Board Members:

Brent Taylor, MD
(Chair)

Lydia Mielke
Public Member
(Secretary)

David Barnes, DO

Matt Heilala, DPM

David Paulson, MD

Samantha Smith, PA-C

David Wilson
Public Member

Upcoming Meetings:

June 19, 2025
at 4:00 p.m.

July 17, 2025
at 4:00 p.m.

August 15, 2025
At 9:00 a.m.

ALASKA STATE MEDICAL BOARD

QUARTERLY MEETING

FRIDAY, MAY 16, 2025

DRAFT – AGENDA - REVISED

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Board/Zoom room during executive session.

Location: 550 W 7th Ave, Atwood Building, Room 1540
To participate by zoom:
https://us02web.zoom.us/meeting/register/NNhnygXqRAqq4_1y_KjqgQ

Agenda

8:30 a.m. 1. Call to Order / Roll Call

8:32 a.m. 2. Review / Approval of Agenda

8:35 a.m. 3. Review / Approval of Minutes

- February 21, 2025
- March 20, 2025
- March 28, 2025
- April 17, 2025

8:40 a.m. 4. Ethics Disclosure

8:45 a.m. 5. Deliberative Session - Closed to the Public
Case #: OAH 23-0113-MED (C.D.)

9:15 a.m. 6. Public Comments & Board Correspondence

9:30 a.m. 7. Full Board Review – Executive Session – Closed to the Public

- Harold Hollander, D.O.
- Jacob Stephenson, D.O.

9:45 a.m. 8. Break

10:00 a.m. 9. Interviews

- Adam Fitzgerald, M.D.
- Justin Sterett, M.D.

10:45 a.m. 10. New Business

- Notice regarding Industrial Hemp

- Medical Spa Work Group Update & Discussion

11:45 a.m. 11. Lunch Break

12:45 p.m. 12. Investigations Update – Executive Session – Closed to the Public
- Investigation and Probation Quarterly reports
- Case# 2023-001023, W.A.
- Case# 2024-001176, R.C.
- Case# 2024-001224, C.F.
- Case# 2023-000549. K.P.
- Case# 2024-000094, K.S.

1:45 p.m. 13. Old Business
- 2025-2026 Board Priorities / Goal
- FY 2025 Annual Board Reports
- Reauthorization – Delegation of Authority

2:45 p.m. 14. Break

3:00 p.m. 15. Malpractice Case Reviews – Executive session -Closed to the Public
- Daniel Bade, MD
- David Christianson, MD
- James Cagle, DO
- Kara Perrelli, MD
- Ravi Patel, DO
- Scott Boruchov, MD
- Stephen Kujansuu, MD
- Thomas Kelley, DO

4:00 p.m. 16. Wrap Up / Adjourn

Tentative date for the next meeting: June 19, 2025, at 4:00 p.m.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Friday, February 21, 2025

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a quarterly meeting of the Alaska State Medical Board was held Friday, February 21, 2025.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Taylor at 8:31 a.m.

Roll Call
Board members present:

David Barnes, DO
Matt Heilala, DPM
Sarah Bigelow Hood, PA-C (Vice-Chair)
Lydia Mielke, Public Member (Secretary)
David Paulson, MD
Brent Taylor, MD (Chair)
David Wilson, Public Member

Board staff present: Natalie Norberg, Executive Administrator; Jason Kaeser, Licensing Supervisor; Kendra Senior Investigator; Shelley Irons, Investigator

2. **Review / Approval of Agenda**

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote the Alaska State Medical Board approved the agenda as presented.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow-Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

3. **Review/Approval of Minutes**

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved the minutes for the November 15, 2024; December 19, 2024; and January 16, 2025, meetings with corrections as noted for the November 15, 2024 minutes.

It was noted that Dr. Heilala's name was missing from some of the roll call votes during the November 14, 2024, meeting minutes, although he was present for the entire meeting. It was

agreed that the EA would correct any errors concerning Dr. Heilala's voting record during the November 14 meeting before finalizing the minutes.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow-Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

4. Ethics Disclosures

Ethics reporting by board members is done on a quarterly basis and is a standing item on the quarterly meeting agenda. The Chair requested Ms. Norberg query each board member.

There were no ethical disclosures made by board members.

5. Pharmacy Agreement Presentations

Chair Taylor invited Ashley Schaber, Chair, Board of Pharmacy and Brandy Seignemartin, Executive Direction, Alaska Pharmacy Association to address the board. Both presenters shared slides. Dr. Schaber provided an overview of the history and purpose of Cooperative Practice Agreements, emphasizing that practice agreements help to increase access to patient care. Dr. Seignemartin explained how the education, training and experience obtained by pharmacists prepares them to participate in direct patient care through a standard of care model. The presenters responded to questions and concerns from board members.

6. Public Comments

Chair Taylor opened the floor for members of the public to address the board.

- **Sarah Spencer** introduced herself as a physician, board certified in family and addiction medicine. Dr. Spencer explained that Cooperative Practice Agreements are a critical tool to addressing the opioid abuse pandemic in Alaska. One of the most effective treatments to opioid use disorder is long-acting injective buprenorphine, a medication that lasts for 30 days. Using cooperative practice agreements, patients can be the administered the medication by a pharmacist at a location much more convenient and accessible to the patient. Dr. Spencer urged the Board to approve cooperative practice agreements for the treatment of opioid use disorders.
- **Donna Galbreath** introduced herself as a family practice doctor at Southcentral Foundation and ANMC. Dr. Galbreath shared how pharmacists are embedded in their practice and part of their clinical team. Physicians rely on pharmacists to help monitor patients on their medications and make adjustments as needed based on protocols. Dr. Galbreath urged the Board to approve the ANMC agreement.

7. Old Business

- **Pending Physician Pharmacy Agreements**

Chair Taylor facilitated a discussion regarding the three pending Physician-Pharmacy Cooperative Practice agreements presented for the Board's consideration for approval. Board members expressed concerns regarding the breadth of clinical activities to be delegated to pharmacists as detailed in some of the agreements. However, it was also noted that there are approximately 27 agreements already in use in Alaska, that were previously approved by the Board, in which the clinical activities attributed to pharmacists mirrors or exceeds the duties outlined in the agreements before the Board today.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood the Alaska State Medical Board approved the Physician-Pharmacy Cooperative Practice agreements as

presented for ANMC & the Southcentral Foundation; ANMC and their Diabetes Clinic and Foundation Health.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow-Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

- **Telehealth Regulations**

Dr. Taylor reminded the board that a decision regarding whether to adopt the 2022 FSMB guidelines, *Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, by reference into regulation to replace the 2014 FSMB guidelines was tabled during a previous meeting. As requested, Ms. Norberg presented a side-by-side comparison of the 2014 and the 2022 guidelines.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board decided to adopt the 2022 FSMB Telemedicine guidelines by reference to replace the 2014 guidelines referenced in regulation 12 AAC 40.943 (a) and initiate a regulation project to reflect this change.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow-Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

Break - the Board went off the record for a break at 10:14 a.m. and returned on the record at 10:30 a.m.

- **Legal Consultation**

Chair Taylor recommended the Board enter into executive session.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, the board entered executive session in accordance with AS 44.62.310(c)(3), for the purpose of discussing a matter related to attorney-client privilege with AAG Liz Leduc and Board staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The Board entered executive session at 10:32 a.m. The Board returned on the record at 11:12 a.m.

8. New Business and Board Correspondence

- **Legislative Priorities & Board Liaison**

Chair Taylor invited Jenny Fayette, with the Alaska Physician Assistant Association to introduce and explain the newly introduced SB 89, pertaining to Physician Assistant scope of practice. Ms. Fayette responded to questions and concerns from board members regarding language in the bill concerning insurance parity, surgery, criteria for determining a practice specialty, assessment, and rural practice. Members of the board voiced concerns about physician assistants being given parity of practice with family physician practitioners; concerns about a lack of transparency regarding the motivation for seeking independent practice and concerns about the rigidness of having scope of practice detailed in statute rather than regulation, which allows less flexibility to fix problems when they arise.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, the Alaska State Medical Board directed the Executive Administrator to work with the Board Chair to draft a letter to be addressed to members of the legislature in favor of SB 89 but with recommendations.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Taylor, and Mr. Wilson.
Nays: Dr. Paulson

Chair Taylor opened the floor for a discussion regarding whether to elect a legislative liaison. Several members of the board voiced their support for a liaison. Dr. Heilala volunteered for this role.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, the Alaska State Medical Board delegated Dr. Heilala to represent the Board in legislative matters.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

9. Lunch Break - The Board recessed for lunch at 12:02 p.m. and returned on the record at 12:40 p.m.

- **Legislative Priorities continued – HB 95 pertaining to Midwife scope of practice**.

Chair Taylor opened the floor for a discussion regarding HB 95. It was noted that this bill appears to expand the scope of practice for midwives and prohibits midwives from being required to be under the supervision of a physician. Questions were raised regarding the meaning and depth of "preconception care." Board members generally agreed to postpone making a statement regarding the bill.

10. Board Interview

Dr. Taylor queried Mr. Bossert who requested to have his interview conducted in executive session.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions, for the purpose of discussing Gerald Bossert's application for licensure with Mr. Bossert to remain for part of the session and Board staff to remain during the entire session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The Board entered executive session 12:58 p.m. The Board returned on the record at 1:17 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved Gerald Bossert a license to practice as a physician assistant in the state of Alaska.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

11. Deliberative Session

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered a deliberative session under AS 44.62.310(d) solely concerning a partial reconsideration in the Office of Administrative Hearing's findings

In the Matter of Timothy Carey,
Office of Administrative Hearings Case Number 24-0001-MED
Board Case Numbers: 2022-000262/276/436 & 20223-000119

with ALJ Cheryl Mandala and special counsel to the Board, AAJ Robert Bacaj included if invited and all others to be excluded during the deliberative session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The Board entered executive session 1:21 p.m. The Board returned on the record at 1:31p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board decided to take no further action in the Timothy Carey matter as referenced.

It was noted that no counsel was invited to join the Board during the deliberative session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

12. Investigations

- **Case#: 2022-001090**

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board entered executive session in accordance with AS 44.62.310(c)(4), for the purpose of discussing Case# 2023--000070, with Board and Investigative staff remaining during the session and the reviewing board member excluded from the session.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

The Board entered executive session at 1:33 p.m. The Board returned on the record at 1:55 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and decided by roll call vote, the Alaska State Medical Board tabled a decision in Case# 2023—000070 until further information is gathered.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

Abstained: Dr. Heilala

- **DUI Policy and Flowchart**

Chair Taylor invited Investigator Wardlaw to address the Board. First, Ms. Wardlaw introduced herself, noting that she was recently promoted as the Senior Investigator for the Medical Board and PDMP program, replacing Sonia Lipker and Billy Homestead in these roles. Ms. Wardlaw also introduced newly assigned investigators to the Medical Board, Aaron Poland and Jesse Massey. Next, Ms. Lipker explained that a procedural concern has been raised related to referrals to the Physician Health Committee (PHC) when the referral is not "ordered" by the Board. The problem is when the PHC recommends follow up treatment for a self-referred licensee and the licensee refuses to follow those recommendations; there is no recourse or mechanism to enforce the recommendations. A potential solution would be to draft regulation making it an offense considered unprofessional conduct for failure to comply PHC recommendations. It was clarified that such an offense would trigger an investigation, followed by review and action to be taken by the board; the PHC would not be given independent authority to discipline a licensee.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board decided to direct Senior Investigator Wardlaw to work with the department of law to recommend a regulatory change to be presented to the board for consideration concerning the referral process for licensees who refuse to comply with PHC recommendations.

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

13. **Applicant Review**

Board members were queried about their individual applicant reviews, no concerns were identified.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Alaska State Medical Board approved the following list of applicants for full licenses:

	Lic Type	First Name	Last Name
1.	DO	Lance	Robbins
2.	MD	Iram	Ahmad
3.	MD	Paul	Beck
4.	MD	Mark	Byard
5.	MD	John	Diveris
6.	MD	Steven	Foley
7.	MD	Timo	Hakkarainen
8.	MD	Patrick	Healey
9.	MD	Angela	Jackson-Lopez
10.	MD	Gregory	Myrick
11.	MD	William	Seeds
12.	MD	James	Sibbet
13.	MD	George	Wu

14.	PA	John	Milstead
15.	PA	Cheryl	McGovern

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

14. Break the Board went off the record for a break at 2:27 p.m. and returned on the record at 2:39 p.m.

15. Malpractice Case Reviews

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Board entered executive session in accordance with AS 44.62.310 (c)(3), and Alaska Constitutional Right to Privacy Provisions, with board staff to remain in the session, for the purpose of discussing malpractice cases involving the following practitioners:

1) John Adan, MD
2) Peter Buetow, MD
3) Priscilla Codiga, MD
4) Peggy Downing, MD
5) Taichi Imamura, MD
6) Debra Kontny, DO
7) Samantha Lancaster, MD
8) Marc Slonimski, MD
9) Eric Wallace, MD
10) David Wrigley, MD

The Board entered executive session at 2:40 p.m. The Board returned on the record at 3:07 p.m.

On a motion duly made by Ms. Mielke, seconded by Ms. Bigelow Hood, and approved by roll call vote, the Board decided to take no further action with respect to the malpractice cases related to the following physicians:

1) John Adan, MD
2) Peter Buetow, MD
3) Priscilla Codiga, MD
4) Peggy Downing, MD
5) Taichi Imamura, MD
6) Debra Kontny, DO
7) Samantha Lancaster, MD
8) Marc Slonimski, MD
9) Eric Wallace, MD
10) David Wrigley, MD

Roll Call: Yeas, Dr. Barnes, Ms. Bigelow Hood, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, and Mr. Wilson.

