been treated, in another center, with an autologous cancellous bone graft between the fourth and seventh month after the injury. The graft was harvested with an open procedure from the anterior iliac crest in five patients and from the posterior iliac crest in two at an average of four months (range, three to six months) before the aspiration of the bone marrow graft; the aspiration was done at a minimum of 2 cm from the area of the previous graft harvest.

The definition of nonunion was a failure of the fracture to heal in six months in a patient in whom progressive repair had not been observed radiographically between the third and sixth month after the fracture. All nonunions were considered atrophic because they showed very little callus formation. The time between the fracture and the bone marrow injection ranged from six to twelve months (average, eight months and three weeks).

At the time of the bone marrow grafting, the nonunions were considered to be not infected according to preoperative assessment for the presence of systemic infectious parameters. The absence of infection was confirmed postoperatively by the results of culture of aspirate obtained from the nonunion site just before the bone marrow injection.

The displacement of the bone fragments at the time of the bone marrow grafting was measured, on anteroposterior and lateral radiographs, as a percentage of the width of the bone at the level of the fracture. Fragment displacement ranged from 0% to 20%, with an average of 6%. The maximum gap between the fragments was always <3 mm.

Management of the Nonunions Before and After Bone Marrow Grafting
Anteroposterior and lateral radiographs and a computerized tomography scan were made preoperatively. Postoperatively, radiographs were made at three and four weeks to assess the appearance of the callus and then every month thereafter, until bone healing occurred, to monitor the progression of the callus.

The volume of mineralized callus was calculated from measurements made on the computerized tomography scans. The area of callus resulting from the injection was considered to be the sector of new bone formation between the time of the preoperative computerized tomography scan and the time of the computerized tomography performed four months postoperatively. The protocol for the computerized tomography scanning consisted of 3-mm-thick sections over a length of 6 cm at the level of the nonunion (3 cm proximal and 3 cm distal). The level of each cut was controlled visually to be certain that the measurements on the preoperative and follow-up scans were made at the same level. The images were analyzed with use of a set of custom algorithms to determine pixel intensity and the extent of mineralized bone surface at the fracture site. Because unmineralized tissue cannot be evaluated accurately with computerized tomography, it was not analyzed in this study. Although the computerized tomography scan is two-dimensional, it provides information from a three-dimensional slab. For each slice, the volume of callus was calculated by multiplying the area of callus by the slice thickness. The total volume of callus was the sum of the individual volumes of each slice. Computerized tomography was not used to determine union or as a guide to ascertain when to allow full weight-bearing.

The only therapeutic intervention performed in the present study was percutaneous injection of bone marrow. The same external fixation (for the open fractures) or plaster-cast immobilization (for the closed fractures) was used after the bone marrow grafting. All of the patients were treated with a standard protocol during the first month following the injection. As they had atrophic nonunion and mobility at the fracture site, weight-bearing was not allowed during the first month following the injection to avoid mechanical disruption of the tissue-regeneration and bone-healing processes. After one month, if (and only if) callus was observed on radiographs, partial weight-bearing was allowed with the plaster cast or external fixation in place. There was a one-month transition period between the beginning of partial weight-bearing and that of full weight-bearing. At the end of that month, if the patient had no pain and there was cortical bridging or disappearance of the fracture lines on at least three of the four cortices viewed on the anteroposterior and lateral radiographs, the plaster cast or the external fixation was removed.

The treatment was considered to be a success when there was definite radiographic evidence of fracture union and fulfillment of the clinical criteria of healing within six months after the autologous bone-marrow grafting. The clinical criteria of healing included full weight-bearing and no tenderness at the fracture site on palpation. When a patient did not have bone-healing six months after the bone marrow grafting, a secondary intervention to promote fracture union was proposed to him or her and the treatment was considered a failure. Each patient was followed for at least three years after the bone marrow grafting.

Bone Marrow Analysis
To measure the number of connective-tissue progenitor cells that were transplanted, we used the fibroblast colony-forming unit (CFU-F) as an indicator of stromal cell activity. The fibroblast is not an osteogenic cell but, according to the theory of pluripotential cell lines, osteocytes develop from colony-forming-unit progenitor cells in the marrow. There seems little doubt that these colonies are clonal (i.e., originate from a single cell), and in this paper the terms "stem cell," "connective-tissue progenitor cell," "progenitor," and "CFU-F" will be considered synonymous. The aggregate of the marrow was cultured in vitro before and after concentration in order to de-
termine how much the concentration process altered the number of stem cells in the sample. The number of nucleated cells was counted with use of a standard Malassez hemocytometer (Polarlab, Strasbourg, France). Cells were washed once and resuspended in Hank's balanced salt solution without Ca++ or Mg++. Buffy coats were collected after centrifugation of the aspirates at 1200 g for 10 minutes.

For the fibroblast colony-forming units (CFU-F), quadruplicate aliquots of 2 × 10⁵ cells were inoculated in 25-cm² tissue-culture flasks containing 10 mL of culture medium supplemented with 20% fetal calf serum, 1% L-glutamine, penicillin (100 U/mL), and streptomycin (100 μg/mL). The culture flasks were placed in a humidified incubator with 5% CO₂ and maintained at 37°C. The growth medium was completely renewed every three to four days, and the cultures were evaluated on the tenth day. Fibroblast colonies were Giemsa-stained and were counted under an inverted microscope at 25X magnification. An aggregate of cells containing more than fifty fibroblasts was scored as a colony. Results were expressed as the mean number of fibroblast colony-forming units per 10⁵ bone marrow cells. The fibroblastic nature of the colonies was demonstrated by immunofluorescence staining with antibodies against fibronectin and type-I and III collagen.

Statistical Methods

Data are reported as the mean and standard deviation, and the significance level was set at a probability value of <0.05. The outcome variables were the success of the treatment, the volume of the mineralized callus at four months, and the time needed to obtain union after the bone marrow grafting. The therapeutic factors that could influence the outcome variables were the total number and the concentration of fibroblast colony-forming units injected at the nonunion site. The patient and fracture variables included age, sex, associated comorbidities, fracture displacement, and type of open injury according to the classification of Gustilo and Anderson. A multivariate analysis was conducted to evaluate the relationship between the outcome and the set of variables. Correlations between the outcome variables and the cell factors were determined with use of the Spearman correlation test. The nonparametric Mann-Whitney U test was used to identify the significance of the differences between groups. The chi-square test was used to identify trends within groups with categorical variables.

Results

None of the patients had complications during anesthesia; in particular, no patient had a decrease in oxygen saturation or a change in pulse or blood pressure during the procedure. A compartment syndrome did not develop in any patient after injection of the bone marrow. There were no infections, hematomas, or chronic pain at the site of the bone marrow injection.

Patient and Bone Marrow Variables (Table 1)

An average of 306 ± 24 mL of marrow was aspirated from the two iliac crests of each patient. The number of nucleated cells obtained from the individual patients ranged from 1 to 24 million/mL, with a mean of 18 ± 7 million/mL. The mean number of fibroblast colony-forming units per one million nucleated cells obtained from the individual patients ranged from 7 to 51, with a mean of 33 ± 8. The number of nucleated cells was found to decrease significantly with age (Spearman test, p = 0.03), but with the numbers available, no significant difference between men and women was found (p = 0.26).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No.</th>
<th>Nucleated cells (million/mL)</th>
<th>Progenitors of CFU-F (colonies/million nucleated cells)</th>
<th>Progenitors in the Graft (no./cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>60</td>
<td>18 ± 7</td>
<td>33 ± 8</td>
<td>91 ± 38</td>
</tr>
<tr>
<td>Male</td>
<td>38</td>
<td>19 ± 8</td>
<td>35 ± 7</td>
<td>53 ± 41</td>
</tr>
<tr>
<td>Female</td>
<td>22</td>
<td>16 ± 6</td>
<td>30 ± 10</td>
<td>48 ± 37</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>28</td>
<td>16 ± 10</td>
<td>29 ± 12</td>
<td>45 ± 43</td>
</tr>
<tr>
<td>No comorbidities</td>
<td>22</td>
<td>20 ± 6</td>
<td>37 ± 6</td>
<td>57 ± 32</td>
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<tr>
<td>Closed fractures</td>
<td>12</td>
<td>17 ± 11</td>
<td>29 ± 9</td>
<td>48 ± 22</td>
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<tr>
<td>Open fractures</td>
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<tr>
<td>I</td>
<td>36</td>
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<td>51 ± 27</td>
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<td>8</td>
<td>20 ± 7</td>
<td>47 ± 5</td>
<td>82 ± 19</td>
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<td>III</td>
<td>4</td>
<td>19 ± 12</td>
<td>46 ± 7</td>
<td>53 ± 20</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>&gt;40 yr</td>
<td>30</td>
<td>15 ± 6</td>
<td>32 ± 7</td>
<td>49 ± 33</td>
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<tr>
<td>&lt;60 yr</td>
<td>30</td>
<td>21 ± 9</td>
<td>36 ± 9</td>
<td>52 ± 22</td>
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</table>

*The values are given as the mean and standard deviation.
There was no significant change in the prevalence of progenitor cells with increasing age (p = 0.12) and, when men and women were analyzed separately, there was no significant change with age in men (p = 0.28); however, the prevalence of progenitor cells was observed to decrease significantly with increasing age in women (p = 0.04).

An average of 1 CFU-E/30 × 10⁶ bone marrow nucleated cells was obtained in the samples incubated in vitro. The bone marrow obtained by aspiration from the iliac crests contained an average of 612 ± 134 progenitors/cm³ (range, 12 to 1224 progenitors/cm³). After concentration, the bone marrow contained an average of 2579 ± 1121 progenitors/cm³ (range, 60 to 6120 progenitors/cm³). A mean of 20 cm² (range, 17 to 22 cm²) of bone marrow graft was injected into each nonunion site. The average total number of fibroblast colony-forming units injected into each nonunion site (i.e., the product of the nucleated cells and the prevalence of progenitors in the bone marrow graft obtained after concentration) was 51 × 10⁶ (range, 1200 to 1224 × 10⁶).

Analysis of the total population demonstrated that age had no significant effect on the total number of progenitor cells received by each patient (p = 0.08). Also, when men and women were analyzed separately, age was found to have no significant effect on the number of cells received by the men; however, increasing age was found to be associated with a significant decrease in the total number of progenitors received by the women (p = 0.04). With the number of patients available, the comorbidities of smoking, alcohol abuse, diabetes, and use of pharmaceutical agents were not associated with significant changes in the population of cells that were harvested.

Outcomes of Management of the Nonunions

Nonunion outcome variables were defined as the success of the treatment; the healing time; the volume of callus; and the change in displacement, shortening, or angulation during bone-healing.

Bone union was obtained in fifty-three of the sixty patients, with the callus typically appearing on radiographs between the third week and the second month after the injection. Radiographic evidence of fracture union (Fig. 2) was observed at an average of twelve weeks (range, four to sixteen weeks). The volume of the mineralized callus measured at four months on the computerized tomography scans of these fifty-three patients ranged from 0.8 to 5.3 cm³, with a mean value of 3.1 cm³. During healing after the bone marrow grafting, shortening ranged from 0 to 25 mm, with an average of 5.4 mm. Fifty nonunions healed with <15 mm of shortening, and three healed with >15 mm of shortening. During healing, forty-nine patients did not have an increase of 3° in angulation in the frontal plane, and fifty patients did not have an increase of 3° in angulation in the sagittal plane. Four patients had an increase in angulation of between 3° and 7° in the frontal plane, and three patients had an increase in angulation of between 3° and 8° in the sagittal plane. Forty-six nonunions healed with no more displacement in any plane, and seven had an increase in displacement (ranging from 5% to 10%) during healing.