16. Wrap up/Adjourn

Dr. Taylor and members of the Board acknowledged and thanked Ms. Bigelow Hood and Ms. Mielke for their many years of service to the Board, whose terms will end on March 1, 2025. Both Ms. Bigelow Hood and Ms. Mielke have graciously agreed to remain on the Board as is allowed by regulation until their replacements have been appointed.

The next meeting is scheduled for March 20, 2025, at 4:00 p.m.

The meeting was adjourned by unanimous consent at 3:12 p.m.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Thursday March 20, 2025

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a special meeting of the Alaska State Medical Board was held Thursday, March 20, 2025.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Taylor at 4:04 p.m.

New member, Samantha "Sam" Smith, PA-C was welcomed and invited to introduce herself. Ms. Smith moved from Maryland to Alaska approximately 5 years ago with an educational background in orthopedic and sports medicine. She currently practices in Anchorage in regenerative and biophysics medicine. She is inspired by the hard-working citizens of Alaska and is committed to ensuring they have good health care.

Roll Call
Board members present:
Brent Taylor, MD, Chair
David Barnes, DO
Samantha Smith, PA-C
Matt Heilala, DPM
Lydia Mielke, Public Member (Secretary)
David Wilson, Public Member

Absent: David Paulson, MD

State employees present: Kendra Wardlaw, Lead Investigator; Jason Kaeser, Licensing Supervisor; and Natalie Norberg, Executive Administrator

2. Review / Approval of Agenda

On a motion duly made by Ms. Mielke and seconded by Dr. Heilala. the Alaska State Medical Board approved the agenda as presented.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

3. Investigations Update

On a motion duly made by Ms. Mielke and seconded by Dr. Heilala, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(4, for the purpose of

discussing Case#2023-000878 and 2023-001036 with Division staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

The Board entered executive session at 4:09 p.m. The Board returned on the record at 4:13 p.m.

On a motion duly made by Ms. Mielke and seconded by Dr. Barnes the Alaska State Medical Board accepted the imposition of civil fines as presented in case numbers 2023-000878 and 2023-001036.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

On a motion duly made by Ms. Mielke and seconded by Dr. Taylor, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(4, for the purpose of discussing Case # 2024-000994 with Division staff remaining during the session and reviewing board members excluded from the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

The Board entered executive session at 4:13 p.m. The Board returned on the record at 4:23 p.m.

On a motion duly made by Ms. Mielke and seconded by Dr. Heilala the Alaska State Medical Board accepted the voluntary surrender of license for Michael Todd in Case # 2024-000994.

Roll Call: Yeas, Dr. Heilala, Ms. Mielke, Ms. Smith, Mr. Wilson
Abstained: Dr. Barnes and Dr. Taylor
Absent: Dr. Paulson

On a motion duly made by Ms. Mielke and seconded by Dr. Heilala, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(4, for the purpose of discussing Case # 2023-000195 with Division staff remaining during the session and reviewing board members excluded from the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

The Board entered executive session at 4:27 p.m. The Board returned on the record at 4:47 p.m.

On a motion duly made by Ms. Mielke and seconded by Dr. Taylor the Alaska State Medical Board accepted the consent agreement as proposed in Case #2023-000195.

Roll Call: Yeas, Ms. Mielke, Ms. Smith, Mr. Wilson and Dr. Taylor
Abstained: Drs. Barnes and Heilala
Absent: Dr. Paulson

4. Deliberative Session

On a motion duly made by Ms. Mielke and seconded by Dr. Taylor the Alaska State Medical Board entered into a deliberative session in accordance with AS 44.62.310(d) solely to make a decision concerning the Office of Administrative Hearing's decision in the matter of Brent Meredith, Office of Administrative Hearings Case Number 24-0640-MED with Administrative Law Judge Joan Wilson to be included if invited and all others to be excluded during the deliberative session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

The Board entered the deliberative session at 4:51p.m. The Board returned on the record at 5:58 p.m.

It was noted that Administrative Law Judge Joan Wilson was not invited to join the deliberative session.

On a motion duly made by Ms. Mielke and seconded by Dr. Taylor the Alaska State Medical Board accepted the consent agreement as presented by the Office of Administrative Hearing in accordance with AS 44.64.060(e)(1) in the matter of Brent Meredith, Office of Administrative Hearings Case Number 24-0640-MED.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

5. Board Statement

Chair Taylor opened the floor for board members to discuss a draft statement on the treatment of gender dysphoria in minors. Dr. Heilala acknowledged that a primary mission of the Board is the protection of public health and safety, and as it pertains to minors, this mission is taken very seriously. He asserted that after extensive deliberation and thought, which is "rooted in compassion and concern for families and individuals facing this issue" the Board should formalize its position on this topic. Board members including Dr. Barnes and Ms. Smith voiced their support for the statement, noting that the statement is well written and emphasizes evidenced-based care.

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by a roll call vote, the Alaska State Medical Board adopted the statement as presented concerning the treatment of gender dysphoria and minors and approved to have the statement conveyed to the legislature.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by a roll call vote, the Alaska State Medical Board delegated Dr. Heilala as the board's liaison to communicate to the legislature regarding this statement.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson

Absent: Dr. Paulson

6. New Physician-Pharmacy Agreement

Chair Taylor invited board members to discuss the Genoa Health Physician Pharmacy Cooperative Practice agreement presented for the Board's approval. Ms. Norberg provided a brief overview of the agreement, confirming that all requested edits were made, and the agreement is in compliance with all regulatory requirements.

On a motion duly made by Ms. Mielke, seconded by Dr. Heilala and approved by a roll call vote, the Alaska State Medical Board approved the Physician Pharmacy Agreement for Genoa Health Care as presented.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

On a motion duly made by Ms. Mielke, seconded by Dr. Heilala and approved by a roll call vote, the Alaska State Medical Board granted Dr. Taylor the authority and discretion to approve physician pharmacy agreements on behalf of the board in the future as appropriate.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

7. Reconsideration: Letter of Support for SB 89

Chair Taylor explained that the Board received a letter of concern from the Alaska State Medical Association (ASMA) with respect to the Medical Board's letter of conditional support sent to legislators regarding SB 89. ASMA's letter requests that the Medical Board amends it letter to the legislature. Chair Taylor invited board members to offer their input on this request. Ms. Smith noted that one of the concerns identified in the ASMA letter was the limited clinical experience of physician assistants. Ms. Smith provided examples from her training and education, stating the students in her cohort averaged 3000 hours of clinical experience before entering their physician assistant program, and most students have extensive work experience in a clinical health setting before obtaining their physician assistant degree. Dr. Heilala shared that he spoke with several legislators concerning the bill and a common theme is that they want to see physician assistants work for more than 4000 hours with a collaborating physician before obtaining independent practice. Dr. Heilala suggested that to assist with having the bill pass, the Board should recommend increasing the number of hours that physician assistant works under a collaborative plan. Several board members voiced support for an increase in supervised hours. Chair Taylor recognized members of the public, Lisa Alexia and Mehan Hall, to answer board member questions regarding the training and credentialing process for nurse practitioners. Chair Taylor also recognized member of the public, Jenny Fayette, who reiterated that physician assistants are not trying to be recognized as being on the same level as physicians and, having physician assistant training experience match a physician's training level is not the purpose of this bill. Ms. Fayette stated there are three times as many nurse practitioners practicing in Alaska as there are physician assistants. She further stated that physician assistants deserve parity in the work force, which is why the physician assistants' profession needs to be solidified in statute, which is what SB 89 does, while still allowing the Medical Board the ability to regulate certain aspects of licensing. Ms. Norberg reminded meeting participants that the meeting was not intended nor noticed as being open for oral public comments.

Chair Taylor highlighted the four specific recommendations made by ASMA, encouraging board members to weigh in. Board members voiced general support for adopting all four of the recommendations.

On a motion duly made by Me. Mielke, seconded by Dr. Taylor and approved by a roll call vote, the Alaska State Medical Board agreed to direct the Executive Administrator and Board Chair to revise and re-transmit its letter of conditional support for SB 89 to request that the bill be amended to include the four points as discussed:

- **Increasing the experience hours for initial independent licensing from 4000 to 10000**
- **Requiring a minimum number of 6000 hours (rather than a maximum) to switch specialties**
- **Specifying that a physician assistant shall practice at a licensed health care facility, facility with a credentialing and privileging system, physician-owned facility or practice, or facility or practice approved by the state medical board.**
- **Requiring clarity and transparency about credentials when providing or advertising medical services.**

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Dr. Paulson

8. Wrap up / Adjourn

Board members were advised that the need for a special meeting next week is anticipated for the consideration of a summary suspension. Board members agreed to hold meeting at 4:00 PM on Friday, March 28.

The meeting was adjourned by unanimous consent at 5:44 p.m.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Friday, March 28, 2025

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a special meeting of the Alaska State Medical Board was held Friday, March 28, 2025.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Taylor at 4:00 p.m.

Roll Call
Board members present:
Brent Taylor, MD, Chair
David Barnes, DO
Samantha Smith, PA-C
Matt Heilala, DPM
David Wilson, Public Member

Absent: Lydia Mielke and David Paulson, MD

State employees present: Kendra Wardlaw, Lead Investigator, Shelley Irons, Investigator and Natalie Norberg, Executive Administrator

2. Review / Approval of Agenda

On a motion duly made by Dr. Heilala and seconded by Dr. Taylor, the Alaska State Medical Board approved the agenda as presented.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Smith, Dr. Taylor, Mr. Wilson
Absent: Ms. Mielke, Dr. Paulson

The zoom call was briefly ended and resumed at 4:06 p.m.

Roll Call
Board members present:
Brent Taylor, MD, Chair
David Barnes, DO
Samantha Smith, PA-C
Matt Heilala, DPM
David Paulson, MD

Absent: Lydia Mielke and Mr. Wilson

3. Investigations Update

On a motion duly made by Dr. Heilala and seconded by Dr. Taylor, the Alaska State Medical Board entered into executive session in accordance with AS 44.62.310(c)(4, for the purpose of discussing case numbers 2024-000586 and 2024-000698 with Division staff remaining during the session and the reviewing board member excluded from the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Dr. Paulson Ms. Smith, Dr. Taylor
Absent: Lydia Mielke and Mr. Wilson

The Board entered executive session at 4:08 p.m. The Board returned on the record at 4:11 p.m.

Mr. Wilson rejoined the meeting at 4:10 p.m.

On a motion duly made by Dr. Heilala and seconded Dr. Taylor the Alaska State Medical Board granted the Division's Petition as presented and ordered a summary suspension of physician license #MEDS3364 in case numbers 2024-000586 and 2024-000698.

Roll Call: Yeas, Dr. Heilala, Dr. Paulson, Ms. Smith, Dr. Taylor, Mr. Wilson
Abstained: Dr. Barnes
Absent: Lydia Mielke

4. Wrap up / Adjourn

Board members were advised that the next meeting is scheduled for Thursday, April 17, 2025, at 4:00 p.m.

The meeting was adjourned by unanimous consent at 4:14 p.m.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING

STATE MEDICAL BOARD
MINUTES OF MEETING
Thursday April 17, 2025

These are DRAFT minutes prepared by staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, a meeting of the Alaska State Medical Board was held Thursday, April 17, 2025.

1. Call to Order/ Roll Call
The meeting was called to order by Chair Taylor at 4:02 p.m.

Roll Call
Board members present:
Brent Taylor, MD, Chair
David Barnes, DO
Matt Heilala, DPM
Lydia Mielke, Public Member (Secretary)
David Paulson, MD

Absent: Samantha Smith, PA-C
David Wilson, Public Member

State employees present: Charley Larson, Investigator, Kendra Wardlaw, Lead Investigator; Jason Kaeser, Licensing Supervisor; and Natalie Norberg, Executive Administrator

2. Review / Approval of Agenda

On a motion duly made by Ms. Mielke and seconded by Dr. Heilala. the Alaska State Medical Board approved the agenda as presented.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor
Absent: Ms. Smith and Mr. Wilson

3. Ethics Disclosure
The Chair asked board members regarding any potential financial or personal conflicts to declare. There were no ethical disclosures made by board members.

Mr. Wilson joined the meeting at approximately 4:08 p.m.

4. Board Interview
Chair Taylor asked Dr. Salahuddin Ahmed whether he would like to have his interview in public or in private. Dr. Ahmed chose to have his interview in public. Dr. Ahmed answered questions from the Chair and board members concerning current state licenses, clinical privileges and employment status, as well

as questions regarding his completion of requested evaluations. Dr. Ahmed granted permission for the board to deliberate regarding his application in executive session.

On a motion duly made by Ms. Mielke, seconded by Dr. Barnes and approved by roll call vote, the Alaska State Medical Board entered executive session in accordance with AS 44.62.310(c)(2), and the Alaska Constitutional Right to Privacy Provisions for the purpose of discussing Dr. Ahmed's application for licensure with Ms. Norberg remaining during the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

The board entered the executive session at 4:14 p.m. and returned on the record at 4:21 p.m.

On a motion duly made by Dr. Taylor and seconded by Mr. Wilson the board approved to grant Dr. Ahmed a license to practice in Alaska.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

5. Investigations Update

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by roll call vote, the Alaska State Medical Board entered executive session in accordance with AS 44.62.310(c)(4), for the purpose of discussing Case numbers: 2023-001128, 2024-000301, 2024-000531, and 2023-000334 with Division staff remaining during the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

The board entered the executive session at 4: 24 p.m. and returned on the record at 4:28 p.m.

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by roll call vote, the Alaska State Medical Board accepted the imposition of civil fines as presented in case numbers: 2023-001128, 2024-000301, 2024-000531, 2023-000334.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by roll call vote, the Alaska State Medical Board entered executive session in accordance with AS 44.62.310(c)(4), for the purpose of discussing Case# 2019-000664 with Division staff to remain during the session and the reviewing board member excluded from the session.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

The board entered the executive session at 4:30 p.m. and returned on the record at 4:34 p.m.

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by roll call vote, the Alaska State Medical Board accepted the voluntary surrender of license for Dr. Claribel Tan.

Roll Call: Yeas, Dr. Barnes, Ms. Mielke, Dr. Paulson, Dr. Taylor, Mr. Wilson
Abstained: Dr. Heilala
Absent: Ms. Smith

6. Division / Legislative Update

Deputy Director Saviers was invited to address the Board. The Deputy Director introduced and requested the board's support for the Nurse License Compact and Universal Temporary Licensing bills. Ms. Saviers responded to questions related to the nature of the Nursing Association's opposition to the Compact, whether the public was contacted to weigh in on the Nurse Compact and whether the temporary licensure bill would change the way the medical board currently issues temporary licenses. Next, Ms. Saviers provided an overview of Senate Bill 147 and its companion bill, House Bill 195 related to Pharmacist Prescriptive Authority.

7. Pharmacy Board Update

Dr. Ashley Schaber, Chair of Board of Pharmacy, was invited to provide the board with additional information regarding the Pharmacist Prescriptive Authority bills. Dr. Schaber responded to questions related to how the levels of expertise are determined for pharmacists, the determination of the conditions that pharmacists would be allowed to treat independently, the liability for misdiagnosis, the billing process, whether pharmacists carry malpractice insurance, and the accountability process for pharmacists when a patient has a complaint. Board members voiced concerns about pharmacists causing patient harm by treating patients outside of their experience and training and about pharmacists in general not having the training to provide patient care. A board member reported a lack of trust and frustration when pharmacists refuse to fill prescriptions ordered by a physician.

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by roll call vote, the Board directed the executive administrator to work with the Chair to draft a letter of support for HB 158 and SB 145 related to Professional Licensing to be forwarded to members of the legislature.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson, Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by roll call vote, the Board directed the executive administrator to work with the Chair to draft a letter of support for HB 131 and SB 124 related to the Nurse License Compact to be forwarded to members of the legislature.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

A letter drafted by Dr. Taylor, containing language in opposition to the Pharmacist Prescriptive Authority bills, was presented. Board members stated they agreed with the letter and believed it was brief and well written.

On a motion duly made by Ms. Mielke, seconded by Dr. Taylor and approved by roll call vote, the Board approved the draft letter of opposition to SB 147 as presented.

Roll Call: Yeas, Dr. Barnes, Dr. Heilala, Ms. Mielke, Dr. Paulson Dr. Taylor, Mr. Wilson
Absent: Ms. Smith

8. Wrap up / Adjourn

The next board meeting will be an in-person meeting held in Anchorage, and also accessible by zoom on May 16, 2025, from 8:30 to 4:30 p.m.

The meeting was adjourned by unanimous consent at 5:41 p.m.

From: sarah spencer <sarahspencerak@gmail.com>
Sent: Friday, February 21, 2025 5:51 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Public Comment for feb 21 2025 meeting

I will be attending the board meeting this morning to make comment on the update to regulations on pharmacist collaborative agreements and wanted to include links to these resources related to this topic

The first is the American Society of Addiction Medicine Public Policy Statement on the Role of Pharmacists in Medications for Addiction Treatment,

The second is an article highlighting a project to expand access to long-acting injectable buprenorphine through telemedicine and pharmacy administration.

in 202 and 2023 Alaska experienced the greatest increases in overdose death nationwide. Pharmacists can play a key role in expanding access to medication for opioid use disorder (MOUD) in Alaska.

https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/public-policy-statements/final-pps-on-the-role-of-pharmacists-in-medications-for-addiction-treatment_with-amendments.pdf?sfvrsn=d3dac290_1

https://drugstorenews.com/bicycle-health-make-sublocade-available-patients-albertsons-pharmacies

From: Jenny Fayette <jennyfayette@yahoo.com>
Sent: Saturday, February 22, 2025 9:17 AM
To: Norberg, Natalie M (CED) <natalie.norberg@alaska.gov>
Subject: Follow Up SB89

Dear Alaska State Medical Board,

Thank you for reviewing the new PA Modernization Senate Bill (SB89) and for allowing us to address your questions.

We appreciate your recognition of the PA profession's vital contributions to Alaska's healthcare team and your support for our efforts to secure statutory recognition.

Attached, please find the research submitted with the previous SB115 bill packet, that was referenced in the meeting.

I have also included articles on medical school and PA enrollment, and the latest Alaska workforce report.

Recent data indicate that MD enrollment continues to increase—approaching 100,000 students nationwide—and PA enrollment remains stable at about 560 new students per year. Thankfully no decline in enrollment has happened for either profession.

As I referenced as well, the 2024 Alaska Healthcare Workforce Analysis reports licensing growth rates from 2022-2024 of MD 19% (5,493), DO 26% (802), Podiatry 10% (33), APRN 32% (2,602), and PA 14% (903). So although all the professional licensees have grown in Alaska —MD, DO, Podiatrists, and PAs have not seen the growth of APRNs. We need all to satisfy the growing needs of Alaskans.

We will continue collaborating with legislators and stakeholders to refine the language of the surgery exclusion. Our aim is to preserve the current performance of surgical assist PAs without expanding their scope to include independent surgical practice, as Dr. Paulson noted.

Thank you all for your time and energy over the last 2 years. Strong statutory and regulatory support is essential for maintaining and increasing the PA role in Alaska. With your help we will continue to retain current PAs and attract new medical professionals to our beautiful state.

We deeply appreciate your ongoing support.

Respectfully,

Jenny Fayette, PA-C

AKAPA Legislative Committee

New AAMC Data on Medical School Applicants and Enrollment in 2024
https://www.aamc.org/news/press-releases/new-aamc-data-medical-school-applicants-and-enrollment-2024

EDUCATION

ETHICS

HEALTH & SOCIAL SERVICES

JUDICIARY

TRANSPORTATION

ALASKA STATE LEGISLATURE

SENATOR Löki Gale Tobin

Education Committee Chair

WHILE IN SESSION
STATE CAPITOL
JUNEAU, AK 99801
(907) 465-3704

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WHILE IN ANCHORAGE
1500 W BENSON BLVD
ANCHORAGE, AK 99503
(907) 269-0169

Senate Bill 115: Summary of Research Examining the Safety, Effectiveness, and Affordability of PA-Delivered Care

Quality and Outcomes Related to PA Delivered Care (with intermittent cost assessment)

2021	Quality, Outcomes and Cost	Study: Malloy et al. Hidden Costs in Resident Training: Financial Cohort Analysis of First Assistants in Reduction Mammaplasty. Plast Reconstr Surg Glob Open https://doi.org/10.1097/GOX.0000000000003333 Findings: Operative time and procedural charges between a surgical resident and a PA first-assisting in surgery were compared. It was determined that procedures completed by residents took 34 minutes longer than PAs and were $3,750 more expensive.
2020	Quality and Outcomes	Study: Fejleh et al. Quality metrics of screening colonoscopies performed by PAs. JAAPA https://doi.org/10.1097/01.JAA.0000657192.96190.ab Findings: Authors explored differences in quality measures of PAs and MDs in screening colonoscopies. PAs performed flexible sigmoidoscopies comparably to gastroenterologists. Comparisons of attending physicians and PAs grouped by years of experience did not show differences in performance. PAs performed superior to GI fellows with regard to performance of thoroughness of the procedure and withdrawal time. No significant difference was found between the thoroughness of the procedure of PAs and attending gastroenterologists.
2020	Quality and Outcomes	Study: Fung et al. The impact of adding a physician assistant to a rural community hospital intensive care unit. Journal of Canada's Physician Assistants https://doi.org/10.5203/jcanpa.v2i6.873 Findings: The outcomes of adding a PA to an ICU team was compared to an ICU without a PA. The PA provided care to 132 patients, who experienced lower 30-day mortality (26.85 patients died within 30-days on the PA ICU team versus 42.03 for the ICU team without a PA). There were no significant differences in hospital readmission rates between the two groups.

2019	Quality and Outcomes	Study: Everett et al. Primary care provider type: Are there differences in patients' intermediate diabetes outcomes? JAAPA https://doi.org/10.1097/01.JAA.0000558239.06875.0b Research question: Are there differences in diabetes outcomes between patients (n = 609,668) with different types of primary and supplemental providers (physicians, PAs and NPs)? Findings: No clinically meaningful differences were observed in intermediate diabetes outcomes between care delivered by a primary care PA and care delivered by either a physician alone or a physician and a PA.
2018	Quality and Outcomes	Study: Faza et al. Effectiveness of NPs and PAs in managing diabetes and cardiovascular disease. JAAPA https://doi.org/10.1097/01.JAA.0000534983.61613.91 Findings: A group of 185,694 patients with chronic cardiovascular disease and diabetes treated by NPs were compared to 66,217 treated by PAs in a primary care setting. Measurements of blood pressure, beta blockers, statins, antiplatelets, primary or specialty care visits, lipid panels, and the number of stress tests ordered was comparable between the two groups. No differences in using resources between PAs and NPs in the VA were noted.
2018	Quality and Outcomes	Study: Jackson. Intermediate Diabetes Outcomes in Patients Managed by Physicians, Nurse Practitioners, or Physician Assistants: A Cohort Study. Annals of Internal Medicine Findings: This study found that patients with diabetes who received primary care services at VA facilities from a physician, an NP, or a PA over a two-year period saw no significant variation in health outcomes. Authors conclude that "similar chronic illness outcomes may be achieved by physicians, NPs, and PAs.
2018	Quality and Outcomes	Study: Rymer et al. Advanced Practice Provider Versus Physician-Only Outpatient Follow-Up After Acute Myocardial Infarction. Journal of the American Heart Association https://doi.org/10.1161/JAHA.117.008481 Findings: For patients recovering from acute myocardial infarction, there was no difference in medication adherence, readmission, mortality, or major adverse cardiovascular events for patients seen by PAs and NPs and those seen by physicians. The authors also note that the prevalence of PAs and NPs providing follow-up for MI appeared to be less in certain regions (e.g., the southeast) due to licensure, supervision/collaboration, and scope of practice-related restrictions.
2017	Quality and Outcomes	Study: Kurtzman and Barnow. A comparison of nurse practitioners, physician assistants, and primary care physicians' patterns of practice and quality of care in health centers. Medical Care https://doi.org/10.1097/MLR.0000000000000689

		Findings: A first-of-its-kind study found that PAs and NPs delivered similar quality of care, services, and referrals in community health centers as physicians. Researchers at The George Washington University School of Nursing reviewed five years of data from the National Ambulatory Medical Care Survey's Community Health Center subsample and compared nine patient outcomes by practitioner type. The study could have implications for the structure of community health centers in the future.
2017	Quality and Outcomes	Study: Liu et al. The impact of using mid-level providers in face-to-face primary care on health care utilization. Medical Care https://doi.org/10.1097/MLR.0000000000000590 Findings: Greater use of NP/PAs in primary care visits in the Kaiser Permanente system in Georgia was not associated with higher specialty referrals, advanced imaging, ED visits, or inpatient stays. The authors conclude that using PAs and NPs in face-to-face primary care may be a promising primary care delivery model from an efficiency standpoint.
2017	Quality and Outcomes	Study: Rattray et al. Prime movers: Advanced practice professionals in the role of stroke coordinator. Journal of the American Association of Nurse Practitioners https://doi.org/10.1002/2327-6924.12462 Findings: The authors followed a stroke quality improvement clustered randomized trial and a national acute ischemic stroke directive in the VHA in 2011. The study examined the role of PAs and NPs in quality improvement activities among stroke teams. The authors conclude that the presence of PAs and NPs related directly to group-based evaluation of performance data, implementing stroke protocols, monitoring care through data audit, convening interprofessional meetings involving planning activities, and providing direct care. Further, the authors state that, because of their boundary spanning capabilities, the presence of PAs and NPs is an influential feature of local context crucial to developing an advanced, facility-wide approach to stroke care.
2017	Quality and Outcomes	Study: Yang et al. Nurse Practitioners, Physician Assistants, and Physicians Are Comparable in Managing the First Five Years of Diabetes. The American Journal of Medicine https://doi.org/10.1016/j.amjmed.2017.08.026 Findings: The article posits that the increased use of NPs and PAs is a potential solution to the issue of primary care provider shortages in the United States. In this specific investigation, the study found that diabetes management by NPs and PAs were similar to the treatment provided by physicians. Consequently, the researchers believe that employing NPs and PAs in a broader sense may combat the shortages of providers observed in the health care setting.

2016	Quality and Outcomes	Study: Agarwal et al. Process and outcome measures among COPD patients with a hospitalization cared for by an advance practice provider or primary care physician. Plus One https://doi.org/10.1371/journal.pone.0148522 Findings: Compared to patients cared for by physicians, patients cared for by PAs and NPs were more likely to receive short acting bronchodilator, oxygen therapy and been referred to pulmonologist. Patients cared for by PAs and NPs were less likely to visit an ER for COPD compared to patients cared for by physicians, conversely there was no difference in hospitalization or readmission for COPD between physicians and PAs/NPs.
2016	Quality, Outcomes and Cost	Study: Capstack et al. A comparison of conventional and expanded physician assistant hospitalist staffing models at a community hospital. Journal of Clinical Outcomes Management https://www.mdedge.com/jcomjournal/article/146081/practice-management/comparison-conventional-and-expanded-physician Findings: The researchers found that an expanded PA hospitalist staffing model at a community hospital provided similar outcomes and a lower cost of care than a conventional model. Researchers did a retrospective study comparing two hospitalist groups at a 384-bed community hospital in Annapolis, MD. One group had an expanded PA staffing model, with three physicians and three PAs. The other group had a "conventional" staffing model, with nine physicians and two PAs.
2016	Quality and Outcomes	Study: Pavlik et a. Physician assistant management of pediatric patients in a general community emergency department: a real world analysis. Pediatric Emergency Care https://doi.org/10.1097/PEC.0000000000000949 Findings: Based on the outcome measure of 72-hour recidivism, PA management of pediatric patients 6 years or younger is similar to that of attending emergency physicians (EPs). In addition, this study suggests that the PAs have the ability to recognize more severely ill children and elicit the input of a physician in those cases.
2016	Quality and Outcomes	Study: Virani et al. Comparative effectiveness of outpatient cardiovascular disease and diabetes care delivery between advanced practice providers and physician providers in primary care: implications for care under the Affordable Care Act. American Heart Journal https://doi.org/10.1016/j.ahj.2016.07.020 Findings: This study found that physicians and PAs and NPs provided comparable diabetes and cardiovascular disease (CVD) care quality with clinically insignificant differences. The authors conducted the research with diabetic and CVD patients in 130 Veterans Affairs facilities, and found that there is a need to improve performance regardless of provider type.