Of the sixty patients, seven did not have union, with the volume of mineralized callus in those patients measuring <0.5 cm³ on the computerized tomography scan. Three of the seven patients had an increase in angulation of >10° and an increase in displacement of >20%. These seven patients required additional surgery to achieve healing. Intramedullary nailing was performed in three, open bone-grafting, in three; and fibular osteotomy, in one.

Statistical Analysis

Success of treatment: Of the variables that were explored with multivariate analysis, the number of transplanted cells was deemed to be the most relevant to the outcome (Figs. 3 and 4). As the volume of the graft was relatively constant (average, 20 cm³; range, 17 to 22 cm³), the concentration of transplanted cells also appeared to be relevant to the outcome. The bone marrow grafts used for the fifty-three patients who subsequently had bone union contained a mean of 2835 ± 1160 progenitors/cm³ and a mean of 54,962 ± 17,431 progenitors in total, and all of the grafts in these patients contained >1500 progenitors/cm³. The grafts used in the seven patients in whom the treatment failed contained a significantly lower concentration (mean, 634 ± 187 progenitors/cm³; p = 0.001) and total number (mean, 19,324 ± 6843, p < 0.01) of progeni-

Fig. 2
Anteroposterior radiographs of a twenty-five-year-old patient who had sustained a type II open fracture. The radiographs were made at the time of fracture (a); at the time of nonunion, before injection of autologous bone marrow (b); at one month after bone marrow injection, at which time the patient was allowed to begin partial weight-bearing (c); at two months after bone marrow injection (d); and at three months after bone marrow injection, at which time the internal fixation was removed (e).
Discussion

During the past two decades, numerous techniques have been developed to treat fracture nonunions, ranging from invasive interventions (including internal fixation with the use of bone graft or bone graft substitutes) to noninvasive procedures (ultrasound and pulsed electromagnetic fields). The percutaneous technique of autologous bone-marrow grafting that we used is a minimally invasive alternative.

Our study showed that percutaneous autologous bone-marrow grafting is a safe treatment for uninfected atrophic nonunions of the tibial diaphysis, as we encountered no local or systemic complications. One theoretical criticism of this technique is that there is a risk of fat embolism during the injection of the bone marrow into the nonunion site. However, in our study, the bone marrow aspirates were filtered to separate the marrow and fat, and none of the patients had complications during anesthesia.

Fifty-three of the sixty nonunions healed, which confirms the effectiveness of this technique for the treatment of atrophic nonunions. Historically, resection of the fibrous tissue at the nonunion site combined with mechanical stabilization has been described as being essential for the treatment of an atrophic nonunion. In this series, the trocar was not used to remove the intervening callus or fibrous tissue. The fibrous tissue interposed between the bone ends ossified after...
the injection of the bone marrow. It is difficult to explain the exact mechanism that allows the transformation of fibrous tissue into callus. Bone marrow was injected both in the nonunion gap and around the bones. It is not possible to know whether the injected marrow was able to convert the fibrous tissue into bone or if the interposed tissue was transformed into bone only after the bridging callus (obtained from the graft around the bone) stopped micromotion at the nonunion site and allowed union of the gap.

Like all techniques, this new option of bioactive cell stimulation has its limitations, one of which is that it has not been evaluated in the presence of internal fixation (plates or intramedullary nails). One potential weakness of the present study is the absence of a cohort with a placebo treatment such as injection of saline solution. Also, the cell counts were determined retrospectively; thus, we cannot determine if the technique should have been used as the sole treatment method. Percutaneous injection of bone marrow cannot be used when there is pre-existing angular deformity or shortening, both of which require direct access to the nonunion site. As the volume of callus obtained with this technique is limited, the fracture fragment gap size and displacement should be limited as well.

Another important finding of this study is the relationship between the volume of the callus and the number of progenitors in the graft. The addition of bone-marrow-derived cells has been shown to enhance bone-healing in animals. There are limited data on the number of progenitors that are resident in bone marrow grafts in humans. The variability in the osteogenic potential from patient to patient is a limitation of the technique, and little is known about the extent to which these cells are susceptible to activation for bone repair after they are implanted. Because we initially had no data on the number of cells necessary to obtain bone-healing, the volume of the aspirate and volume of the transplanted graft were similar for all of the patients. In this series, the number of progenitors was determined retrospectively, and there was variation among the patients.

Differences among connective-tissue progenitors harvested from various individuals are beginning to be understood. These differences depend on many variables, such as age, gender, and local and systemic disease and the variability in the osteogenic potential from patient to patient represents a limitation of the technique. One of the challenges in the operating room for the surgeon using this technique could be the evaluation of the number of cells obtained by aspiration. Bone marrow cellularity declines with age, and there is also a decrease in the prevalence of connective-tissue progenitors with increasing age, even if this was not evident in our small series of patients. However, as can be observed by examining the data in our Table I and the information in other reports, age and gender account for only a fraction of the variation; thus, connective-tissue progenitors can be obtained by bone marrow aspiration from patients of all ages. It may be useful for surgeons to know the cellularity of the bone marrow when operating on older patients. The number of progenitors can be determined only with a culture, but the quantity of medullary nuclear cells can be evaluated in the operating room (if necessary) by the equation presented in the Appendix. Since the total number of progenitors represents the product of the nucleated cells and the prevalence of progenitors in the aspirate, a decline in the number of nucleated cells can be corrected by an increase in the volume of aspiration. However, a larger volume of aspiration decreases the concentration of progenitor cells because of dilution with peripheral blood.

Still another important observation in this study was the influence that the concentration of bone marrow by centrifugation had on the results. The seven patients who did not obtain union had all received a marrow graft with <1000 progenitors/cm³ and <30,000 progenitors in total; both the mean concentration and the mean number were significantly lower than those for the patients for whom the treatment did not fail. Therefore, it seems reasonable to suggest that a graft needs to contain >1000 progenitors/cm³. This finding has implications regarding the intraoperative processing of bone marrow to select progenitors because bone marrow obtained by aspiration and not concentrated contains only a mean of approximately 600 progenitors/cm³ (range, 12 to 1224 progenitors/cm³).

Our results confirm that it is important to increase the number of progenitors in the graft after aspiration. Connolly et al. examined the possibility of improving the efficacy of an aspirated bone-marrow graft by concentration in a study of animals. Even if the issue of concentration was not directly addressed by our experimental design, we were able to confirm its influence in our clinical study of humans by determining the number of cells in a standardized volume. However, it is not possible for us to know, from the findings in this study, whether the same number of cells in a smaller (or larger) volume would be similarly effective. The importance of the concentration of cells that can be delivered may be related to the survival of these progenitors after transplantation. The amount of available oxygen is probably one of the limiting factors after transplantation. Since the transplanted progenitor cells compete with other cells for oxygen, one way to optimize cell survival is to limit the transplanted cells to those that contribute to the formation of bone (i.e., exclude all others). This was achieved by centrifugation in our series. Use of a porous implantable material has been reported as an alternative method for concentration and selection of connective-tissue progenitors. Other methods to increase the population of progenitors in the bone marrow graft, such as the use of growth factors, will probably be proposed in the future.

Appendix

The quantity of medullary nuclear cells per kilogram of marrow was calculated with use of a formula that takes into account blood dilution. It was estimated that, in each milliliter of aspirate, medullary cells were represented by the difference between the nuclear cell count and the count in peripheral blood (sampled during the period of general anesthesia).

\[ N(10^6/kg) = \frac{(V \times NP) - (V - 100) \times NS}{P} \]

where \( V \) = the total volume of aspirate in milliliters, including
the harvesting medium. NP = the nuclear cell count per milliliter in the collection bag, in which the harvesting medium is included, that leaves the operating room; V = the exact volume of aspirate, after subtraction of the 100 mL of harvesting medium; NS = the nuclear cell count per milliliter of peripheral blood drawn during the period of general anesthesia; and P = the patient's weight in kilograms. As an example: for a total final volume of 300 mL containing 1 x 10^7 nuclear cells/mL, obtained from a 70-kg adult with a leukocyte count of 4 x 10^9/mL, as determined while the patient is under general anesthesia, it can be estimated that the modulatory nuclear cell count is 5 x 10^6/kg, for a total of 0.35 x 10^9 nuclear cells.

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A. Foucard, MD

References

Means of enhancing bone fracture healing: optimal cell source, isolation methods and acoustic stimulation

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Abstract

Background: The human body has an extensive capacity to regenerate bone tissue after trauma. However, large defects such as long bone fractures of the lower limbs cannot be restored without intervention and often lead to nonunion. Therefore, the aim of the present study was to assess the pool and biological functions of human mesenchymal stromal cells (hMSCs) isolated from different bone marrow locations of the lower limbs and to identify novel strategies to prime the cells prior to their use in bone fracture healing. Following, bone marrow from the ilium, proximal femur, distal femur and proximal tibia was aspirated and the hMSCs isolated. Bone marrow type, volume, number of mononuclear cells/hMSCs and their self-renewal, multilineage potential, extracellular matrix (ECM) production and surface marker profiling were analyzed. Additionally, the cells were primed to accelerate bone fracture healing either by using acoustic stimulation or varying the initial hMSCs isolation conditions.

Results: We found that the more proximal the bone marrow aspiration location, the larger the bone marrow volume was, the higher the content in mononuclear cells/hMSCs and the higher the self-renewal and osteogenic differentiation potential of the isolated hMSCs were. Acoustic stimulation of bone marrow, as well as the isolation of hMSCs in the absence of fetal bovine serum, increased the osteogenic and ECM production potential of the cells, respectively.

Conclusion: We showed that bone marrow properties change with the aspiration location, potentially explaining the differences in bone fracture healing between the tibia and the femur. Furthermore, we showed two new priming methods capable of enhancing bone fracture healing.

Keywords: Bone marrow, hMSCs, Acoustic stimulation, Cell priming

Background

Musculoskeletal disorders affect the body's muscles, bones, joints, tendons, ligaments and nerves and are the leading cause of chronic disabilities in adults [1]. Significant research efforts have been undertaken during the last decades to ease this disablement and improve patient's mobility and quality of life. Bone fracture repairs have been intensively investigated at both clinical and fundamental level and still 5-10% of fractures resulted in either delayed repair (delayed union) or no repair (nonunion) [2]. At present there are two primary treatment strategies: (1) surgical intervention that implies the use of bone autografts/allografts, demineralized bone matrix or synthetic materials and (2) noninvasive treatments such as the application of acoustic energy shown to be beneficial in fracture healing [3, 4]. Nevertheless, these strategies rely on the patient's own cells - either stem and/or committed- to induce bone regeneration, posing a challenge in situation whereas those cells are missing and/or less active. In these cases cell-based alternatives, such as the use of human mesenchymal stromal cells (hMSCs) were proposed [5].

In this study we explored the yield, proliferation, multilineage differentiation and extracellular matrix (ECM)
production potential of hMSCs isolated from bone marrow (BM) aspirated from the lower limbs, such as the ilium, proximal femur, distal femur and proximal tibia. Additionally, we examined the inter- and intra-donor variation between the BM-derived hMSCs from the different locations. It has been shown that the nonunion rate in bone fracture healing (BFH) differs with regard to their location, with fractures at tibia diaphysis healing slower (nonunion rate of 18.5% [6]) than fractures in the femoral shaft (nonunion rate of 1.7% [7]). Accordingly, we hypothesize that BM located at the fracture site might play an important role in the fracture healing rate, due to differences in cell number, self-renewal-, proliferative-, ECM production- and multilineage differentiation potential.

Additionally, as cell-based therapies are already used in musculoskeletal pathologies, such as bone fracture, pseudarthrosis and osteochondral defects [8, 9], we explored the potential of priming BM-derived hMSCs towards the osteogenic lineage in order to accelerate tissue regeneration upon reimplantation. We explored two distinct priming strategies: (1) the use of acoustic energy applied on BM and (2) varying the initial culture conditions of the isolated hMSCs.

Ultrasound has been shown to have beneficial effects on BFH showing an increase in bone formation [10, 11], however not consistently [12–14]. Moreover, a 42% acceleration in fracture healing in patients exposed to a twenty minutes daily ultrasound treatment is still not optimal [11]. Therefore, we believe that the use of acoustically stimulated BM injected at the fracture site might have a greater impact on BFH than the actual standard ultrasound treatment. Mechanical stimulation has been shown to pre-commit hMSCs towards the osteogenic lineage [15] and thus we hypothesize that acoustic energy applied directly on BM might induce the commitment of hMSCs towards osteogenesis. It is clinically feasible and simple to apply a short period of acoustic stimulation on a BM aspirate during fracture surgery after which the BM can be administrated to the fracture site either in initial surgery during high risk cases or as an adjuvant to revision surgery in case of pseudarthrosis.

Secondly, cell-based therapies often involve the in vitro expansion of cells, where the isolation procedure plays an important role in the selection of desired cell population [16–18]. The isolation of hMSCs from BM is mainly achieved by plastic adherence and it is recognized that both the number of mononuclear cells (MNCs) plated and the culture media have a strong influence on the selection of certain hMSCs populations [19]. Accordingly, we hypothesize that low MNCs seeding density might select hMSCs with higher self-renewal potential, while the use of serum free (SF) media might select a hMSCs subpopulation with enhanced potency.

The phenotype of the isolated hMSCs under the aforementioned conditions were compared to a previously described isolation procedure [20].

Following, with this study we aimed to find the optimal ratio between aspirated BM volume and MNCs concentration, to explain the difference in cell phenotype between the different BM locations of the lower limb extremities and to propose new methods that could accelerate BFH. A schematic overview of the experimental design is presented in Fig. 1.

Methods

Aspiration of bone marrow

BM aspirates were obtained from patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA). An 8G Jamshidi BM needle fit with a 50-mL Luer lock syringe containing 1 mL of 1,000 U heparin per 10 mL BM was used to aspirate the BM. Subsequently, the BM was transferred to blood collection tubes (BD-367526) for the transport from the operating theatre to the laboratory. The BM was kept at ambient room temperature until processed within the same day.

BM was aspirated from four different locations: the supra acetabular alaicus (ilia) in twelve donors, the medullary cavity or lateral diaphysis of the femur (proximal femur) in seven donors, and the epiphysis or medullary cavity from the distal femur or proximal tibia in seven more donors.

Isolation and culture of hMSCs

BM aspirate was passed through a 70 μm pore-size cell strainer to remove the presence of tissue pieces after which MNCs concentration from the ilium and proximal femur was analyzed using the Beckman Coulter ACT diff 2. The number of MNCs for samples collected from the distal femur and proximal tibia was not analyzed due to technical limitations.

Based on the isolation method used, different concentrations of MNCs/cm² were plated. We defined three isolation/culture conditions: heterogeneous (classical MNCs seeding density, previously described and standardized hMSCs isolation protocol within our laboratory [21]), multiclonal (low MNCs seeding density, permisive for single cell clonal expansion) and SF (high MNCs seeding density in the absence of fetal bovine serum proteins during the initial phase).

For the heterogeneous isolation condition, BM aspirate was plated at a density of 5×10⁶ MNCs/cm² and cultured in growth media (GM) consisting of α-minimal essential media (αMEM, Life Technologies - Cat. No: 22571-020), 10% Fetal Bovine Serum (FBS, Gibco - Cat. No: 10270106), 0.2 mM L-ascorbic acid 2-phosphate magnesium salt (Sigma - Cat. No: A8960), 2 mM L-glutamine (Gibco - Cat. No: 29050037)
Fig. 1 Schematic representation of the experimental design. Aspiration of BM from different locations of the lower limb extremities and selection of the optimal cell source, based on MSC number and phenotype in vitro priming of BMSC by use of acoustic stimulation or varying the initial culture conditions with the final aim to enhance in vivo bone fracture healing.

BE17-605E), 100 units/mL penicillin and 100 mg/mL streptomycin (Gibco – Cat. No: 15140-122).

For the monoclonal isolation condition, BM aspirate was plated at a clonal density of 5x10³ MNCs/cm² and cultured in GM.

For the SF condition, BM aspirate was plated at a cell density of 1.5x10⁶ MNC/cm² in α-MEM containing no additives for the first three days.

At the fourth day, the non-adherent cell fraction was removed and the media was changed to GM for all three conditions. Hereafter, media was refreshed twice a week. At semi-confluence cells were trypsinized and used for sub-culturing or stored in liquid nitrogen for future use.

In total, BM was aspirated from 19 donors and subsequently divided between the different experiments. BM from 14 donors was used to evaluate the most convenient aspiration site location. BM was plated under heterogeneous condition, with exception of distal Femur and proximal Tibia where 2 ml BM was plated each time, as the initial amount of MNCs was unknown. BM
from 11 donors was plated in heterogeneous condition and used to evaluate the effects of acoustic energy stimulation and BM from 6 donors was used to evaluate the effects of varying the initial isolation conditions of the hMSCs.

Donor number, BM aspiration location, BM volume and concentration of MNCs/ml can be found in Table 1. BM was cultured at 37 °C and 5% CO₂.

<table>
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<th>BM color</th>
<th>BM aspirated volume (ml)</th>
<th>MNC/ml (10⁶)</th>
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hMSCs population doubling
To assess hMSC proliferation, cells from passage 1 (P1) were seeded in GM at 5 000 cells/cm² in T175 tissue culture flasks. At semi confluence the cells were trypsinized and counted. Population doubling (PD) was calculated according to the formula $PD = \log_2(N_2/N_1)$, where $N_2$ and $N_1$ are the number of hMSCs obtained at passage 2 (P2) and P1, respectively.

Colony forming unit and colony forming unit-osteoblast potential (mineralization)
The colony forming unit (CFU) assay was used as an indicator of cell renewal potential of the hMSCs and the CFU-osteoblast (CFU-Ob) assay was used as an indicator of their osteogenic potential. Two million MNCs were seeded in duplicate in T25 culture flasks and grown in GM for the first 7 days, followed by transition to mineralization media for further 7 days. The mineralization media consisted of GM containing 0.1 M β-glycerophosphate (BGP, Sigma - Cat. No: G9422) and 10⁻⁸ M Dexamethasone (Dex, Sigma - Cat. No: D8993). At day 14, the cultures were fixed with 10% formalin for 15 min at ambient temperature, after which alkaline phosphatase (ALP) positive colonies were stained using the Leucocyte Alkaline Phosphatase Kit - ALP (Sigma - Cat. No: 85 L2) following the manufacturer's instructions. Subsequently, colonies were stained using 0.5% Coomassie Brilliant Blue staining (Fluka - Cat. No: 27815) solution for 10 minutes and images of the stained colonies were acquired using an Epson Perfection V750 PRO scanner. The total number of CFUs and ALP positive colonies was quantified using ImageJ 1.45 s software and the percentage of ALP positive CFUs calculated.

Extracellular matrix production
hMSCs at P2 or P3 were seeded in quadruplicate at 100 000 cells/well in a 384-well plate in GM (without serum) consisting of 50 μg/mL insulin transferrin selenium-premix (Sigma - Cat. No: 13146) and 40 μg/mL proline (Sigma - Cat. No: P56067) and incubated for 24 h to allow cell adhesion. The next day the medium was refreshed and 10 ng/mL transforming growth factor beta 3 (R&D Systems - Cat. No: 243-B3) and 10⁻⁷ M Dex was added to the wells. After seven days the formed nodules were fixed in 10% formalin for 15 min at ambient temperature and images were captured using a Nikon bright field microscope. The nodule area and the number of nodules formed were quantified using ImageJ 1.45 s software. The early cell condensation phenotype and the increase in nodule size was associated with ECM production.

Alizarin red staining (mineralization)
hMSCs at P2 or P3 were seeded in triplicate at 50 000 cells/well in T25 and grown in control media consisting
of GM containing 0.01 M BGP and in mineralization medium consisting of GM containing 0.01 M BGP and 10^{-8} M Dex. The media was refreshed twice a week. After 28 days, cells were fixed in 10% formalin for 15 min at ambient temperature and stained with 2% Alizarin red solution (Sigma – Cat. No: A5533) for 5 min. Images were captured using a Nikon bright field microscope.

Oil red O staining (Adipogenesis)

hMSCs at P2 or P3 were seeded in triplicate at 25,000 cells/well in 24-well plates and grown in control medium consisting of GM or adipogenic medium consisting of GM containing 0.2 mM indomethacin (Cat. No.: 7378), 0.5 mM isobutylmethylxanthine (Cat. No.: 15879), 10^{-6} M Dex and 10 μg/ml human insulin (Cat. No.: 19278), all from Sigma. The media was refreshed twice a week. After three weeks the cells were fixed with 10% formalin for 15 min at ambient temperature, after which the cell monolayer was incubated for 5 min in 60% isopropanol, and subsequently stained with Oil red O solution (3 mg/ml in 60% isopropanol, Sigma – Cat. No.: 0625). After five minutes, samples were rinsed with demineralized water and images were captured using a Nikon bright field microscope. After the imaging, Oil red O staining was extracted from the cells in 1% Nonidet P40 (Fluka, Cat. No.: 74385) in isopropanol and absorbance was measured at 540 nm (Lambda 40; Perkin Elmer). One hundred percent Oil red O was included in the calibration curve measurements, from which the percentage of Oil red O staining was calculated.

Flow cytometry

hMSCs at P3 or P4 were expanded in T175 until they reached confluence. The cells were trypsinized and incubated for 30 min in blocking buffer consisting of 17% bovine serum albumin (Sigma – Cat. No: F7524) in PBS followed by incubation with FITC- or PE-conjugated mouse anti-human antibodies for 30 min at 4 °C in the dark. The samples were then washed three times with a washing buffer consisting of 3% bovine serum albumin in PBS. The expression levels were analyzed using FACS Aria flow cytometer (BD Bioscience). For phenotypic characterization the following antibodies were used: CD90, CD73, CD146, CD105, CD271, CD34, CD14, CD79a, HLA-DR, CD45 and IgG1 and IgG2a as isotype controls (all from BD Pharmingen).

Acoustic stimulation of bone marrow

Acoustic stimulation of BM was achieved using the bone marrow aspirate concentration device, previously described by Ridgway et al. [22]. BM was placed into the processing chamber of the device and acoustic vibration was applied using a voice-coil which produced a geometric standing waveform pattern on the BM fluid surface. Different frequencies were tested by manual adjustment using an Oscilloscope (Agilent Technologies, InfiniVision, MSO-X-3014A Mixed Signal Oscilloscope) and two frequencies, 300 Hz (48 mW/cm²) and 500 Hz (73 mW/cm²), were selected for further experimental research. The BM was processed one time for 5 and 10 min for both selected frequencies. The baseline was defined as unstimulated BM.