2015	Quality and Outcomes	Study: Virani et al. Provider type and quality of outpatient cardiovascular disease care. Journal of American College of Cardiology https://doi.org/10.1016/j.jacc.2015.08.017 Findings: The large national study sought to determine whether there were clinically meaningful differences in the quality of care delivered by teams of physicians and PAs or NPs versus physicians-only teams. Patients with coronary artery disease (CAD), heart failure and atrial fibrillation received comparable outpatient care from physicians, PAs and NPs. There was a higher rate of smoking cessation screening and intervention and cardiac rehabilitation referral among CAD patients receiving care from PA/NPs.
2014	Quality and Outcomes	Study: Costa et al. Nurse practitioner/physician assistant staffing and critical care mortality. Chest Journal https://doi.org/10.1378/chest.14-0566 Findings: ICUs are increasingly staffed with NPs and PAs. The authors examined the association between NP/PA staffing and in-hospital mortality for patients in the ICU, and found NPs/PAs to be a safe adjunct to the ICU team. The findings support NP/PA management of critically ill patients.
2013	Quality and Outcomes	Study: Everett et al. Physician assistants and nurse practitioners perform effective roles on teams caring for Medicare patients with diabetes. Health Affairs https://doi.org/10.1377/hlthaff.2013.0506 Findings: Medicare claims and electronic health record data from a large physician group was used to compare outcomes for two groups of adult Medicare patients with diabetes whose conditions were at various levels of complexity: those whose care teams included PAs or NPs in various roles, and those who received care from physicians only. Outcomes were generally equivalent in thirteen comparisons.
2013	Quality and Outcomes	Study: Glotzbecker et al. Impact of physician assistants on the outcomes of patients with acute myelogenous leukemia receiving chemotherapy in an academic medical center. Journal of Oncology Practice https://doi.org/10.1200/JOP.2012.000841 Findings: The data demonstrated equivalent mortality and ICU transfers, with a decrease in length of stay, readmission rates, and consults for patients cared for in the PA service. This suggests that the PA service is associated with increased operational efficiency and decreased health service use without compromise of healthcare outcomes.
2013	Quality and Outcomes	Study: Nabagiez et al. Physician assistant home visit program to reduce hospital readmissions. Journal of Thoracic Cardiovascular Surgery https://doi.org/10.1016/j.jtcvs.2012.09.047 Findings: A PA home care (PAHC) program was initiated to improve the care of patients who had undergone cardiac surgery. The 30-day

		readmission rate was reduced by 25% in patients receiving PAHC visits. The most common home intervention was medication adjustment, most commonly to diuretic agents, medications for hypoglycemia, and antibiotics.
2012	Quality, Outcomes and Access	Study: Nestler et al. Effect of a Physician Assistant as a Triage Liaison Provider on Patient Throughout in an Academic Emergency Department. Academic Emergency Medicine https://doi.org/10.1111/acem.12010 Findings: The article discusses overcapacity issues that routinely inhibit various emergency departments. According to this article, studies suggest that triage liaison providers (TLPs) may benefit emergency departments struggling with overcapacity by shortening a patient's length of stay (LOS). Additionally, the article posits that enabling PAs to serve in such a role, TLPs, may reduce the number of patients who leave the emergency department without being seen. The findings of this study suggest that the LOS for patients was shorter, treatment room times were shorter, and fewer patients left without being seen.
2011	Quality, Outcomes and Cost	Study: Kawar and Digiovine. MICU care delivered by PAs versus residents: do PAs measure up? JAAPA https://doi.org/10.1097/01720610-201101000-00008 Findings: Clinical outcomes between patients admitted to a resident and a PA in the medical intensive care unit (MICU) were compared. Authors examined 5,346 patient admissions to a MICU (3,971 to 32-bed MD-managed MICU and 1,375 to a 16-bed PA-managed medical ICU) and found that there was no in-hospital difference of mortality or intensive care unit mortality between the two groups. Survival analyses showed no difference in 28-day survival between the two groups. A PA-managed MICU produced no significant differences in survivorship compared to a MD-managed MICU and hospital average length of stay was similar between the two groups.
2011	Quality and Outcomes	Study: Singh et al. A comparison of outcomes of general medical inpatient care provided by a hospitalist-physician assistant model vs a traditional resident-based model. J Hosp Med https://doi.org/10.1002/jhm.826 Findings: 2,171 inpatients cared for by PA hospitalists were compared to 7,510 inpatients cared for by medical residents. The risk of readmission at 7, 14, and 30 days and the risk of inpatient death were similar between the two groups.
2010	Quality and Outcomes	Study: Moote et al. PA-driven VTE risk assessment improves compliance with recommended prophylaxis. Journal of American Academy of Physician Assistants https://doi.org/10.1097/01720610-201006000-00008 Findings: A PA-driven venous thromboembolism (VTE) risk assessment process resulted in a dramatic increase in the number of patients within

		the health system who were prescribed appropriate orders for VTE prophylaxis according to published guidelines and according to individual patient risk.
2009	Quality and Outcomes	Study: Dhuper and Choski. Replacing an academic internal medicine residency program with a physician assistant-hospitalist model: a comparative analysis study. American Journal of Medical Quality https://doi.org/10.1177/1062860608329646 Findings: This study describes a comparative analysis of replacing medical residents with PA-hospitalist teams on patient outcomes in a community hospital. Quality of care provided by the PA-hospitalist model was equivalent to resident physician provided care.
2008	Quality and Outcomes	Study: Roy. Implementation of a physician assistant/hospitalist service in an academic medical center: impact on efficiency and patient outcomes. J Hosp Med https://doi.org/10.1002/jhm.352 Findings: The quality and efficiency of patient care of a PA hospitalist service was compared with that of traditional MD house staff services. 992 patients admitted to the PA hospitalists experienced no difference in inpatient mortality, readmissions, or patient satisfaction compared with those admitted to MD hospitalists. There was also no difference in ICU transfers or length of stay. The total cost of care was marginally lower for patients admitted to PA hospitalists.
2005	Quality and Outcomes	Study: Wilson et al. Quality of HIV care provided by nurse practitioners, physician assistants, and physicians. Annals of Internal Medicine https://doi.org/10.7326/0003-4819-143-10-200511150-0001 Findings: For the measures examined, the quality of HIV care provided by NPs and PAs was similar to that of physician HIV experts and generally better than physician non–HIV experts. NPs and PAs can provide high-quality care for persons with HIV. Preconditions for this level of performance include high levels of experience, focus on a single condition, and either participation in teams or other easy access to physicians and other clinicians with HIV expertise.
2004	Quality, Outcomes and Cost	Study: Hooker. Physician assistants in occupational medicine: how do they compare to occupational physicians? Occup Med https://doi.org/10.1093/occmed/kqg126 Findings: Authors assessed the care delivered by 12 OEM PAs during 80,764 patient encounters and found that they assessed patients in the same way as OEM MDs. The injury severity scale, patient age, and gender were matched for both providers. The use of resources was the same, but the number of days for disability was shorter by 1.8 for the PA as compared to the MD. PA cost of care is 50% less due to wages.
2004	Quality and Outcomes	Study: Oswanski. Comparative review of use of physician assistants in a level I trauma center. The American Surgeon PMID: 15055854

		Findings: Outcomes of 479 patients who received care from PAs in a PA-assisted trauma program (without residents) were compared to 293 patients who received care from a MD resident-assisted trauma program. No differences in mortality rates were found between the two groups. PA-delivered care reduced the length of stay by 1 day.
1998	Quality and Outcomes	Study: Miller et al. Use of physician assistants as surgery/trauma house staff at an American College of Surgeons-verified level II trauma center. The Journal of Trauma: Injury, Infection, and Critical Care https://doi.org/10.1097/00005373-199802000-00025 Findings: Utilization of a trauma surgeon-PA model resulted in a 43% decrease in transfer time to the OR, 51% decrease in transfer time to the ICU, 13% decrease in overall length of stay and 33% decrease in length of stay for neurotrauma intensive care.
1994	Quality and Outcomes	Study: Carzoli et al. Comparison of neonatal nurse practitioners, physician assistants, and residents in the neonatal intensive care unit. American Medical Association, Archives of Pediatrics and Adolescent Medicine https://doi.org/10.1001/archpedi.1994.02170120033005 Findings: Patient charts were analyzed to compare care provided in the neonatal intensive care unit by teams of resident physicians and teams of PAs and NPs. Results demonstrated no significant differences in management, outcome, or charge variables between patients cared for by the two teams.
1977	Quality, Outcomes and Cost	Study: Tompkins et al. The effectiveness and cost of acute respiratory illness medical care provided by physicians and algorithm-assisted physicians' assistants. Med Care https://doi.org/10.1097/00005650-197712000-00003 Findings: 2,149 patients with acute respiratory illness treated by PAs were compared to 389 patients treated by MDs. Diagnostic test costs by the PA were less than the MD group ($4.26 vs. $5.48). ($p < 0.05$). Direct medical care costs were significantly lower: PA group = $12.78 vs MD group = $16.86.

Cost of PA-Delivered Care

2020	Cost	Study: Smith et al. Utilization and Costs by Primary Care Provider Type: Are There Differences Among Diabetic Patients of Physicians, Nurse Practitioners, and Physician Assistants? Med Care. https://doi.org/10.1097/MLR.0000000000001326 Findings: The cost of care provided to 25,352 patients cared for by PAs were compared to 301,361 patients cared for by MDs and NPs. Patients of PAs have lower odds of inpatient admission and lower emergency department use, which this translates into PAs having ~$500–$700 less health care costs per patient per year than MDs.

2019	Cost	Study: Morgan et al. Impact Of Physicians, Nurse Practitioners, And Physician Assistants On Utilization And Costs For Complex Patients. Health Aff https://doi.org/10.1377/hlthaff.2019.00014 Findings: The healthcare use and the total costs of care among 47,236 medically complex patients (veterans with diabetes) by physician, NP, and PA primary care providers were compared. The 2,806 patients who received care from PAs were less likely than patients of MDs to incur hospitalization related to their ambulatory care. PAs utilized fewer resources than MDs for the same matched group of chronically ill patients even in expanded roles. Estimated annual medical expenditures of PAs vs MDs: total (inpatient, outpatient, pharmacy) $32,350 (PAs) vs $34,650 (MDs).
2016	Cost	Study: Eilrich. The Economic Effect of a Physician Assistant or Nurse Practitioner in Rural America. Journal of the American Academy of PAs https://doi.org/10.1097/01.JAA.0000496956.02958.dd Findings: PAs and NPs who provide primary care services in medically-underserved areas can help offset physician shortages and positively impact the local economy.
2016	Cost	Study: Essary et al. Compensation and production in family medicine by practice ownership. Health Services Research and Managerial Epidemiology https://doi.org/10.1177/2333392815624111 Findings: In this national survey of family medicine practices, PA productivity, as defined by mean annual patient encounters, exceeds that of both nurse practitioners (NPs) and physicians in physician-owned practices and of NPs in hospital or integrated delivery system-owned practices. Total compensation, defined as salary, bonus, incentives, and honoraria for physicians, is significantly more compared to both PAs and NPs, regardless of practice ownership or productivity. PAs and NPs earn equivalent compensation, regardless of practice ownership or productivity. Not only do these data support the value and role of PAs and NPs on the primary care team, but also highlight differences in patient encounters between practice settings.
2016	Cost	Study: Mafi et al. Comparing use of low-value health care services among U.S. advanced practice clinicians and physicians. Annals of Internal Medicine https://doi.org/10.7326/M15-215 Findings: A comparison of NPs, PAs and physicians found that the three practitioners provided an equivalent amount of low-value health services. The purpose of the comparison was to dispel physicians' perceptions that PAs and NPs provide lower-value care than physicians for patients presenting with upper respiratory infections, back pain, or headaches.
2016	Cost	Study: Resnick et al. Physician assistants improve efficiency and decrease costs in outpatient oral and maxillofacial surgery. Journal of Oral Maxillofacial Surgery https://doi.org/10.1016/j.joms.2016.06.195

		Findings: The addition of PAs into the procedural components of an outpatient oral and maxillofacial surgery practice resulted in decreased costs whereas complication rates remained constant. The increased availability of the oral and maxillofacial surgeon after the incorporation of PAs allows for more patients to be seen during a clinic session, which has the potential to further increase efficiency.
2016	Cost	Study: Timmons. The effects of expanded nurse practitioner and physician assistant scope of practice on the cost of Medicaid patient care. Health Policy https://doi.org/10.1016/j.healthpol.2016.12.002 Findings: The author examines how changes to occupational licensing laws for nurse practitioners and physician assistants have affected cost and intensity of health care for Medicaid patients. The results suggest that allowing physician assistants to prescribe controlled substances is associated with a substantial (more than 11%) reduction in the dollar amount of outpatient claims per Medicaid recipient. Relaxing occupational licensing requirements by broadening the scope of practice for healthcare providers may represent a low-cost alternative to providing quality care to America's poor.
2013	Cost	Study: Althausen et al. Impact of hospital-employed physician assistants on a level II community-based orthopaedic trauma system. Journal of Orthopaedic Trauma https://doi.org/10.1097/BOT.0b013e3182647f29 Findings: The indirect economic and patient care impact of PAs on the community-based orthopaedic trauma team was evaluated. By increasing emergency room pull through and decreasing times to OR, operative times, lengths of stay, and complications, PAs are clearly beneficial to hospitals, physicians, and patients.
2009	Cost	Study: Eibner et al. Controlling health care spending in Massachusetts: an analysis of options. RAND Corporation, TR-733-COMMASS. https://www.rand.org/pubs/technical_reports/TR733.html Findings: RAND identified a few options that appear to have the potential to slow the rate of increase in health spending in Massachusetts over the next decade. Those ideas include expanding the scope of practice of PAs and NPs and encouraging the greater use of PAs and NPs in primary care.
2008	Cost	Study: Morgan et al. Impact of physician assistant care on office visit resource use in the United States. Health Services Research. https://doi.org/10.1111/j.1475-6773.2008.00874.x Findings: Analysis of Medicare's Medical Expenditure Panel Survey (MEPS) data found adult patients who saw PAs for a large portion of their yearly office visits had, on average, 16 percent fewer visits per year, than patients who saw only physicians. These findings account for adjustments for patient complexity.