Following, part of the BM was plated to assess the self-renewal and proliferation potential as previously described, while the rest of the BM was plated under the heterogeneous hMSCs isolation condition in order to assess the multilineage differentiation potential, ECM production and surface markers expression of the hMSCs at later passage, as previously mentioned.

Bone marrow viscosity

BM viscosity from 6 donors (3 donors for ilium and proximal femur and 3 donors for distal femur and proximal tibia) was measured using the Rheometer Physica MCR-301. A total of thirty different points, with an increasing shear rate from 0 to 250 L/s and periodic pause of 10 s between each point, were measured. The volume of BM used for the measurements was 350 μl per measuring cycle. All samples were measured in duplicates at ambient room temperature.

Statistical analysis

Statistical analysis was performed using Graphpad Prism 6 software. Unpaired Student’s t-test and Mann-Whitney post-test was performed to compare the data when two groups were analyzed. One-way or two-way ANOVA and a Tukey or Bonferroni post-test was used to compare the data when more than two groups were analyzed. The uniform distribution of data, to test inter-donor variation, was assessed using a Chi-squared test. A P ≤ 0.05 indicates a statistical significant difference. The results are shown as mean ± standard deviation.

Results

Inter-donor variability in bone marrow aspirate

The volume of BM aspirated from the different locations varied significant, with larger BM volumes obtained from the ilium (22 ± 7.6 ml) than the proximal femur (6 ± 3.3 ml), distal femur (5 ± 2.9 ml) or proximal tibia (4 ± 2.6 ml). BM volumes from the ilium yielded a higher concentration of MNCs for volumes close to 10 ml (2.6 x 10^{6} MNC/ml), while volumes close and larger than 20 ml yielded a lower concentration of MNCs (1.4 x 10^{5} MNC/ml), however not statistical significant (p = 0.15). Similarly, BM aspirated from proximal femur showed higher MNC yield for volumes lower than 5 ml, 2 x 10^{6} MNC/ml versus 1.6 x 10^{5}
MNC/mL, however not statistical significant (p = 0.7) (Fig. 2A and Table 1).

The concentration of hMSCs obtained at the end of the expansion phase (14 days after MNCs seeding) was on average 566 494 hMSC/mL for the ilium, 245 549 hMSC/mL for the proximal femur, 76 250 hMSC/mL for the distal femur and 122 321 hMSC/mL for the proximal tibia samples (Fig. 2B). No statistical significant differences were found between the groups, however lower p values were obtained from hMSCs isolated from proximal versus distal locations (Additional file 1: Table S1).

Macroscopically, the BM aspirated from the ilium and proximal femur was red, while BM aspirated from distal femur and proximal tibia was yellow, consistent with a higher presence of lipid droplets in the latter (Additional file 2: Figure S1). Compared with the other aspiration locations we observed a significant decrease in BM viscosity for BM aspirated from the proximal tibia (Fig. 2C). The morphological appearance of expanded hMSCs did not show any visible differences between the different BM aspiration locations (data not shown).

Effect of aspiration location on biological characteristics of hMSCs

Proliferation, self-renewal ECM production and multilineage potential (osteogenic- and adipogenic) were assessed for hMSCs isolated from the different locations (Fig. 3). Proliferation capacity and ECM production of hMSC was similar between the different donors regardless of the BM aspiration location (Fig. 3A, B). An average for all donors showed a statistical significant increase in proliferation of hMSCs isolated from distal femur (0.64 ± 0.07) and proximal tibia (0.71 ± 0.08) when compared to the ilium (0.47 ± 0.09) and proximal femur (0.48 ± 0.13) (Fig. 3B), however no statistical significant differences were seen in ECM production (Fig. 3F).

In contrast, the CFU capacity of hMSCs showed a non-uniform distribution for all the donors, independent of the BM location (Fig. 3C). An average for all the donors showed a trend towards a higher CFU capacity of hMSCs isolated from the proximal femur 54 ± 42 CFU than ilium 31 ± 22 CFU, distal femur 14 ± 24 CFU and proximal tibia 19 ± 5 CFU (Fig. 3D). The obtained p values can be visualized in Additional file 1: Table S2.

Similarly, the mineralization capacity showed a similar trend with a higher CFU-Os/Ob potential in hMSCs isolated from the ilium 12 ± 11 CFU-Os/Ob (38% ± 18 CFU-Os/Ob/CFU) and proximal femur 11 ± 10 CFU-Os/Ob (26% ± 16 CFU-Os/Ob/CFU) than distal femur 1 ± 1 CFU-Os/Ob (13% ± 20 CFU-Os/Ob/CFU) and proximal tibia 5 ± 11 CFU-Os/Ob (17% ± 32 CFU-Os/Ob/CFU) (Fig. 3H). The obtained p values can be visualized in Additional file 1: Table S2. The high standard deviation is attributed to the non-uniform distribution over the donors (Fig 3G).

The adipogenic potential of hMSCs showed a uniform distribution for all the donors for BM aspirated from the ilium and proximal femur but not from the distal femur and proximal tibia (Fig. 3I). An average for all the donors showed a significant increase in fat droplets in the proximal tibia 21% ± 6.85 when compared to the ilium 9% ± 2.5. No statistical significant differences were observed between the other groups (Fig. 3J).

Effect of acoustic stimulation on hMSCs

Self-renewal, proliferation, ECM production and multilineage potential (osteogenic- and adipogenic) were assessed from the acoustic stimulated hMSCs.

Different BM volumes harvested from different donors - 11.5 (donor 3), 10 (donor 5), 8 (donor 4), 6 (donor 1), and 5 ml (donor 2) (Additional file 3: Figure S2A) - were stimulated at a frequency of 300 Hz for 5 and 10 min (Additional file 3: Figure S2B–F). Upon acoustic stimulation a significant increase in CFU, mineralization and adipogenesis was observed for hMSC isolated from small BM volumes (5 and 6 ml) compared to larger volumes (8, 10 or 11.5 ml). No statistical significant differences were observed in proliferation or ECM production between the conditions. Based on the above-mentioned results subsequent experiments were performed using small BM volumes (4 ml). An illustration of the device, while 4 ml of BM is acoustic stimulated at 300Hz, is presented in Fig. 4.

Fig. 2 Characterization of BM aspirated (BMA) from different locations. a Correlation between aspirated BM volume and MNCs concentration, for the ilium (grey) and proximal femur (light blue). b Correlation between the plated BM volume and the number of isolated hMSCs. c Heterogenous isolation conditions only. d ECM production and proliferation from different aspiration locations, represented as correlation between the shear rate and the viscosity. The values represented the mean ± standard deviation of three BM donors (n = 3). Statistically significant differences were found with **p < 0.001 and *p < 0.05.
Acoustic stimulation of BM at 300 and 500 Hz for 5 and 10 min did not change hMSC proliferation between the conditions (Fig. 5A, B). In contrast, an increase (not significant) in CFU, ECM production and mineralization but not in adipogenic potential was observed upon acoustic stimulation (Fig. 5c -i).

Surface marker expression on hMSCs isolated from acoustic stimulated BM (300Hz for 5 min) showed a decrease, however not statistically significant, in expression of positive surface markers such as CD105 (22 ± 3% versus 32 ± 17%), CD90 (21 ± 5% versus 23 ± 7%), CD146 (3 ± 1% versus 4 ± 1%) and CD73 (20 ± 8% versus 23 ±
17%), when compared to the baseline (Additional file 4: Figure S3).

**Effect of varying the initial culture condition on hMSCs**

The isolation of hMSCs from the BM was assessed by varying the initial culture conditions and their proliferation, ECM production, multilineage differentiation potential and cell surface marker expression was analyzed. No difference in proliferation (Fig. 6a, b and Additional file 1: Table S3) and osteogenesis (Additional file 5: Figure S4) was observed between the different isolation conditions. In contrast, isolation of hMSCs under SF condition showed a trend in increased ECM production, with 6 out of 6 donors showing statistically significant increase (Fig. 6c). When averaged for all the donors, p values of 0.11 and 0.18 were obtained when compared to heterogeneous and multiclonal conditions (Fig. 6d and Additional file 1: Table S3). Additionally, SF condition showed a trend in decreased adipogenesis, with 5 out of 6 donors showing a statistically significant decrease (Fig. 6e). When averaged for all the donors, p values of 0.48 and 0.13 were obtained when compared to heterogeneous and multiclonal conditions (Fig. 6f and Additional file 1: Table S3). Isolation of hMSCs under multiclonal condition showed a trend towards increased adipogenesis (Fig. 6e). Statistically significant increase in adipogenesis was observed in 5 out of 6 donors in multiclonal when compared to SF isolated hMSCs (Fig. 6e and f, Additional file 1: Table S3).

The expression of CD271, CD34, CD14, CD79a, CD45 and HLA-DR was absent in all conditions regardless of the isolation procedure, while no significant differences where observed in the expression of CD90 (46 ± 31% heterogeneous versus 36 ± 26% multiclonal and 43 ± 36% serum free condition), CD105 (11 ± 6% heterogeneous versus 23 ± 14% multiclonal and 34 ± 31% serum free condition), CD73 (27 ± 7% heterogeneous versus 33 ± 18% multiclonal and 43 ± 33% serum free condition) and CD146 (6 ± 4% heterogeneous versus 5 ± 4% multiclonal and 11 ± 16% serum free condition) between the isolation conditions. However, a trend towards higher expression of CD105 (p = 0.28), CD73 (p = 0.57) and CD146 (p = 0.66) was observed in the hMSCs isolated in SF media when compared to the heterogeneous condition (Additional file 6: Figure S5). The high standard deviation is the result of inter-donor variation.

**Discussion**

The human body has an extensive capacity to regenerate bone tissue after trauma. However, large defects cannot be restored without intervention and often lead to non-union. Long bone fracture repair has been extensively studied at both clinical and as fundamental level, however little is known about the differences in fracture repair between the femur and the tibia [6, 7]. Therefore, the aim of the present study was to assess the pool and biological functions of BM-derived hMSCs in the lower limbs, such as the ilium, proximal femur, distal femur and proximal tibia. Additionally, we broadened our research interest towards methods to prime BM-derived hMSCs for later reimplantation at the fracture site. This should facilitate their homing and commitment towards a faster bone regeneration, as it has been already shown.
Fig. 5 (See legend on next page)
Fig. 5 Biological characterization of isolated hMSCs from apheresic stimulated BM at 300 and 500 Hz for 5 and 10 min. The results are presented as the fold change over the non-stimulated BM baseline. a Proliferation of hMSCs calculated as PD/Day from P1 to P2, donor and isolation procedure dependent. b Proliferation average. c CFU potential of hMSCs donor and isolation procedure dependent. d CFU average. e ECM production, quantification of nodules size area in mm², donor and isolation procedure dependent. f ECM production average. g Adipogenic potential calculated as percentage of ADP positive colonies within the CFU assay, donor and isolation procedure dependent. h Adipogenic average. i Osteogenic potential, quantification of Oil red O staining relative to 100% Oil red O staining solution, donor and isolation procedure dependent. j Osteogenic average. Values are represented as mean ± standard deviation of at least three independent experiments (n ≥ 3). Statistically significant differences were found with ***p < 0.001, **p < 0.01, and *p < 0.05.

Fig. 6 Biological characterization of hMSCs isolated from BM under different isolation procedures. a Proliferation of hMSCs calculated as PD/Day from P1 to P2, donor and isolation procedure dependent. b Proliferation average. c ECM production, percentage of formed nodules, donor and isolation procedure dependent. d ECM production average. e Adipogenic potential, quantification of Oil red O staining relative to 100% Oil red O staining solution, donor and isolation procedure dependent. f Adipogenic average. Values are represented as mean ± standard deviation of at least three independent experiments (n ≥ 3). Statistically significant differences were found with ***p < 0.001 and **p < 0.01.
that a reduced pool of proliferative and multipotent hMSCs are present at the low healing fractures [23].

In the present study we showed that the pool of BM-derived hMSCs differ with respect to the BM aspiration location. We found that after 14 days the number of hMSCs isolated from the ilium and proximal femur was higher (Fig. 2b) and they showed higher self-renewal and osteogenic differentiation potential (Fig. 3d, f) in comparison to hMSCs isolated from the distal femur and proximal tibia, with the latter showing higher adipogenic potential. These findings correspond to the macroscopic appearance of the BM as described by Malkiewicz et al. [24], with red BM found in the ilium and proximal femur, suggesting an active participation to hematopoiesis, and yellow BM found in distal femur and proximal tibia, which is enriched in adipocytes. During aging, red marrow is replaced by yellow marrow and this change in the marrow compartment might contribute to differences in the fracture repair cascade [24]. In this context, we strongly believe that the differences in BFH rate between femur and tibia are the result of insufficient amount of hMSCs present at the fractured site, as well as their poor self-renewal and osteogenic potential. Additionally, previous studies demonstrated the use of bone marrow aspirate and its efficacy in the treatment of fracture nonunion or high nonunion rate repair [25, 26]. Therefore, we propose that the isolation of BM from the ilium, and its delivery to tibial fractures in order to enhance bone healing, could improve the current clinical treatment strategy.

In the process of quantifying the concentration of MNCs with regard to the aspirated BM volume, we found that 10 ml of BM yields the highest MNC concentration. Higher BM volumes yielded low concentrations of MNCs, due to the dilution with peripheral blood during aspiration, while lower BM volumes yielded also lower concentration of MNCs, as described by Fennema EM et al. [27]. Interestingly, in both studies the same average concentration of MNCs (2.6×10^5 MNCs/ml) was found for 10 ml aspirates, henceforth encouraging the surgeons to limit the aspirated BM volume from the ilium to 10 ml.

In order to increase the contribution of cells to bone repair, a new paradigm emerged in tissue regeneration, focusing on rhythms and oscillatory patterns of orchestrating cell fate decision. The use of physical energy, such as ultrasound vibration has shown to affect the cell fate and increase the rate of bone repair [7, 28, 29], however, the therapy has been rather inefficient likely due to the low number of pro-regenerative cells present [6]. Therefore, we propose a different approach: the delivery of acoustic stimulated BM from the ilium (rich in hMSCs) at the fracture site. Based on a previous study by Ridgway J. et al., where acoustic vibration was used to separate cells from BM suspension, by trapping the cells in the pressure node planes of the standing wave and reducing the volume, an increase in CFU-Os potential was observed in the processed BM [22]. We believe that this increase was not only due to the reduction in BM volume but also a change in cell fate. To test this we selected two different frequencies in the range of acoustic vibration, 300 and 500 Hz, and two time points 5 and 10 min. The results obtained showed a trend towards an increased self-renewal, ECM production and a shift towards osteogenic, but not adipogenic, differentiation in acoustic stimulated BM, suggesting that hMSCs may sense the acoustic vibratory frequencies. However, the long expansion period necessary to obtain sufficient cell numbers to perform the assays eventually led to a decrease in the multilineage potential, as cell potential is known to diminish with increased in vitro culture time [30, 31]. In addition, we speculate that the decrease in positive hMSCs surface markers in acoustically stimulated BM is the result of integrin reorganization (cellular mechanoreceptor on the cell surface), followed by surface markers reorganization [32] and change in cell fate. To our knowledge this is the first study where acoustic energy was applied directly to BM and not on cultured cells paving the way to its implementation into a one-step surgical procedure for bone repair. The harvested BM can be first exposed to acoustic stimulation during the surgical intervention followed by administration to the fracture zone in cases where the risk of nonunion is high or in revision surgeries for pseudarthrosis.

While acoustic sound vibration focuses on changing the phenotype of the cells, variation of the initial hMSCs isolation conditions focuses on the selection of a defined cell pool. We found that isolation of hMSCs in SF media selects a pro-ECM cell population, which could be of great help in accelerating the rebuilding process of a native ECM after a bone fracture. In contrast, we found that isolation of hMSCs using low MNC plating densities selects a pro-adipogenic cell population. These findings underline the importance of carefully selecting the right isolation procedure for the right application.

**Conclusion**

Overall, our results suggest that novel approaches to bone fracture healing can be developed based on our improved understanding of bone marrow cell biology. Based on our results we hypothesize that poor BFH in the tibia might be the result of insufficient cell numbers as well as their poor osteogenic potential. Based on this we suggest the aspiration of BM from the ilium and its delivery into the tibia to accelerate fracture healing. Moreover, we proposed two new possible therapeutic approaches for BFH: acoustic stimulation of BM and use of preselected pro-ECM hMSCs pool for delivery at the fracture site.

Assessment of Bone Marrow Aspiration Site Pain in Foot and Ankle Surgery

Abstract: Bone marrow aspiration (BMA) is a validated technique to harvest progenitor cells. BMA has many uses in foot and ankle surgery, however, donor site morbidity is a concern. The purpose of this study was to compare the Visual Analog Scale (VAS) pain scores after BMA at 3 different sites (iliac crest, distal tibia, and calcaneus) over a 12-week postoperative recovery period. This was an institutional review board–approved prospective study of 40 patients who underwent BMA as an adjunct to their primary foot and ankle procedure. Each patient had BMA harvested from the ipsilateral anterior iliac crest, distal tibia, and lateral calcaneus at the time of surgery. Patient follow-up questionnaire forms were filled out at 2, 4, 8, and 12 weeks, with the primary outcome measure being VAS pain scores. Mean VAS scores averaged over the 12-week follow-up period were significantly higher in the calcaneus (20.8 ± 28.5) compared with the distal tibia (7.7 ± 17.6) and the iliac crest (4.2 ± 12.4, p < .05). No significant difference was found between the distal tibia and the iliac crest sites. At 12 weeks, all sites were about equal and without appreciable pain. Our data suggested that donar site selection for BMA affects postoperative pain levels, with BMA from the calcaneus resulting in significantly higher pain scores when compared with the iliac crest or distal tibia. The VAS pain score for the calcaneus was likely confounded by the high number of foot/ankle surgeries performed in the ipsilateral foot.

Levels of Evidence: Therapeutic, Level II: Prospective, comparative trial

Keywords: BMA; osteogenic progenitor cells; postoperative pain

Introduction

Using biological augmentation for healing is growing in popularity among foot and ankle specialists. Bone marrow aspiration (BMA) is used adjunctively in foot and ankle surgery to provide an osteoinductive environment. BMA augments soft tissue and osseous healing by providing hematopoietic cells that have the potential to differentiate into various cells, including osteogenic progenitor cells. The technique for BMA for foot and ankle surgery is validated, straightforward, and simple. Reported complications from BMA are very low.

The purpose of this study was to evaluate postoperative pain via the Visual Analog Scale (VAS) pain score at common BMA harvest sites (iliac crest, distal tibia, and calcaneus) used in foot and ankle surgery.

Methods

This was an institutional review board–approved prospective study. A total of 40 patients underwent BMA as an adjunct to their primary foot and ankle procedure as part of the standard of care at our institution. BMA was done at 3 ipsilateral sites in all patients: iliac crest, distal tibia, and lateral calcaneus. Patients enrolled in the study provided informed consent for the procedure.

Inclusion criteria were a minimum age of 18 years, operative intervention requiring arthrodesis or fracture surgery involving BMA as an adjunct, willingness to provide written informed consent, and availability to complete follow-up questionnaires during the postoperative period.

Reported complications from BMA [bone marrow aspiration] are very low.
Figure 1.
An 11-gauge  × 10-cm Jamshidi needle was used to obtain bone marrow aspirate from the lateral calcaneus and iliac crest.

Figure 2.
Bone marrow aspirate spin down separation.

Figure 3.
The aspirate mixed with cancellous graft was used to augment healing in the patient’s ankle.

Results
In all, 40 patients were prospectively enrolled. There were 22 (55.0%) female and 18 (45.0%) male patients. Of these, 39 patients were available for the 2-week follow-up, 37 for the 4-week follow-up, 37 for the 8-week follow-up, and 33 for the 12-week follow-up. The follow-up rate was 82.5% at week 12. Mean patient age was 51.4 ± 13.3 years, and the mean BMI was 35.9 kg/m². There were 4 (10.0%) isolated ankle fusions, 18 (45.0%) hindfoot reconstructions/fusions, 6 (15.0%) midfoot reconstructions/fusions, 4 (10.0%) forefoot fracture fixations/fusions, 6 (15.0%) combinations of hindfoot and midfoot/forefoot surgeries, and 2 (5.0%) distal tibia fracture fixations.

Mean VAS scores averaged over the 12-week follow-up period were significantly higher in the calcaneus (20.8 ± 28.0) compared with the distal tibia (7.7 ± 17.6) and the iliac crest (1.2 ± 12.4, P < .05). Mean VAS scores between the distal tibia and the iliac crest were not statistically significant (Table 1). At the 2-week follow-up visit, the mean VAS scores with standard deviations were 6.64 ± 18.33 (range = 0 to 100) for the iliac crest, 12.44 ± 21.87 (range = 0 to 77) for the distal tibia, and 35.82 ± 54.52 (range = 0 to 100) for the lateral calcaneus. The 3-week follow-up visit scores were 6.03 ± 15.20 (range = 0 to 82) for the iliac crest, 9.54 ± 20.73 (range = 0 to 82) for the distal tibia, and 17.35 ± 27.79 (range = 0 to 95) for the lateral calcaneus. The 8-week follow-up visit scores yielded 1.22 ± 2.32 (range = 0 to 8) for the iliac crest, 3.41 ± 9.95 (range = 0 to 55) for the distal tibia, and 16.50 ± 25.56 (range = 0 to 100) for the lateral calcaneus. At the 12-week follow-up visit, the mean VAS scores with standard deviations were 3.09 ± 13.87 (range = 0 to 80) for the iliac crest, 5.30 ± 18.03 (range = 0 to 100) for the distal tibia, and 13.84 ± 26.39 (range = 0 to 98) for the lateral calcaneus. Table 2 compares mean VAS scores with standard deviations for the

Consent, and ability to understand the study protocol. Exclusion criteria were previous BMA from the iliac crest, distal tibia or calcaneus, pregnancy, immunosuppression, and active infection or irradiation of the ipsilateral extremity.

BMA was done first from the lateral calcaneus, then from the distal aspect of the tibia, and finally from the iliac crest. An 11-gauge  × 10-cm Jamshidi needle (catalog number 14011X) was used to obtain the aspirate (Figure 1). A volume of aspirate equal to 10 ml was drawn from each site (Figure 2). The aspirate was then used to augment healing in the patient’s foot/ankle in conjunction with the primary surgery (Figure 3).

Patients returned to clinic at 2, 4, 8, and 12 weeks. They were kept non-weight bearing for 8 weeks. At the 8-week mark, they were taken out of the non-weight-bearing cast and placed into a removable walking boot.

Follow-up questionnaire forms were filled out, with the primary outcome measure being the VAS, which was rated on a scale of 0 to 100, with higher numbers being more painful. A 1-way analysis of variance test was used to compare group means at a 95% confidence level.
Table 1.
Mean and Standard Deviation VAS Scores.