2004	Cost	Study: Roblin et al. Use of midlevel practitioners to achieve labor cost savings in the primary care practice of an MCO. Health Services Research https://doi.org/10.1111/j.1475-6773.2004.00247.x Findings: Data from twenty-six primary care practices and approximately 2 million visit records found PAs/NPs attended to 1 in 3 adult medicine visits and 1 in 5 pediatric. Primary care practices that used more PAs/NPs in care delivery realized lower practitioner labor costs per visit than practices that used fewer.
2002	Cost	Study: Grzybicki and Sullivan. The Economic Benefit for Family/General Medicine Practices Employing Physician Assistants. The American Journal of Managed Care https://www.ajmc.com/view/jul02-165p613-620 Findings: The study sought to identify whether or not model PA practice in a family or general medicine practice environment was comparable, in terms of care provided and financial productivity, to a physician-only practice. The study found that the employment of family and/or general medicine PAs lead to significant economic benefits to the practices where they are employed.
2002	Cost	Study: Hooker. Cost analysis of physician assistants in primary care. Journal of the American Academy of Physician Assistants https://www.ncbi.nlm.nih.gov/pubmed/12474431 Findings: This study examines the cost associated with employing PAs from the employer's perspective. Analysis of data on record for episode, patient characteristics, health status, etc., found that for every medical condition managed by PAs, the total episode cost was less than similar episode managed by a physician.

Liability

2021	Liability	Study: Hickman. Evaluating liability in the supervising physician, PA, and employer relationship. JAAPA https://doi.org/10.1097/01.JAA.0000791480.34010.29 Findings: Author reviewed case law and found that courts generally assign liability for the actions of the PA to the PA, but liability to the physician and employer for failure to meet the statutory requirements for oversight of the PA. The author concluded that less cumbersome statutory requirements for PAs would reduce the likelihood of physician liability noncompliance.
2023	Liability	Study: DePalma et al. Medical malpractice payment reports of physician assistants/associates related to state practice laws and regulations. J Med Regul https://doi.org/10.30770/2572-1852-109.4.27 Findings: Authors addressed malpractice payments for physician and PA delivered care in states with either permissive or restrictive PA practice

		laws. Authors found that no significant drawbacks and numerous benefits for states with more permissive practice laws.
2016	Liability	Study: U.S. Department of Health and Human Services, Health Resources and Services Administration. National Practitioner Data Bank. Rockville, Maryland. https://www.npdb.hrsa.gov/analysistool/ Findings: Nationally, there were 1,399 liability claims paid against PAs in the 10 years from 2005-2014. The ratio of claims to PAs averaged 1 claim for every 550 PAs (1:550). By comparison, the number of physician claims paid from 2005-2014 totaled 105,756; the ratio for physicians during that decade averaged one claim for every 80 physicians (1:80).This data can be extracted from the Data Analysis Tool on the NPDB website.
2009	Liability	Study: Hooker et al. Does the employment of physician assistants and nurse practitioners increase liability? Journal of Medical Licensure and Discipline http://www.paexperts.com/Nicholson%20-%20Hooker%20Article.pdf Findings: Seventeen years of data compiled in the United States National Practitioner Data Bank (NPDB) was used to compare and analyze malpractice incidence, payment amount and other measures of liability among physicians, PAs and APNs. Seventeen years of observation suggests that PAs may decrease liability, at least as viewed through the lens of a national reporting system. During the first 17-year study period, there was one payment report for every 2.7 active physicians and one for every 32.5 active PAs. In percentage terms, 37 percent of physicians, 3.1 percent of PAs and at least 1.5 percent of APNs would have made a malpractice payment during the study period. The physician mean payment was 1.7 times higher than PAs and 0.9 times that of APNs, suggesting that PA employment may be a cost savings for the healthcare industry along with the safety of patients. The reasons for disciplinary action against PAs and APNs are largely the same as physicians.

EDUCATION

ETHICS

HEALTH & SOCIAL SERVICES

JUDICIARY

TRANSPORTATION

ALASKA STATE LEGISLATURE

SENATOR Löki Gale Tobin

WHILE IN SESSION
STATE CAPITOL
JUNEAU, AK 99801
(907) 465-3704

•

WHILE IN ANCHORAGE
1500 W BENSON BLVD
ANCHORAGE, AK 99503
(907) 269-0169

Senate Bill 115: Summary of Additional Supporting Documents

The cost-effectiveness of physician assistant/associates: A systematic review of international evidence as found in the Public Library of Science One (PLOS One) peer-reviewed journal in November 2021.

- This paper is a meta-analysis of physician assistant (PA) care globally and the researchers looked at the quality of care as well as the cost efficacy of PAs in that care.
- In 18 studies, PAs were shown to have a quality of care that exceeded that of a physician, and in 15 studies the care was comparable.
- This meta-analysis found that the cost-effectiveness of PA care was lower in both labor and education.

A study of the Medical Malpractice Payment Reports of Physician Assistants/Associates Related to State Practice Laws and Regulations published in the Journal of Medical Regulation in December 2023.

- In a nationwide analysis over a 9-year span, removing the barriers to PA provision of care did not increase malpractice reports.

The 2021 Primary Care Needs Assessment complied by the Alaska Division of Public Health.

- For many across Alaska, all levels of health care providers are only present intermittently.
- There is an increasing need for health care providers, and a recorded shortage of primary care providers – with 69% of providers located in the Anchorage and Mat Su area.

Physicians Assistants: Modernize Laws to Improve Rural Access a policy paper from the National Rural Health Association in April 2018.

- This paper speaks to the nationwide shortage of rural care. The physician shortfall is affecting rural residents at a pace which does not keep up with demand.
- Studies in Iowa, Texas, California, and Washington all show a higher number of PAs practicing in rural areas when compared to physicians.
- According to the National Rural Health Association policy analysis, modernizing regulation helps PAs meet the health care needs of rural communities.

Alaska Healthcare **Licensing**

Alaska Professional License Category	2022 Active Count	2024 Active Count	Change 22-24
Audiologists and Hearing Aid Dealers	**124**	**136**	**10%**
Chiropractic	**336**	**328**	**-2%**
Dental	**3,136**	**3,406**	**9%**
Dietitians	**322**	**407**	**26%**
Direct Entry Midwives	**47**	**41**	**-13%**
Dispensing Opticians	**162**	**168**	**4%**
Medical	**5,817**	**6,517**	**12%**
Cooperative Practice Agreement	-	26	
Osteopathic Physician	635	802	
Osteopathic Physician Courtesy License	2	1	
Osteopathic Physician Resident Permit	31	16	
Osteopathic Physician Temporary Permit	32	10	
Physician	4,619	5,493	
Physician Resident Permit	149	62	
Physician Temporary Permit	244	74	
Podiatrist	30	33	
Nurse Aides	**2,561**	**2,445**	**-5%**
Certified Nurse Aide	2,557	2,434	
Certified Nurse Aide Temporary Permit	4	11	
Nursing	**23,642**	**26,920**	**14%**
Advanced Practice Registered Nurse	1,958	2,602	
Advanced Practice Registered Nurse Preceptorship	50	56	
Advanced Practice Registered Nurse Temp	7	3	
Practical Nurse	577	636	
Practical Nurse Temporary Permit	22	9	
Registered Nurse	20,560	23,434	
Registered Nurse Temporary License	1	2	
Registered Nurse Temporary Permit	465	178	
Nursing Home Administrators	**55**	**53**	**-4%**
Optometry	**238**	**250**	**5%**
Pharmacy	**4,306**	**5,820**	**35%**
Drug Room	40	51	
Out-Of-State Pharmacy	655	NA	
Manufacturer	NA	339	
Out-Of-State Wholesale Drug Distributor	788	5	
Outsourcing Facility	35	32	
Pharmacist	1,025	2,157	
Pharmacy	128	717	
Pharmacy Intern	324	268	
Pharmacy Technician	1,088	1,305	
Remote Pharmacy	1	6	
Third-Party Logistics Provider	199	248	
Wholesale Drug Distributor	21	692	
Physical and Occupational Therapy	**1,895**	**2,161**	**14%**
Physician Assistants	**794**	**903**	**14%**
Speech-Language Pathology	**565**	**622**	**10%**
Telemedicine Business Registry	**1,582**	**1,935**	**22%**
Psychology	**335**	**361**	**8%**
Total	**45,917**	**52,473**	**14%**

Alaska Healthcare Related Active Professional Licenses, 2024

As of November 2024, 52,473 healthcare professional licenses were held in the state of Alaska, up 14% over 2022.

The most common license is for registered nursing, with nearly 27,000 active licenses. In 2024, active registered nursing licenses were up by 14% over 2022, an increase of more than 2,800 licenses.

Source: Alaska Division of Corporations, Business and Professional Licensing, Professional Licensing database download November 8, 2022 and November 3, 2023. www.commerce.alaska.gov/cbp/main/ Note that the category of "Prescription Drug Monitoring Program" had no active licenses in 2023, and thus the category was excluded from the analysis.

Note: Having an Alaska license does not mean the person is an Alaska resident or practices/provides services in Alaska. People can get an Alaska license and not be physically in Alaska.

PAEA **RESEARCH**

Program Report 36

By the Numbers | Data from the 2021 Program Survey

PAEA

Acknowledgements

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PAEA Research Team:
Daphne C. Mills, PhD, Director of Research & Data Operations, PAEA
Dominique Frias-Sarmiento, MA, Mixed Methods Analyst, PAEA
Hannah De La Rosa, MPH, Manager of Research & Data Operations, PAEA
Denise Rizzolo, PhD, MPH, PA-C, Director of Research and Publication, Managing Editor of *JPAE*
Robert Furter, PhD, MBA, Senior Director of Research & Data Operations, PAEA

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PAEA

Program Report 36

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INTRODUCTION

PA EDUCATION ASSOCIATION

Founded in 1972, the PA Education Association (PAEA) represents all physician assistant (PA) education programs in the United States. At the beginning of the 2021 Program Survey administration in November 2021, PAEA represented 284 PA programs. For more information about PAEA and our products and services, visit **PAEAonline.org**.

IMPORTANT NOTICE

These data were collected in late 2021, during the midst of the COVID-19 (coronavirus) pandemic. During the period of the survey administration, the Omicron variant was beginning to spread throughout communities across the United States. In light of the challenges faced by programs due to the constantly changing nature of the pandemic and CDC and state guidelines during the past several academic years, the timeline for the administration of the Program Survey was shifted from late spring/summer as in past administrations to late Fall/winter and the completion window was shortened. In addition, PAEA chose not to make Program survey completion a requirement for its members due to these constraints. As a result, the response rate for the 2021 Program Survey is much lower than in previous administrations. As members utilize the findings within the Program Report, please keep in mind that some figures might be lower than expected, both due to the lowered response rate and due to the changes that programs underwent due to the pandemic. PAEA members are also encouraged to refer back to our limited series of COVID-19 Rapid Response Reports that were released in 2021 and 2022 to find out more out how PA programs have undergone since the onset of the pandemic in March 2020.

METHODS

THE SURVEY INSTRUMENTS

The 2021 Program Survey collected data that are reported in the following sections:

- **Section 1. General Information:** Geographic location of programs, credentials awarded, program length, and program start and end months
- **Section 2. Financial Information:** Program budget sources, expense areas, tuition and fees, and payments for clinical sites
- **Section 3. Program Personnel:** Faculty teaching load, faculty and staff headcounts and full-time equivalents (FTE), and barriers to hiring new faculty
- **Section 4. Students:** Capacity and enrollment, and academic and demographic information for the first-year class and 2021 cohort of PA students
- **Section 5. Specialized Supervised Clinical Practice Experience:** Program usage of Veterans Affairs and Community Health Centers

In addition, the Program Survey contained a section dedicated to **the Support to Advance Research (STAR) Program**. STAR is an initiative developed by the PAEA RMAC and Research Team that allows faculty of PAEA member programs to submit up to 10 questions for inclusion in the Program Survey to gather data for their own research. The data were provided to the principal investigator of the project for separate analysis and publication and are not reported here. The questions in all sections of the survey, except those relating to financial information, reflect the 2020–2021 academic year. The financial information is based on the 2020–2021 fiscal year, as defined by each program. Unless otherwise indicated, the survey covers the professional phase of the program. The "professional phase" is defined as the portion of a PA student's education that occurs in an educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA); this is typically about 27 continuous months in length, with one "year" of classroom and laboratory instruction followed by one "year" of clinical rotations. Students in "pre-PA" or "pre-professional" programs (i.e., the first two or three years of 2+2, 3+2, and similar programs) were not considered to be in the professional phase.