<table>
<thead>
<tr>
<th>Postoperative Week</th>
<th>Calcaneus Versus Distal Tibia</th>
<th>Calcaneus Versus Iliac Crest</th>
<th>Distal Tibia Versus Iliac Crest</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0.0002</td>
<td>&lt;0.0001</td>
<td>0.4833</td>
</tr>
<tr>
<td>4</td>
<td>0.0072</td>
<td>0.0035</td>
<td>0.8021</td>
</tr>
<tr>
<td>8</td>
<td>0.0019</td>
<td>0.0001</td>
<td>0.423</td>
</tr>
<tr>
<td>12</td>
<td>0.001</td>
<td>0.0002</td>
<td>0.6228</td>
</tr>
</tbody>
</table>

Abbreviation: VAS, Visual Analog Scale.

Table 2.
P Values of the Mean VAS Scores Between the 3 Anatomical Sites.

<table>
<thead>
<tr>
<th>Postoperative Week</th>
<th>Iliac Crest</th>
<th>Distal Tibia</th>
<th>Calcaneus</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>6.64 (18.33)</td>
<td>12.44 (21.87)</td>
<td>35.82 (34.53)</td>
</tr>
<tr>
<td>4</td>
<td>6.03 (15.20)</td>
<td>9.54 (20.73)</td>
<td>17.35 (27.79)</td>
</tr>
<tr>
<td>8</td>
<td>1.2 (2.3)</td>
<td>3.4 (9.9)</td>
<td>16 (25)</td>
</tr>
<tr>
<td>12</td>
<td>3.09 (13.37)</td>
<td>5.30 (18.03)</td>
<td>13.94 (26.39)</td>
</tr>
</tbody>
</table>

Abbreviation: VAS, Visual Analog Scale.

Iliac crest, distal tibia, and lateral calcaneus.

At all 4 time intervals, the mean VAS score was lowest in the iliac crest and highest in the calcaneus. Iliac crest pain scores from week 2 to week 8 decreased (P = .0167); pain scores from week 2 to week 12 also decreased (P = .0366). Distal tibia pain scores decreased from week 2 to week 8 (P = .0014) and from week 2 to week 12 (P = .0208). Distal tibia pain scores decreased from week 4 to week 12 (P = .0508). Latent calcaneus pain scores decreased from week 2 to week 4 (P < .0001), week 8 (P < .0001), and week 12 (P < .0001). No other statistically significant changes were observed.

Discussion

Biological augmentation with BMA has been used safely and effectively in tibial nonunions, various foot and ankle surgeries, and in distraction osteogenesis of the tibia. Increasing the concentration of progenitor cells in BMA has been shown to result in higher rates of healing that require bone formation. Hyer et al demonstrated that BMA from the iliac crest, distal tibia, and calcaneus contains osteogenic progenitor cells. The highest concentration of progenitor cells came from the iliac crest, whereas there was no difference in concentration between the distal tibia and calcaneus.

BMA has been safe, with very few complications. Although the morbidity and complication profile is low, we decided to evaluate BMA site pain to better counsel our patients on the procedure and bring to light pain profiles postoperatively. Our data suggested that donor site selection for BMA affects postoperative pain levels. The calcaneal donor site was the most painful at all postoperative time points. A confounding variable existed when recording VAS scores at the calcaneus after a patient underwent hindfoot-related surgery. Patients have a hard time distinguishing pain from a Jamshidi needle versus other operative procedures. This may be the reason why the calcaneal site was more painful.

VAS pain levels were significantly different between the calcaneus and the distal tibia and between the calcaneus and iliac crest. No significant difference was found between the iliac crest and distal tibia. Narcotic use was not recorded as a postoperative pain measurement because it would have been a confounding variable because the BMA harvest was a small adjunct procedure supplementing the larger, primary, and presumably more painful procedure.

In conclusion, BMA site pain was lowest when the iliac crest was used and highest with the calcaneus. Distal tibia and iliac crest sites were about the same throughout the study. All sites had improved VAS scores from week 2 through 12.

References


(1). Are podiatrists in your system credentialed to perform supra-malleolar osteotomy of the tibia or fibula to correct a deformity?

Varies by Hospital but Yes for the majority

(2) Are podiatrists in your system credentialed to perform a harvest of bone marrow aspirate from the proximal tibia for foot or ankle surgery?

Varies by Hospital but Yes for some

(6). What education or standards are required as part of your credentialing of podiatrists to perform these procedures? (Please answer separately for each procedure)

The credentialing varies slightly from hospital to hospital

Podiatrists within OhioHealth are credentialed to perform supramalleolar osteotomies of the tibia and fibula to correct deformities and are able to harvest bone marrow aspirate from the proximal tibia for foot and ankle surgery.

The credentialing for these are the same as all Category II privileges.
At initial appointment: required successful completion of podiatric residency accredited by the Council on Podiatric Medical Education (CPMR) training program or equivalent, board certification/eligibility in foot surgery and documentation of performance of at least 25 type two cases, including hindfoot and ankle procedures during the past two years.
At Reappointment: must provide documentation of performance of 25 type II podiatric procedures including foot and ankle procedures with acceptable results for the past two years reflective of the scope of privileges requested based on results of ongoing professional practice evaluation and outcomes. Evidence of current ability to perform procedures listed is required of all applicants.

CATEGORY II PRIVILEGES
Require board certification or board qualification by the American Board of Foot and Ankle Surgery
Documentation of compliance with specified criteria must be submitted at time of request. This includes a letter of competency from your current Section/Department Chair (or equivalent) or your Program Director.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Weight Loss Rules, 4731-11-04 and 4731-11-041

DATE: October 7, 2021

Rules 4731-11-04 and 4731-11-041 regarding the prescribing of controlled substances for weight loss are pending with the Common Sense Initiative. During the comment period, the Board received a request from physicians specializing in bariatric medicine to meet to discuss their concerns. A virtual meeting was held with Dr. Soin and Medical Board staff in November 2020. In January, 2021, the matter was brought to the Board for discussion.

The comments from the bariatric medicine specialists provide information that the standard of care has evolved such that the treatment of obesity as an acute condition is no longer appropriate. Under the current rules, phentermine can be used for acute weight loss, not to exceed 12 weeks, but there is no mechanism for it to be used for chronic weight management. Qsymia is made up of phentermine and topiramate. It is FDA approved for chronic weight management, but since it is a newer drug, it is not generic and is very expensive.

Other comments centered on the in-person visits and whether there is an opportunity to expand telehealth in this area. Elizabeth Adamson of the Ohio Association of Physician Assistants recommended several changes to rule 4731-11-04.1 to eliminate the distinctions between physicians and physician assistants and to better align with current statutes.

The Board discussed that there are three choices:

1. Keep rules as is;
2. Allow chronic use of phentermine with rigid rules;
3. Allow open access.

The Board expressed concerns about abuse and diversion of phentermine and requested research to review rules in other states and to determine if the Board of Pharmacy can assist with research regarding prescribing numbers in other states. The Board of Pharmacy has been supportive of the Board’s rules remaining as is with the twelve week limit pursuant to the FDA labeling requirement.

The Board of Pharmacy reached out to neighboring states to obtain information regarding phentermine and Qsymia prescribing. Kentucky and Michigan were the only states that provided information. Attached you will find the information showing the comparisons for prescribing with Ohio, Kentucky and Michigan.
Kentucky and Michigan both have higher rates of prescribing phentermine than Ohio. According to the most up-to-date census information, Ohio has a total population of 11,799,448; Michigan, 10,077,331 and Kentucky, 4,505,836.

Michigan does not have a rule specifically addressing the prescribing of controlled substances for weight reduction. Kentucky does have a specific rule, which is attached for your review. Some key differences between the two rules are as follows:

- **Kentucky allows use of medication for BMI at 27 or 25 with co-morbidities; Ohio allows controlled substance medication for BMI at 30 or 27 with co-morbidities.**
- **Kentucky allows for prescribing beyond three months if the need is justified in the record and a Kasper report is run. Ohio does not allow for prescribing past 12 weeks in strict accordance with the FDA label. An OARRS report is required.**
- **Kentucky rule requires the steps that must be documented in the record for each office visit but does not set the timeframe for follow up office visits. Ohio requires the physician to meet with the patient every 30 days and to document indicators of substance abuse and adverse effects.**

Seventeen states have some regulation of weight loss drugs: Alabama, Arkansas, Colorado, Florida, Georgia, Indiana, Kansas, Kentucky, Louisiana, Mississippi, New Jersey, Nevada, Oregon, Tennessee, Utah, Virginia and Wisconsin. It does not appear that any of the other states have a strict FDA labeling requirement like 4731-11-04, OAC.

Nevada and Oregon both have a requirement that the controlled substance prescribing may continue beyond three months if there is documentation in the patient’s record of an average 2 pound per month weight loss during active weight reduction treatment or documentation of maintenance of goal weight. Kansas has a similar rule that prohibits the utilization of controlled substances to treat obesity if the patient has not achieved a weight loss of at least 5% of the patient’s initial weight during the initial 90 days of treatment using controlled substances to treat obesity.

Based on my review of the research, I would like to explore option 2, to allow for chronic use of phentermine with rules to set the standard of care and address abuse and misuse.

**Requested Action: Continue working with Dr. Soin, the Pharmacy Board, and bariatric physicians to develop a rule draft that allows for the chronic use of phentermine, a Schedule IV controlled substance for weight loss with rule requirements that prevent overprescribing, abuse and diversion.**
Phentermine Trends

Multi-State Comparison of Phentermine Dispenses
Ohio, Michigan, and Kentucky
2013 – 2020

ANALYST: Amy Brigham
AGENCY: STATE OF OHIO BOARD OF PHARMACY
REFERENCE #:SOMB
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Restrictions on use of amphetamine and amphetamine-like anorectic controlled substances.

RELATES TO: KRS 311.550, 311.595(9), 311.597, 311.842, 311.850(1)(s)
STATUTORY AUTHORITY: KRS 311.565(1), 311.842(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of licensees. KRS 311.595(9) and 311.597 authorize disciplinary action against physicians for specified offenses. KRS 311.842(1) requires the board to promulgate administrative regulations establishing prescribing and administering standards for physician assistants. This administrative regulation establishes the requirements governing the use of amphetamine and amphetamine-like anorectic controlled substances.

Section 1. Definitions. (1) "Board" is defined by KRS 311.550(1).
(2) "Body mass index" means the weight of the patient in kilograms divided by the height in meters, squared.
(3) "Licensee" means a person licensed to practice medicine or osteopathy or to practice as a physician assistant in the Commonwealth of Kentucky and authorized to prescribe, dispense, or administer controlled substances unless otherwise exempted by law.
(4) "Schedule II amphetamine or amphetamine-like controlled substance" means:
(a) Amphetamine, its salts, optical isomers, and salts of optical isomers; or
(b) Methylphenidate.
(5) "Schedule III or IV amphetamine-like controlled substance" means a drug classified as a stimulant pursuant to 902 KAR 55:015, Section 3 or 4.

Section 2. Prior to prescribing, ordering, dispensing, administering, selling, supplying, or giving an amphetamine or amphetamine-like controlled substance, a licensee shall take into account the:
(1) Drug's potential for abuse;
(2) Possibility that a drug may lead to dependence;
(3) Possibility a patient will obtain the drug for a nontherapeutic use;
(4) Possibility a patient will distribute it to others; and
(5) Potential illicit market for the drug.