SURVEY ADMINISTRATION

The 2021 Program Survey was sent to the program directors of PAEA's 284 member programs in November 2021. The PAEA Research Team sent email reminders to non-respondents and conducted follow-up calls until the survey closed in January 2022. The survey yielded an overall response rate of 71.8.% based on the 204 respondents; however, the response rate varies for individual items. No survey was conducted in 2020 due to the onset of the COVID-19 (coronavirus) pandemic in March 2020. Completion of the 2021 Program Survey was not mandatory due to the ongoing nature of the pandemic in the Fall/Winter of 2021. As a result, the Program survey response rate is significantly lower than response rates for past survey administrations.

DATA CLEANING & ANALYSIS

Responses were checked for logical consistency and examined for extreme values and possible errors. In cases of obvious misinterpretations or inconsistencies in the responses to specific items, respondents were contacted for clarification. Responses that fell outside of reasonable parameters (e.g., total annual program budgets of $1,000) were not included in the analyses. Some reasonably plausible outliers were retained in some statistics, particularly in those presenting financial data. When interpreting financial statistics, readers are advised to rely primarily on medians and trimmed means, which are less susceptible to outlier influence then arithmetic means and are more useful for comparisons across time and between programs within the same year. In general, analyses of the data consisted of calculating descriptive statistics on the variables of interest — percentage, minimum (Min) and maximum (Max) values; arithmetic mean (M); standard deviation (SD); median (Mdn); and 10th, 25th, 50th, 75th, and 90th percentiles (P10, P25, P50, P75, P90). Tables describing financial information also include a 10% trimmed mean (M (T)), the mean when the bottom and top 10% of responses are excluded. For some tables and figures, percentages will not equal 100% due to rounding or when multiple responses were allowed. Total columns on tables and figures are designated by n. Exact financial data were not reported if there were fewer than five respondents. Any other notations not described here are defined in the body of the report.

REPORT ENHANCEMENTS

While PAEA aims to maintain as much consistency as possible in data collection and reporting, some changes are made each year to improve data quality and to add clarity or additional information to the results that have been Program Report fixtures for years. As in recent years, this report includes information on the proportion of programs that did not report demographic information for their first-year class (Table 48) and their 2021 cohort (Table 56). The consolidation of statistics on missing student demographic data was a necessary inclusion due to this recurring problem, which has potentially adverse effects for the PA profession as a whole and for PA education, specifically. Diversity is a core aspect of the PAEA mission and one of the dominant themes of the PAEA **Strategic Plan**. When programs do not report student demographic information — either because they did not collect this information or chose not to provide it — critical information about the national PA student body is lost. This not only limits the Research Team's reporting and capacity for empirical research on the PA student body, but it also weakens the data that PAEA's Government Relations Team uses to advocate for debt relief and the support of PA education in state and federal policy. While the PAEA Research Team is exploring methods for improving these data and making collecting them less onerous, programs are encouraged to prioritize the accurate collection and tracking of student demographic information to ensure the most reliable data are available for the profession. In addition, for the first time, Program Report 36 includes information about member programs' Minority Serving Institution status, rurality/urbanicity (locale classification), Veterans Affairs (VA) and community health centers as clinical placements, and use of MAT Waiver Training.

LIMITATIONS

As previously noted, impacts of the COVID-19 pandemic may significantly limit the generalizability of this report. This report does not contain complete coverage of all PAEA member programs at the time of survey administration. Still, the response rate of 71.8.% does ensure that the results presented here are broadly representative of the entire landscape of PA programs in the United States. Cognizant that a 100% response rate was not going to be possible this year, the PAEA Research Team investigated whether non-responding and responding programs differed based on certain program characteristics, such as institution type and Academic Health Center status. Fortunately, no clear patterns were identified, but this analysis revealed inconsistencies in reported program characteristics over the years. As with any survey, all data presented in this and prior reports are self-reported by programs and may vary in response rate and accuracy; thus, yearly fluctuations in the data do occur. For example, some programs reported changing public/private statuses where no record could be found in changes at the institutional level. Additionally, in questions addressing student demographics, some programs only reported headcounts of students belonging

to a non-majority demographic group (e.g., in response to the question about first-year students' ethnicities, a program might report two Hispanic students but no non-Hispanic students). If substantial changes in any data occur in a particular year, PAEA recommends waiting until the following year's report is released before taking any permanent actions in your program, in order to identify whether the change was unique to that year (e.g., due to response rate or random fluctuation).

QUESTIONS & DATA REQUESTS

The data from the 2021 Program Survey, as well as custom reports using these data, are available upon request. For more information, refer to **PAEA's Data Request & Sharing Policies**. Please direct inquiries regarding data requests or this report to the Research Team at **data@PAEAonline.org**.

SECTION 1. GENERAL INFORMATION

FIGURE 1. CUMULATIVE TOTAL NUMBER OF PROGRAMS SINCE 1965

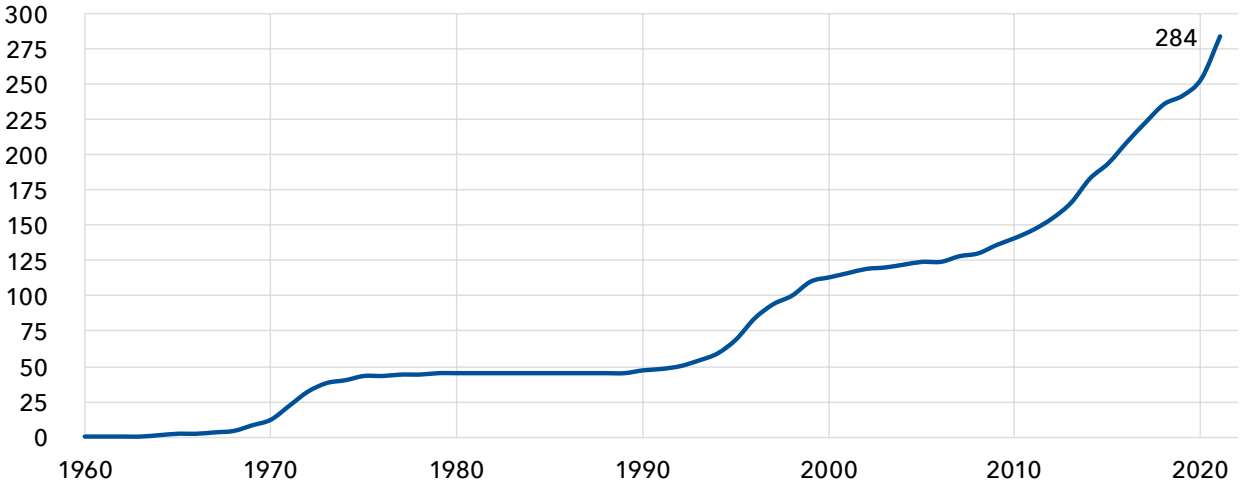


TABLE 1: SPONSORING INSTITUTION ATTRIBUTES

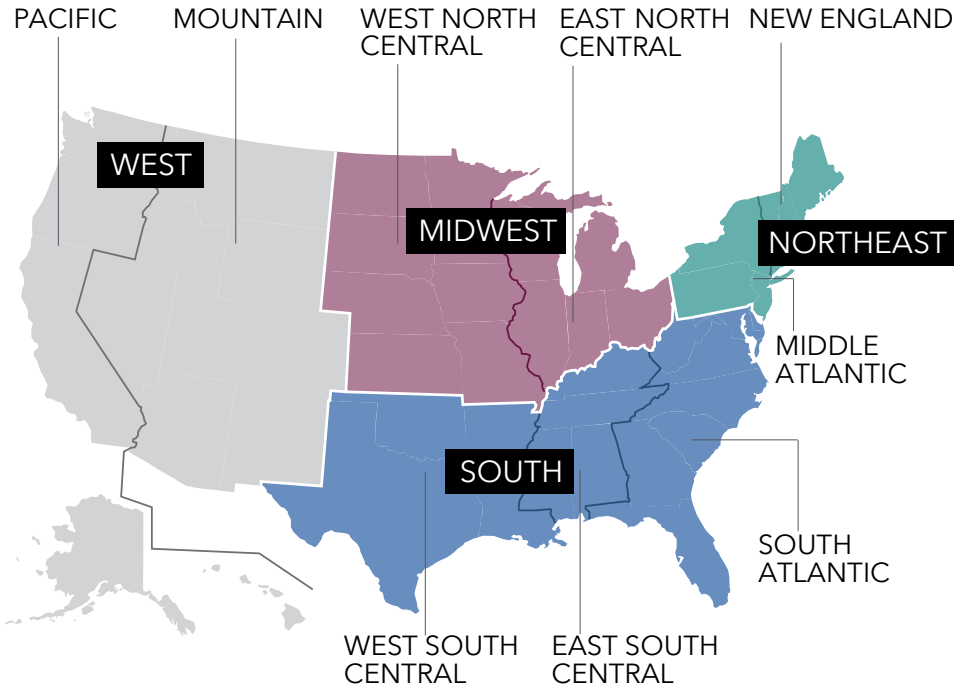
	n	%
Type of Institution		
Private, non-profit	127	62.3
Public	64	31.4
Private, for-profit	8	3.9
Public/private hybrid	5	2.5
Academic Health Center Status		
Non-AHC	143	70.1
AHC	61	29.9
Administrative Housing		
School of Allied Health/Health Professions/Health Sciences	106	52
Department of PA Studies/PA Program	42	20.6
College/School of Medicine	34	16.7
Other	2	1
College of Graduate/Professional Studies	8	3.9
Science Department	6	2.9
Other health discipline (e.g., Nursing, Pharmacy, Podiatry etc)	5	2.5
College of Arts and Sciences	1	0.5
Total	**204**	**100**

TABLE 2: MINORITY SERVING INSTITUTION STATUS

	n	%
Historically Black College or University	1	0.5
Hispanic-Serving Institution	8	3.9
Predominantly Black Institution	1	0.5
Native American Serving Institution	1	0.5
Total	**11**	**5.4**

***Note: According to the US Department of the Interior's Office of Diversity, Inclusion, and Civil Rights, MSIs are institutions of higher education that serve minority populations and include Historically Black Colleges and Universities (HBCUs), Hispanic-Serving Institution (HSIs), Tribal Colleges and Universities (TCUs), and Asian American and Pacific Islander Serving Institutions (AAPISIs). PAEA began collecting this data in 2021 during the COVID-19 Rapid Response Series.*

FIGURE 2. U.S. CENSUS BUREAU REGIONS AND DIVISIONS



Note: Numbers in parentheses indicate the number of PAEA member programs in each state

REGION 1 NORTHEAST (78 PROGRAMS)

DIVISION 1 NEW ENGLAND
Connecticut (6)
Maine (1)
Massachusetts (8)
New Hampshire (2)
Rhode Island (2)
Vermont (0)

DIVISION 2 MIDDLE ATLANTIC
New Jersey (6)
New York (28)
Pennsylvania (25)

REGION 2 MIDWEST (65 PROGRAMS)

DIVISION 3 EAST NORTH CENTRAL
Illinois (7)
Indiana (8)
Michigan (9)
Ohio (14)
Wisconsin (5)

DIVISION 4 WEST NORTH CENTRAL
Iowa (5)
Kansas (2)
Minnesota (5)
Missouri (4)
Nebraska (4)
North Dakota (1)
South Dakota (1)

REGION 3 SOUTH (101 PROGRAMS)

DIVISION 5 SOUTH ATLANTIC
Delaware (0)
District of Columbia (1)
Georgia (6)
Florida (17)
Maryland (4)
North Carolina (11)
South Carolina (6)
Virginia (8)
West Virginia (5)

DIVISION 6 EAST SOUTH CENTRAL
Alabama (4)
Kentucky (4)
Mississippi (2)
Tennessee (11)

DIVISION 7 WEST SOUTH CENTRAL
Arkansas (2)
Louisiana (4)
Oklahoma (5)
Texas (11)

REGION 4 WEST (39 PROGRAMS)

DIVISION 8 MOUNTAIN
Arizona (3)
Colorado (4)
Idaho (1)
Montana (1)
Nevada (2)
New Mexico (2)
Utah (3)
Wyoming (0)

DIVISION 9 PACIFIC
Alaska (0)
California (18)
Hawaii (0)
Oregon (3)
Washington (2)

PUERTO RICO AND THE OUTLYING AREAS (1 PROGRAM)

Puerto Rico (1)

TABLE 3. GEOGRAPHIC DISTRIBUTION OF PROGRAMS

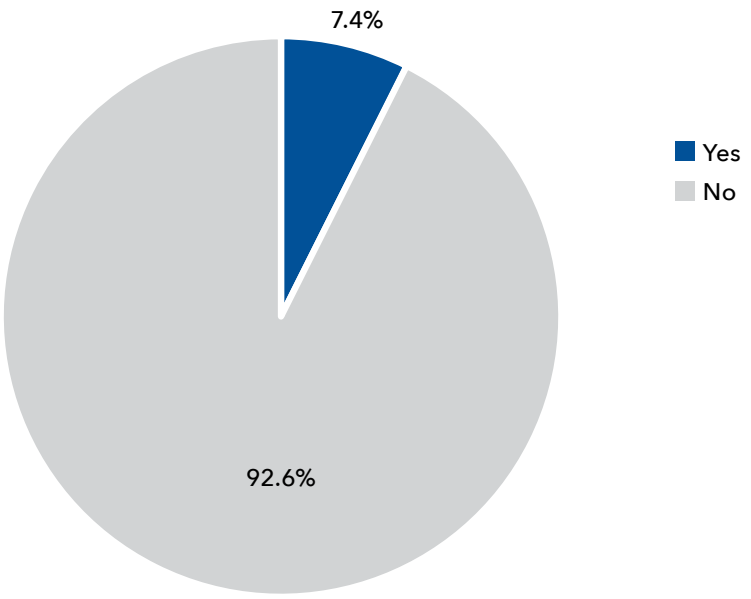
	Represented Programs		All Programs	
	n	**%**	***n***	**%**
Northeast Region				
New England Division	15	7.4	19	6.7
Middle Atlantic Division	42	20.6	59	20.8
Subtotal	57	27.9	78	27.5
Midwest Region				
East North Central Division	32	15.6	43	15.1
West North Central Division	19	9.3	22	7.8
Subtotal	51	24.9	65	22.9
South Region				
South Atlantic Division	42	20.6	58	20.4
East South Central Division	15	7.4	21	7.4
West South Central Division	15	7.4	22	7.8
Subtotal	72	35.4	101	35.6
West Region				
Mountain Division	11	5.4	16	5.6
Pacific Division	13	6.4	23	8.1
Subtotal	24	11.8	39	13.7
Puerto Rico and the Outlying Areas	0	0	1	0.4
Total	**204**	**100.0**	**284**	**100.0**

TABLE 4. PROGRAMS BY LOCALE CLASSIFICATION

	Represented Programs		All Programs	
	n	**%**	***n***	**%**
City				
Large	65	32.0	89	31.3
Midsize	32	15.8	42	15.1
Small	34	16.7	40	14.1
Subtotal	131	64.5	172	60.6
Suburban				
Large	41	20.2	64	22.5
Midsize	3	1.5	4	1.4
Small	2	1.0	5	2.1
Subtotal	46	22.7	74	26.1
Town				
Fringe	9	4.4	9	3.2
Distant	13	6.4	15	5.3
Remote	1	0.5	7	2.5
Subtotal	23	11.3	31	10.9
Rural				
Fringe	3	1.5	6	2.1
Distant	0	0.0	1	0.4
Remote	0	0.0	0	0.0
Subtotal	3	1.5	7	2.5
Total	**203**	**100.0**	**284**	**100.0**

Note: For more information about locale classifications, visit NCES Locale Definitions.