Section 3. Schedule II Amphetamine or Amphetamine-like Controlled Substances. (1) The patient’s record shall denote the diagnosis that justifies treatment with a Schedule II amphetamine or amphetamine-like controlled substance.
(2) A Schedule II amphetamine or amphetamine-like controlled substance shall be used to treat only:
(a) Narcolepsy;
(b) Attention deficit/hyperactive disorder;
(c) Resistant depressive disorder in combination with other antidepressant medications, or if alternative antidepressants and other therapeutic modalities are contraindicated;
(d) Drug-induced brain dysfunction;
(e) A diagnosis for which the clinical use of the Schedule II amphetamine or amphetamine-like controlled substance is investigational and the investigational protocol has been submitted, reviewed, and approved by the board prior to the clinical use of the drug; or
(f) An adult patient with a moderate to severe binge-eating disorder, if diagnosed according to criteria set forth in the Diagnostic and Statistical Manual of Mental Disorders at the time of
(3) A Schedule II amphetamine or amphetamine-like controlled substance shall not be utilized to treat obesity.

Section 4. Treatment of Obesity with a Schedule III or IV Amphetamine-like Controlled Substance. (1) Prior to prescribing, administering, dispensing, ordering, selling, supplying, or giving a Schedule III or IV amphetamine-like controlled substance to treat obesity in a patient sixteen (16) years of age or older, the licensee shall:
   (a) Establish a licensee /patient relationship;
   (b) Determine that the patient is obese or overweight with medical risk factors and is a proper candidate for weight reduction treatment;
   (c) Determine and record the extent of prior anorectics or other controlled substances used by the patient. The prescribing licensee shall obtain and review a KASPER report for the twelve (12) month period immediately preceding the patient encounter, before prescribing or dispensing controlled substances to the patient;
   (d) Determine that the patient has either:
      1. A body mass index of twenty-seven (27) or more, unless the body mass index is twenty-five (25) to twenty-seven (27) and the patient has a co-morbidity such as a cardiovascular disease, diabetes mellitus, dyslipidemia, hypertension, or sleep apnea;
      2. Body fat greater than or equal to thirty (30) percent in females or greater than or equal to twenty-five (25) percent in males;
      3. Current body weight greater than or equal to 120 percent of a well-documented, long-standing, healthy weight that the patient maintained after age eighteen (18);
      4. A waist-hip ratio or waist circumference at a level indicating that the individual is known to be at increased cardiovascular or co-morbidity risk because of abdominal visceral fat; or
      5. Presence of a co-morbid condition or conditions aggravated by the patient’s excessive adiposity; and
   (e) Provide the patient with carefully prescribed diet, together with counseling on exercise, behavior modification, and other appropriate supportive and collateral therapies.

(2) During treatment for obesity, a licensee shall:
   (a) Maintain a licensee /patient relationship throughout the treatment process;
   (b) Maintain an adequate patient record in accordance with subsection (4) of this section; and
   (c) Justify in the patient record the use of any Schedule III or IV amphetamine-like controlled substance beyond three (3) months. Before the licensee continues the use of a substance beyond three (3) months, the licensee shall obtain and review a current KASPER report.

(3) A licensee shall terminate the use of Schedule III or IV amphetamine-like controlled substances if:
   (a) The patient does not demonstrate weight loss and does not attempt to comply with exercise and dietary changes;
   (b) The body mass index of the patient without a co-morbid condition is less than twenty-seven (27) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;
   (c) The body mass index of the patient with a co-morbid condition is less than twenty-five (25) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;
   (d) The patient has regained the weight lost, using sympathomimetics as part of a complete program and reuse of the medication does not produce loss of the weight gain to help maintain a minimum of five (5) percent weight loss; or
(e) The patient has obtained a Schedule III or IV amphetamine-like controlled substance from another provider without the licensee's knowledge and consent.

(4) The board shall consider the following factors in reviewing the adequacy of a patient record:

(a) Medical history, including:
   1. Illnesses, with particular emphasis on cardiovascular diseases;
   2. Surgery;
   3. Lifestyle;
   4. Medications, including controlled substances;
   5. Eating habits;
   6. Exercise;
   7. Weight gain or loss;
   8. Prior efforts at weight control or reduction;
   9. Prior treatment compliance;
   10. Menstruation or pregnancy; and
   11. Psychiatric history with particular reference to depression, paranoia, psychosis, or chemical dependency;

(b) Social history;

(c) Family history;

(d) Complete physical examination;

(e) Evaluation of laboratory tests including:
   1. CBC;
   2. Fasting blood sugar;
   3. Thyroid panel or TSH;
   4. Lipid profile;
   5. Serum potassium;
   6. Liver function test; and
   7. Renal function test;

(f) An informed consent signed by the patient that cites the limitations and risk of anorectic treatment including potential dependency or psychiatric illness;

(g)1. A signed agreement that the patient has voluntarily agreed to:
   a. Have one (1) prescribing licensee for controlled substances;
   b. Use one (1) pharmacy to fill prescriptions for controlled substances;
   c. Not have early refills on the prescriptions for controlled substances; and
   d. Provide full disclosure of other medications taken; or
   2. Documentation that:
      a. The licensee requested the patient sign an agreement meeting the requirements of subparagraph 1 of this paragraph;
      b. The patient declined to sign the agreement; and
      c. Indicates the licensee’s clinical reasons for prescribing, or continuing to prescribe, a Schedule III or IV amphetamine-like controlled substance to the patient, in light of the patient’s refusal to sign the agreement; and

(h) A record of each office visit, including:
   1. The patient's weight;
   2. The patient's blood pressure;
   3. The patient's pulse;
   4. The presence or absence of medication side effects or complications;
   5. The doses of medications prescribed;
   6. The patient's body mass index; and
7. Evaluation of the patient’s compliance with the total treatment regimen.

Section 5. Waiver. For a legitimate medical purpose, a licensee may apply in writing for a written waiver of any requirement in this administrative regulation. The board may issue a waiver with terms and conditions it deems appropriate.

Section 6. Failure to comply with the requirements of this administrative regulation shall constitute dishonorable, unethical, or unprofessional conduct by a licensee which is apt to deceive, defraud, or harm the public under:

1) KRS 311.595(9) and 311.597; or

2) KRS 311.850(1)(s). (10 Ky.R. 69; eff. 12-2-1983; Am. 13 Ky.R. 1087; eff. 1-13-1987; 15 Ky.R. 1285; 1645; eff. 12-13-1988; 16 Ky.R. 1223; eff. 2-3-1990; 28 Ky.R. 443; 1794; eff. 2-7-2002; 40 Ky.R. 108; 785; eff. 10-16-2013; 42 Ky.R. 2796; eff. 7-20-2016; 47 Ky.R. 364, 941; eff. 11-196-2020.)
ADOPTED REGULATION OF THE
BOARD OF MEDICAL EXAMINERS

LCB File No. R021-15

Effective December 30, 2015

EXPLANATION – Matter in *italics* is new; matter in brackets [*omitted-material*] is material to be omitted.

AUTHORITY: §§1 and 2, NRS 630.130 and 630.275.

A REGULATION relating to standards of practice for the provision of health care; revising provisions relating to certain publications adopted by the Board of Medical Examiners by reference; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:
Existing law authorizes an agency to adopt by reference in a regulation material published by another authority if certain requirements are satisfied. (NRS 233B.040) Under existing regulations, the Board of Medical Examiners has adopted by reference the publication *Nutrition and Your Health: Dietary Guidelines for Americans*. (NAC 630.205) Section 1 of this regulation provides instead that the Board adopts by reference the 7th edition of *Dietary Guidelines for Americans, 2010*, and any subsequent revision of that publication that has been approved by the Board for use in this State.

Existing regulations authorize certain physicians and physician assistants to prescribe an appetite suppressant to control the weight of a patient if certain requirements are satisfied. Those requirements include either a determination by the physician or physician assistant that the patient’s obesity represents a threat to the patient’s health or the fact that the patient’s weight exceeds by not less than a certain percentage the upper limit of the patient’s healthy weight as set forth in the publication *Nutrition and Your Health: Dietary Guidelines for Americans*. (NAC 630.205) Section 2 of this regulation revises this provision to instead refer to the patient’s healthy weight as described in the publication adopted by reference in section 1.

Section 1. NAC 630.187 is hereby amended to read as follows:

630.187 1. The Board hereby adopts by reference [*the*]:

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Adopted Regulation R021-15
(a) The Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013, published by the Federation of State Medical Boards of the United States, Inc. [1]; and

(b) The Dietary Guidelines for Americans, 2010, 7th edition, published jointly by the United States Department of Health and Human Services and the Department of Agriculture pursuant to 7 U.S.C. § 5341,

and any subsequent revision of [the publication] those publications that has been approved by the Board for use in this State. Each revision of [the publication] those publications shall be deemed approved by the Board unless it disapproves of the revision within [60] 180 days after the date of publication of the revision.

2. The most recent publication of [the]:

(a) The Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain that has been approved by the Board will be available for inspection at the office of the Board of Medical Examiners, 1105 Terminal Way, Suite 301, Reno, Nevada 89502, or may be obtained, free of charge, from the Federation of State Medical Boards of the United States, Inc., 400 Fuller Wiser Road, Euless, Texas 76039, or from the Federation of State Medical Boards of the United States, Inc., at the Internet address http://www.fsmb.org.

(b) The Dietary Guidelines for Americans that has been approved by the Board will be available for inspection at the office of the Board of Medical Examiners, 1105 Terminal Way, Suite 301, Reno, Nevada 89502, or may be obtained, free of charge, from the Office of Disease Prevention and Health Promotion of the United States Department of Health and Human Services at the Internet address http://www.health.gov/dietaryguidelines.
3. The Board shall:

(a) Review each revision of [the] a publication described in subsection 1 to ensure its suitability for this State; and

(b) File a copy of each revision of [the] a publication described in subsection 1 that it approves with the Secretary of State and the State Library, [and] Archives and Public Records Administrator.

Sec. 2. NAC 630.205 is hereby amended to read as follows:

630.205 1. A physician or physician assistant who is authorized to prescribe controlled substances may prescribe an appetite suppressant to control the weight of a patient if the appetite suppressant is prescribed for use in the treatment of exogenous obesity as part of a program of medical treatment which includes dietary restrictions, modification of behavior and exercise and:

(a) The physician or physician assistant determines that the patient’s obesity represents a threat to the patient’s health; or

(b) The patient’s weight exceeds by not less than 20 percent the upper limit of the patient’s healthy weight as [set forth in Figure 3 of Nutrition and Your Health] described in the Dietary Guidelines for Americans [], fourth edition, published jointly by the United States Department of Health and Human Services and Department of Agriculture, which the Board hereby adopts] adopted by reference [. A copy of the publication may be obtained from the Consumer Information Center, Department 378-C, Pueblo, Colorado 81009, for the cost of $0.50.] in NAC 630.187.

2. A physician or physician assistant shall not prescribe an appetite suppressant for more than 3 months, unless the patient:
(a) Has lost an average of not less than 2 pounds per month since he or she began taking the appetite suppressant; or

(b) Has maintained his or her weight at the level which was established by the patient's physician or a physician assistant under the supervision of his or her physician.

3. A physician or physician assistant who prescribes an appetite suppressant for more than 3 months shall maintain a record of the patient's weight at the beginning and end of each month during which the patient takes the appetite suppressant.

4. Before prescribing an appetite suppressant, a physician or physician assistant shall obtain a medical history and perform a physical examination of the patient and conduct appropriate studies to determine if there are any contraindications to the use of the appetite suppressant by the patient.

5. As used in this section, “appetite suppressant” means a drug or other substance listed in schedule IV pursuant to NAC 453.540 which is used to suppress the appetite of a natural person.
Chapter 847

Division 15
GENERAL LICENSING RULES, RELATING TO CONTROLLED SUBSTANCES

847-015-0010
Schedule III or IV Controlled Substances — Bariatrics Practice

(1) A licensee shall not utilize a Schedule III or IV controlled substance for purposes of weight reduction, other than in accordance with federal Food and Drug Administration (FDA) product guidelines in effect at the time of utilization and with all the provisions of this rule.

(2) A licensee may utilize a Schedule III or IV controlled substance for purposes of weight reduction in the treatment of Exogenous Obesity in a regimen of weight reduction based on caloric restriction, behavior modification and prescribed exercise, provided that all of the following conditions are met:

(a) Before initiating treatment utilizing a Schedule III or IV controlled substance, the licensee thoroughly reviews the licensee’s own records of prior treatment, or thoroughly reviews the records of prior treatment which another treating health care professional or weight-loss program has provided to the licensee, that one of the following conditions exist:

(A) Patient’s body mass index exceeds 30 Kg/M sq; or

(B) Patient’s body mass index exceeds 27 Kg/M sq and the excess weight represents a threat to the patient’s health (as with hypertension, diabetes, or hypercholesterolemia.)

(b) Before initiating treatment utilizing a Schedule III or IV controlled substance, the licensee obtains a thorough history, performs a thorough physical examination of the patient, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized.

(3) Continuation of Schedule III or IV designated as FDA short term use controlled substances beyond three (3) months requires documentation of an average two (2) pound per month weight loss during active weight reduction treatment, or documentation of maintenance of goal weight. Use of Schedule III or IV controlled substances with FDA approval for bariatric therapy and designated for long term use where FDA guidelines are followed may also be used beyond three months.

(4) A violation of any provision of this rule, as determined by the Board, shall constitute Unprofessional Conduct as the term is used in ORS 677.188(4)(a), (b), or (c), whether or not actual injury to a patient is established.

Statutory/Other Authority: ORS 677.265
Statutes/Other Implemented: ORS 677.188(4) & 677.190(24)

History:
OMB 8-2016, f. & cert. ef. 7-8-16
BME 4-2001, f. & cert. ef. 1-25-01
BME 17-2000(Temp), f. & cert. ef. 10-30-00 thru 2-28-01
BME 9-1998, f. & cert. ef. 7-22-98
ME 1-1997, f. & cert. ef. 1-28-97
ME 1-1995, f. & cert. ef. 2-1-95
ME 1-1987, f. & ef 1-20-87

Please use this link to bookmark or link to this rule.
A person shall not dispense or prescribe controlled substances to treat obesity, as defined by this regulation, except in conformity with the following minimal requirements.

(a) Amphetamines shall not be dispensed or prescribed to treat obesity.
(b) The treating physician shall personally examine the patient. The physical examination shall include checking the blood pressure and pulse, examining the heart and lungs, recording weight and height, and administering any other appropriate diagnostic tests. The examination and patient history shall determine if controlled substances are indicated and if any co-morbidity exists. The treating physician shall enter each of these findings in the patient’s record.
(c) The treating physician shall prescribe nutritional counseling, including behavior modification and appropriate exercise for weight loss, and record these parameters on the patient record.
(d) The treating physician shall not dispense or prescribe more than a 30-day supply of controlled substances, at one time, to treat obesity.
(e) Except as provided by subsection (f) of this regulation, the treating physician may continuously dispense or prescribe controlled substances to treat obesity when the physician observes and records that the patient significantly benefits from the controlled substances and has no serious adverse effects related to the drug regimen. A patient significantly benefits from the controlled substances when weight is reduced, or when weight loss is maintained and any existing co-morbidity is reduced. At the time of each return patient visit, the treating physician shall monitor progress of the patient; the treating physician or a person acting at the treating physician’s order shall check the patient’s weight, blood pressure, pulse, heart, and lungs. The findings shall be entered in the patient’s record.

(f) The treating physician shall not dispense or prescribe additional controlled substances to treat obesity for a patient who has not achieved a weight loss of at least 5% of the patient’s initial weight, during the initial 90 days of treatment using controlled substances to treat obesity.

(g) As used in this regulation, the term “controlled substance” means any drug included in any schedule of the Kansas uniform controlled substances act.

(h) As used in this regulation, the term “obesity” means a documented diagnosis of excess adipose tissue, resulting in body mass index of \(30\) or higher (BMI \(>30\) kg/m\(^2\)), or a body mass index of \(27\) or higher in the presence of other risk factors (BMI \(>27\) kg/m\(^2\)). Body mass index is calculated by dividing measured body weight in kilograms by body height in meters squared (kg/m\(^2\)); expected body mass index is \(20-25\) kg/m\(^2\).

Kan. Admin. Regs. § 100-23-1

134th General Assembly Legislative Update: October 13, 2021 (Bills with activity since the last meeting are noted with **)  

**Actively monitoring**

**HB 122 – Telehealth (Rep. Fraizer)**
To establish and modify requirements regarding the provision of telehealth services.

Of note:
- 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.


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

Of note:
- Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.


**HB 286 – Court of Common Pleas (Rep. Bill Seitz) (companion SB 189)**
To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.

Of note:
- 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.


SB 189 – Change venue for appeal from an agency order (Sen. Lang and Sen. McColley) (companion SB 286)

To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.

Of Note:
• 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.


SB 131 – Occupational Licensing (Reciprocity) (Sen. Roegner and Sen. McColley) (companion HB 203)

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.

Of note:
• Requires automatic licensure of out of state applicants that meet certain criteria.


HB 203 – Occupational Licenses (Rep. Powell) (companion SB 131)

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.

Of Note:
• Requires automatic licensure of out of state applicants that meet certain criteria.


To Regulate the practice of surgical assistants.

Of Note:

- Creates a new license type for surgical assistants to be overseen by the Medical Board.


To revise the law governing the practice of anesthesiologist assistants.

Of Note:

- 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.


Regards drug offenses and treatment.

Of Note:

- 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.
- Limits opioid prescriptions for acute pain to three days. Then, re-examination of the patient is required, and the prescriber may issue a new prescription for more than 3 days.
- Allows health related licensing board to adopt rules specifying circumstances under which a prescriber may issue an initial prescription for an opioid to treat acute pain in an amount that exceeds three days.
- In addition to the three-day limit, allows health related licensing board to adopt rules otherwise limiting the amount of an opioid that may be prescribed in a single prescription.

Closely monitoring


Regards emergency prescription refills.

**Of Note:**

- 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.

**Status:** Passed out the House 5/5/2021. Third Senate Health hearing 10/6/2021.


To exempt certain mental health care providers’ residential and familial information from disclosure under the Public Records Law.

**Of Note:**

- 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.

**Status:** Passed out the House 2/4/2021. Third Senate Health hearing 10/6/2021.


To extend certain timelines for qualified civil immunity and expand immunity to include hearing aid dealers and hearing aid fitters; to authorize emergency medical technicians to administer COVID-19 tests; to expressly cover COVID-19 vaccine injuries under the workers’ compensation system.

**Of Note:**

- Sunsets June 30, 2023
- Provides vaccine mandate exemption for vaccines that have not received an FDA biologics license.
- Most public and private sector would be able to receive exemptions:
  a) Medical contraindications; - shall provide a written statement from primary care provider
  b) Natural immunity: - responsible for any costs or fees associated with demonstrating natural immunity to the employer.
  c) Reasons of conscience, including religious convictions. -shall provide a written statement

**SB 9 – Regulations (Sen. McColley and Sen. Roegner)**

To reduce regulatory restrictions in administrative rules.

**Of Note:**

- 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.


**HB 138 – Emergency Medical Services (Rep. Baldridge)**

Regarding the scope of emergency medical services provided by emergency medical service personnel.

**Of Note:**

- 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.


Regarding electronic prescriptions and schedule II-controlled substances.

**Of Note:**

- Requires that all schedule II drugs be prescribed electronically.


**SB 55 – Massage Therapy (Sen. Brenner) (companion bill HB 81)**

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

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

**Status:** Passed out of Senate health committee 5/19/2021.


To authorize the use of medical marijuana for autism spectrum disorder.

**Of Note:**  
- Allows autism spectrum disorder to be included in qualifying conditions.


**SB 150 — Physician Contracts (Sen. Johnson and Sen. Williams)**

To prohibit the use of noncompete provisions in physician employment contracts.

**Of Note:**  
- Would prohibit the use of noncompete provisions in physician employment contracts.


**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.

**Of Note:**  
- 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.


**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.

**Of Note:**
- Outlines medical treatment for mothers and infants in emergency situations or infants with a disability.


**SB 48 – Cultural Competency (Sen. Maharath and Sen. Antonio)**
To require certain health care professionals to complete instruction in cultural competency.

**Of Note:**
- 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.


**HB 160 – Health Estimates (Health care price transparency) (Rep. Holmes)**
Regarding the provision of health care cost estimates.

**Of Note:**
- 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.


To authorize public bodies to meet via teleconference and video conference.

**Of Note:**
- 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.


**SB 123 – Abortion (Sen. Roegner and Sen. O'Brien)**
To enact the Human Life Protection Act to prohibit abortions based upon a condition precedent.

**Of Note:**
• 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.


**SB 161 – Surgical Smoke (Sen. Brenner)**

Regards surgical smoke.

**Of Note:**

• 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.

**Status:** Introduced in the Senate 4/15/2021. First Senate Health hearing 9/22/2021.


To license and regulate art therapists and music therapists.

**Of Note:**

• Creates a new license type for music therapists to be regulated under the Medical Board

**Status:** Introduced in the Senate 7/1/2021. Assigned to Senate Health 9/8/2021.


To modify the laws governing the practice of advanced practice registered nurses and to designate these provisions as the Better Access, Better Care Act.

**Of Note:**

• 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.


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.

**Of Note:**
- 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.

**Status:** Introduced in the House 5/19/2021. Referred to House Families, Aging and Human Services 6/24/2021.


To license and regulate art therapists and music therapists.

**Of Note:**
- Creates a new license type for music therapists to be regulated under the Medical Board


Regarding pretreatment notice about the possibility of reversing a mifepristone abortion.

**Of Note:**
- 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 who 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.

**Status:** Introduced in the House 7/15/2021. Referred to House Health 9/16/2021.

**HB 388 – Vaccine Refusal (Rep. Jordan)**

To prohibit taking certain actions against an individual because the individual refuses to be vaccinated against a disease.

**Of Note:**
• Prohibits certain discriminatory actions against unvaccinated people

**Status:** Introduced in the House 8/12/2021.


To regulate the practice of certified professional midwives and to name this act the Ohio Midwife Practice Act.

Of Note:

• Regulates the practice of certified professional midwives

**Status:** Introduced in the House 8/12/2021. Referred to House Families, Aging and Human Services 9/21/2021.

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**Operationalizing**

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

Of Note:

• Actively working through implementation

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

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**HB 110 – State Operating Budget (Rep. Oelslager)**

Creates appropriations for FY 2022-2023.

Of Note:

• The Medical Board budget request was granted in the first version of the bill and remained in the final version.

Enacted but no operational changes needed

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.

Of Note:

- 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 a disease to those 13 and older.
- Allows podiatrists to administer vaccinations for individuals seven and older for influenza and COVID-1.


To revise the law governing the practice of athletic training.

Of note:

- 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.
- Amendment was included in the final version to prohibit an athletic trainer from administering intratendinous and intra-articular injections.