FIGURE 3. SATELLITE CAMPUSES



15 programs reported operating a total of 21 satellite campuses. Of those programs with satellite campuses, 4 (26.7%) had separate admissions processes.

ACADEMIC TERMS & SCHEDULES

TABLE 5. ACADEMIC TERMS

	n	%
Semesters	171	83.8
Trimesters	14	6.9
Quarters	16	7.8
Other	3	1.5
Total	**204**	**100.0**

TABLE 6. CREDITS REQUIRED FOR COMPLETION BY ACADEMIC TERM

	n	Min	Max	*M*	*SD*	*Mdn*
Semesters	170	54.0	147.0	109.2	15.6	108.0
Trimesters	14	85.0	130.0	122.8	11.1	115.0
Quarters	16	110.0	193.0	149.0	24.3	146.5
Other	3	109.0	116.0	112.8	3.5	113.5
Total	**203**	**54.0**	**193.0**	**112.7**	**19.3**	**112.0**

FIGURE 4. PROGRAM START AND END MONTHS

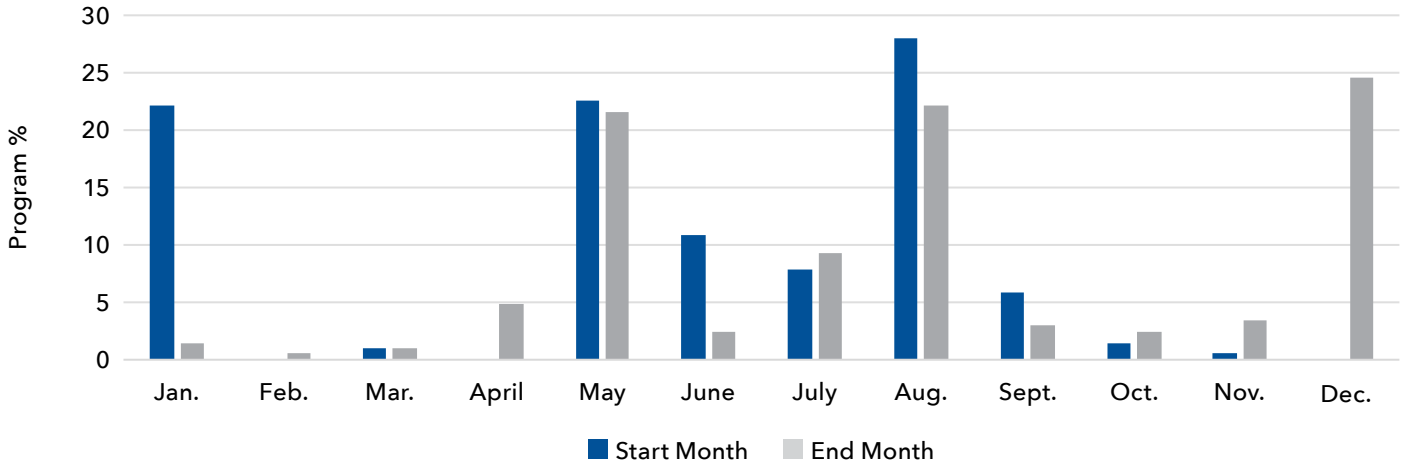


TABLE 7. PROGRAM LENGTH (WEEKS)

	n	Min	Max	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Didactic phase	202	43.0	94.0	56.6	9.0	48.0	52.0	52.0	63.0	68.0
Clinical phase	202	26.0	78.0	54.8	7.8	48.0	50.0	52.0	60.0	68.0
Vacation	203	2.0	33.0	9.4	4.4	5.0	7.0	8.0	11.0	14.0

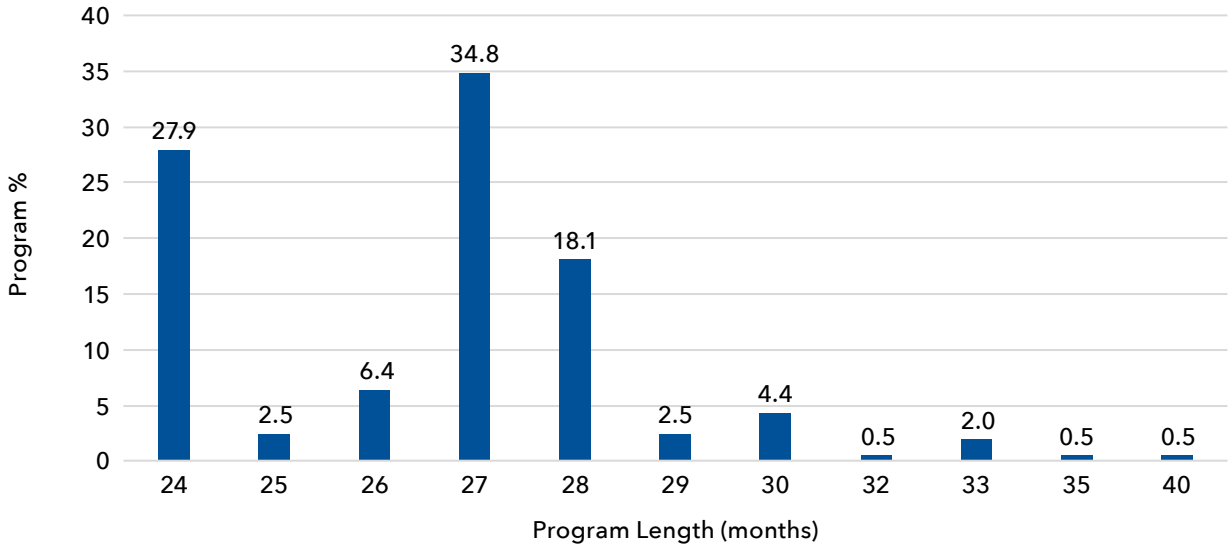
Note: The length of didactic and clinical phases did not exclude vacations or other time off. 46 programs (22.5%) offered clinical experiences during the didactic phase. On average, these programs offered clinical experiences on 14.9 days (Min =2.0, Max = 40.0, SD = 9.5, Mdn = 9.0).

48 programs (23.5%) offered clinical experiences during the didactic phase. On average, these programs offered clinical experiences on 14.9 days (Min = 2.0, Max = 160.0, SD = 23.6, Mdn = 9.0).

TABLE 8. TOTAL PROGRAM LENGTH (MONTHS)

	n	Min	Max	*M*	*SD*	*Mdn*
PA program length	204	24.0	40.0	26.7	2.3	27.0

FIGURE 5. TOTAL PROGRAM LENGTH (MONTHS)



ADMISSIONS

Programs were asked to report how many students were admitted during the graduate, professional phase of the 2020–2021 academic year from three categories:

- Admitted from undergraduate, pre-professional track to the graduate phase
- Direct program admission (not through CASPA) to the graduate phase
- CASPA applicant to the graduate phase (not part of undergraduate, pre-professional track)

TABLE 9. ADMISSIONS

	n (P)	**n *(S)***	***M***	***SD***	**P10**	**P25**	**P50 *(Mdn)***	**P75**	**P90**	**Mean % of Admissions**
Admitted from undergraduate, pre-professional track to the graduate phase	16	440	27.5	20.7	3.7	7.5	28.0	39.3	61.7	50.7
Direct program admission (not through CASPA) to the graduate phase	19	318	16.7	17.9	1.0	2.0	5.0	32.0	44.0	45.0
CASPA applicant to the graduate phase (not part of undergraduate, pre-professional track)	192	8,760	45.6	24.8	24.0	30.0	40.0	54.0	80.0	97.1

Note: "n (P)" refers to the number of reporting programs. "n (S)" refers to the number of students reported by the programs. "Mean % of admissions" represents the average percentage of admissions for that category for programs that reported admissions from that category. For example, for the 16 programs reporting that they admitted from undergraduate, pre-professional track to the graduate phase, on average 50.7% of their admissions used this pathway.

TABLE 10. USE OF CASPA IN ADMISSIONS

	n	**%**
All students were admitted through CASPA	170	83.7
Some but not all students were admitted through CASPA	22	10.8
No students were admitted through CASPA	11	5.4
Total	**203**	**100.0**

94.1% of programs reported using CASPA to admit some or all students.

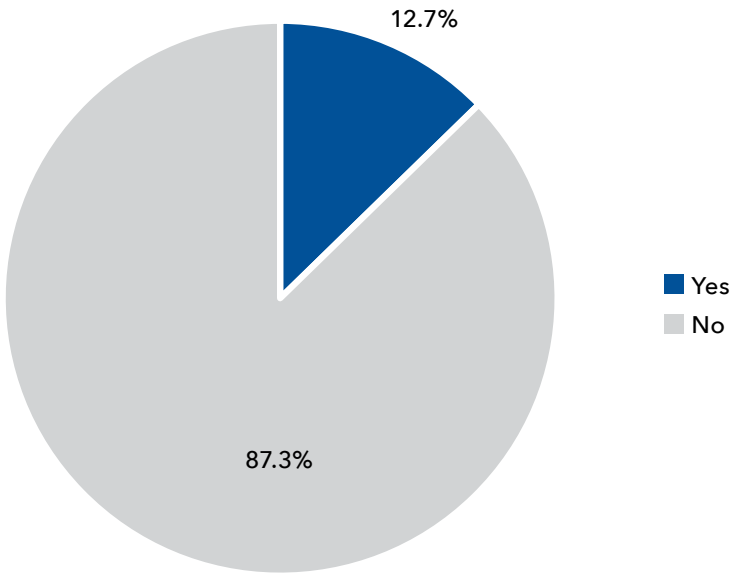
CREDENTIALS

TABLE 11. PRIMARY CREDENTIAL AWARDED TO PA GRADUATES

	n	%
Master's degree (not Master's of Public Health)	194	95.1
Master's of Public Health (MPH) as part of a dual Master's degree program	8	3.9
Dual Degree	1	0.5
Certificate of Completion	1	0.5
Total	**204**	**100.0**

PRE-PROFESSIONAL PHASE

FIGURE 6. PROGRAMS WITH A PRE-PROFESSIONAL PHASE



26 programs (12.7%) reported having a pre-professional phase. These programs reported admitting a total of 853 preprofessional students (Min = 2, Max = 150, M =35.5, SD = 35.5, Mdn = 29.5) in the 2020-2021 academic year.

TABLE 12. PROGRAM MODELS FOR THE PRE-PROFESSIONAL PHASE

	n	%
3+2	14	56.0
4+2	4	16.0
3+3	1	4.0
2+3	1	4.0
Other	5	20.0
Total	**25**	**100.0**

SECTION 2. FINANCIAL INFORMATION

Programs were asked to supply their financial information for the 2020–2021 fiscal year, as defined by the program, rather than the 2020–2021 academic year.

PAEA members are encouraged to read our limited series of **COVID-19 Rapid Response Reports** for information on how the pandemic impacted PA program finances.

Missing values, obvious and extreme outliers, and reports of $0 were excluded prior to analysis.

Throughout this section:

- **"% reporting"** refers to the proportion of responding programs that provided a dollar amount for a budget source, expense, or fee, divided by the total number of programs that provided dollar amounts for at least one budget source, expense, or fee. These numerators exclude programs that were unable to provide dollar amounts for that specific category.
- ***"n"*** refers to the number of programs that reported a dollar amount.
- ***"M*(T)"** refers to the 10% trimmed mean, or the mean when the top and bottom 10% of values are excluded. When interpreting financial statistics, readers are advised to rely primarily on medians and trimmed means, which are less susceptible to outlier influence then arithmetic means and are more useful for comparisons across time and between programs within the same year.

TABLE 13. FISCAL YEAR DEFINITIONS

	n	%
July 1 – June 30	154	75.5
June 1 – May 31	31	15.2
September 1 – August 31	8	3.9
October 1 – September 30	6	2.9
January 1 – December 31	4	2.0
Other (August 1 – July 31)	1	0.5
Total	**204**	**100.0**

PROGRAM BUDGET

Programs were asked to indicate all funding sources for their 2020–2021 fiscal year operations budgets, excluding in-kind contributions, from a list of 11 sources. Programs could provide up to five "Other" sources, which were recoded into existing categories when possible. Programs were then asked to report the dollar amount of funding received from each selected source. **"Total budget"** refers to the sum of each program's itemized budget sources. Programs that reported total budgets of under $120,000 were excluded. A total of 185 programs reported dollar amounts. **"Mean % of budget"** was calculated by dividing each program's amount of financial support from each source by the program's total budget, then taking the average percentage across reporting programs. The percentages do not sum to 100% because not all programs reported receiving financial support from each source.

TABLE 14. SOURCES OF PROGRAMS' FINANCIAL SUPPORT ($)

	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90	Mean % of Budget
Budgeted funds from sponsoring institution	66.5	123	1,733,623	1,368,184	1,994,526	235,183	659,043	1,348,754	2,062,724	3,341,105	82.8
Tuitions and fees received directly by the program	50.8	94	2,681,918	2,318,889	2,421,957	119,129	626,531	2,340,668	3,651,167	5,778,248	74.2
Federal grant/contract	13.0	24	236,641	209,970	230,313	13,893	66,022	126,918	351,369	632,200	10.5
Private donations and gifts	11.9	22	38,792	25,748	59,352	1,082	1,565	11,250	64,401	118,589	6.7
State appropriations	11.4	21	828,846	730,824	766,100	32,915	246,857	689,535	1,175,113	1,616,758	37.9
Other	11.4	21	356,777	189,233	694,944	9,214	19,298	47,259	348,054	1,552,399	21.3
Endowment	5.9	11	130,108	103,340	174,653	2,499	18,950	35,112	291,947	475,000	5.6
State grant/contract (not appropriations)	4.9	9	155,056	155,056	215,732	42,508	51,500	60,000	176,500	355,000	4.4
Clinical practice income	2.7	5	64,348	64,348	50,777	17,503	25,143	38,796	116,330	120,945	2.8
Total		**185**	**2,733,660**	**2,237,345**	**2,555,044**	**464,781**	**1,294,775**	**1,928,050**	**3,270,555**	**6,014,248**	**100.0**

TABLE 15. SOURCES OF FINANCIAL SUPPORT AMONG PUBLIC AND PRIVATE PROGRAMS ($)

	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90	Mean % of Budget
Public											
Budgeted funds from sponsoring institution	66.1	39	1,650,664	1,205,471	2,250,066	273,183	660,000	1,114,532	1,689,449	3,525,733	75.9
Tuition and fees received directly by the program	49.2	29	1,754,054	1,423,656	2,141,633	119,057	263,116	1,457,828	2,419,823	3,592,315	60.1
State appropriations	35.6	21	828,846	740,631	766,100	32,915	246,857	689,535	1,175,113	1,616,758	37.9
Federal grant/contract	16.9	10	263,750	263,750	201,634	71,734	91,214	197,193	470,521	579,168	17.4
Private donations and gifts	11.9	7	27,395	27,395	29,971	1,289	1,300	8,000	71,168	71,198	1.4
Endowment	8.5	5	121,310	121,310	189,968	9,731	11,882	35,112	273,838	319,070	8.4
Total		**59**	**2,395,486**	**1,911,273**	**2,349,249**	**731,697**	**1,190,570**	**1,689,449**	**2,728,088**	**3,939,195**	**100.0**
Private											
Budgeted funds from sponsoring institution	67.5	83	1,781,866	1,476,676	1,886,710	231,706	633,580	1,507,000	2,131,400	3,341,105	85.8
Tuition and fees received directly by the program	52.0	64	3,087,459	2,788,276	2,458,223	115,866	1,591,960	2,742,691	4,037,582	6,357,670	80.7
State appropriations	11.4	14	217,278	186,408	245,169	7,500	31,484	94,208	340,580	742,500	5.6
Federal grant/contract	12.2	15	44,111	32,080	68,845	880	1,600	12,500	32,145	182,762	7.5
Private donations and gifts	30.0	6	137,439	137,439	143,695	13,475	16,213	65,369	312,710	333,474	3.2
Endowment	4.9	6	62,251	62,251	16,210	46,254	48,127	56,500	84,000	84,000	1.9
Total		**123**	**2,912,190**	**2,443,811**	**2,662,966**	**336,180**	**1,425,230**	**2,066,424**	**3,566,944**	**6,529,690**	**100.0**

Note: Sources with fewer than 5 programs reporting dollar amounts were excluded.

Average class size was calculated as the sum of first-, second-, and third-year enrollment (total enrollment) divided by the total number of enrolled cohorts. This number was then classified into one of the following categories:

- 25 or fewer students
- 26–50 students
- 51–75 students
- 76–100 students

TABLE 16. SOURCES OF FINANCIAL SUPPORT BY AVERAGE CLASS SIZE ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90	Mean % of Budget
25 or fewer students										
Budgeted funds from sponsoring institution	16	1,013,942	923,610	796,211	97,209	431,006	945,200	1,309,061	2,442,771	77.0
Federal grant/contract	6	185,239	185,239	217,547	10,000	51,022	78,672	369,848	439,698	20.4
State appropriations	5	537,798	537,798	314,868	238,114	246,857	516,666	839,305	869,258	39.2
Tuition and fees received directly by the program	17	1,270,704	1,226,864	976,833	99,646	274,450	1,112,712	1,985,940	2,841,305	73.2
Total	**28**	**1,938,577**	**1,549,170**	**2,404,582**	**291,310**	**1,107,743**	**1,505,763**	**2,101,408**	**3,183,454**	**100.0**
26-50 students										
Budgeted funds from sponsoring institution	73	1,529,315	1,217,106	1,529,315	235,183	470,618	1,235,783	1,752,458	2,692,085	82.4
Endowment	5	151,243	151,243	169,286	18,950	20,795	47,676	333,474	341,779	3.8
Federal grant/contract	11	212,905	170,773	275,134	7,557	36,050	101,784	300,000	777,000	6.2
Private donations and gifts	16	37,225	24,531	67,789	910	1,340	6,175	44,979	171,389	6.9
State appropriations	10	724,709	700,576	509,197	42,826	275,816	664,048	1,109,376	1,586,398	31.5
Tuition and fees received directly by the program	56	2,724,426	2,491,769	2,099,185	94,150	1,509,063	2,562,855	3,584,944	5,097,369	2.1
Total	**109**	**2,554,311**	**2164551**	**2,226,450**	**397,138**	**1,369,566**	**1,775,534**	**3,222,661**	**4,700,000**	**100.0**

TABLE 16 (CONTINUED). SOURCES OF FINANCIAL SUPPORT BY AVERAGE CLASS SIZE ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90	Mean % of Budget
51-75 students										
Budgeted funds from sponsoring institution	26	2,274,094	1,965,491	1,976,492	149,039	1,176,671	1,959,250	2,658,531	4,577,600	85.5
Federal grant/contract	6	311,539	311,539	176,779	85,000	166,000	289,575	470,521	506,043	9.8
State appropriations	6	1,244,948	1,244,948	1,219,610	30,502	39,550	1,237,000	2,037,575	2,461,310	47.5
Tuition and fees received directly by the program	14	2,972,067	2,603,624	3,109,695	105,428	243,790	2,411,863	5,163,837	8,444,569	65.2
Total	**37**	**3,633,317**	**2,859,241**	**4,439,279**	**219,621**	**1,547,272**	**2,465,293**	**3,950,020**	**7,648,640**	**100.0**
76-100 students										
Total	**6**	**5,408,354**	**5,408,354**	**2,890,229**	**2,336,374**	**2,394,801**	**5,132,291**	**8,508,965**	**8,717,446**	**100.0**

Note: Subgroups with fewer than 5 programs reporting dollar amounts were excluded. Therefore, subgroup "n"s may not sum to the subtotal "n"s.

TABLE 17. SOURCES OF FINANCIAL SUPPORT BY AVERAGE CLASS SIZE AMONG PUBLIC AND PRIVATE PROGRAMS ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
Public									
Budgeted funds from sponsoring institution									
25 or fewer students	9	892,417	892,417	637,389	51,000	320,538	833,399	1,247,469	1,518,791
26-50 students	19	1,735,957	1,254,500	2,450,797	395,633	659,043	1,116,523	1,689,449	3,525,733
51-75 students	7	2,411,400	2,411,400	3,233,651	16,627	731,697	1,280,000	20,758,380	5,085,228
Subtotal	39	1,650,664	1,205,471	2,250,066	273,183	660,000	1,114,532	1,689,449	3,525,733
Tuition and fees received directly by the program									
25 or fewer students	5	635,092	635,092	461,680	119,057	181,573	612,000	1,100,157	1,102,668
26-50 students	18	1,604,711	1,578,631	1,103,954	37,378	343,284	1,689,077	2,368,880	3,276,222
Subtotal	29	1,754,054	1,423,656	2,141,633	119,057	263,116	1,457,828	2,419,823	3,592,315
Total budget									
25 or fewer students	12	1,275,403	1,300,816	530,754	323,610	1,107,743	1,156,065	1,720,554	2,056,279
26-50 students	31	2,353,547	2,072,815	1,916,073	889,329	1,474,368	1,713,215	2,935,626	3,578,999
51-75 students	10	3,029,554	3,029,554	2,711,804	784,168	1,515,752	2,320,440	3,212,539	9,667,615
Subtotal	59	2,395,486	1,911,273	2,349,249	731,697	1,190,570	1,689,449	2,728,088	3,939,195

TABLE 17 (CONTINUED). SOURCES OF FINANCIAL SUPPORT BY AVERAGE CLASS SIZE AMONG PUBLIC AND PRIVATE PROGRAMS ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
Private									
Budgeted funds from sponsoring institution									
25 or fewer students	7	1,170,190	1,170,190	996,272	295,900	399,987	1,057,000	1,348,754	2,105,868
26-50 students	53	1,465,885	1,308,640	1,460,724	224,863	420,869	1,372,580	1,968,502	2,692,085
51-75 students	19	2,223,508	2,223,508	1,389,313	108,000	1,507,000	2,131,400	3,000,000	3,917,378
Subtotal	83	1,781,866	1,476,676	1,886,710	231,706	633,580	1,507,000	2,131,400	3,341,105
Tuition and fees received directly by the program									
25 or fewer students	12	1,535,542	1,522,751	1,024,826	90,400	410,925	1,752,105	2,306,944	3,051,114
26-50 students	38	3,254,818	3,148,224	2,256,438	100,050	2,131,578	3,073,040	4,000,570	5,902,826
51-75 students	9	3,818,932	3,818,932	3,496,490	91,656	236,366	3,711,881	6,357,670	7,347,032
Subtotal	64	3,087,459	2,788,276	2,458,223	115,866	1,591,960	2,742,691	4,037,582	6,357,670
Total budget									
25 or fewer students	16	2,435,957	1,802,698	3,096,018	282,130	1,095,997	1,848,523	2,669,886	6,515,340
26-50 students	76	2,669,879	2,455,977	2,365,001	336,452	1,204,646	2,015,294	3,535,749	6,211,177
51-75 students	23	3,252,520	3,008,100	2,390,717	522,231	1,574,326	2,538,616	4,506,396	6,642,657
76-100 students	5	4,829,928	4,829,928	2,816,461	2,336,374	2,375,326	4,437,582	7,480,704	7,811,445
Subtotal	123	2,912,190	2,443,811	2,662,966	336,180	1,425,230	2,066,424	3,566,944	6,529,690

TABLE 17 (CONTINUED). SOURCES OF FINANCIAL SUPPORT BY AVERAGE CLASS SIZE AMONG PUBLIC AND PRIVATE PROGRAMS ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
All programs									
Budgeted funds from sponsoring institution									
25 or fewer students	16	1,013,942	1,013,942	796,211	97,209	431,006	945,200	1,309,061	2,442,771
26-50 students	73	1,529,315	1,292,296	1,749,649	235,183	470,618	1,235,783	1,752,458	2,692,086
51-75 students	26	2,274,094	2,061,122	1,976,492	149,039	1,176,671	1,959,250	2,658,531	4,577,600
Subtotal	123	1,733,623	1,368,184	1,994,526	235,183	659,043	1,348,754	2,062,724	3,341,105
Tuition and fees received directly by the program									
25 or fewer students	17	1,270,704	1,270,704	976,833	99,646	274,450	1,112,712	1,985,940	2,841,305
26-50 students	56	2,724,426	2,562,023	2,099,185	94,150	1,509,063	2,562,855	3,584,944	5,097,369
51-75 students	14	2,972,067	2,812,210	3,109,695	105,428	243,790	2,411,863	5,163,837	8,444,569
Subtotal	94	2,681,918	2,318,889	2,421,957	119,129	626,531	2,340,668	3,651,167	5,778,248
Total budget									
25 or fewer students	28	1,938,577	2,166,887	2,404,582	291,310	1,107,743	1,505,763	2,101,408	3,183,454
26-50 students	109	2,554,311	2,287,246	2,226,450	397,138	1,369,566	1,775,534	3,222,661	4,700,000
51-75 students	34	3,198,486	3,071,667	2,415,094	841,089	1,595,232	2,501,955	3,945,087	6,555,234
76-100 students	6	5,408,354	5,408,354	2,890,229	2,336,374	2,394,801	5,132,291	8,508,965	8,717,446
Subtotal	185	2,733,660	2,237,345	2,555,044	464,781	1,294,775	1,928,050	3,270,555	6,014,248

Note: Subgroups with fewer than 5 programs reporting dollar amounts were excluded. Therefore, subgroup "n"s may not sum to the subtotal "n"s.

TABLE 18. SOURCES OF FINANCIAL SUPPORT BY ACADEMIC HEALTH CENTER STATUS ($)

	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90	Mean % of Budget
Academic Health Center											
Budgeted funds from sponsoring institution	53.7	29	1,966,494	1,752,271	2,016,702	273,183	695,849	1,517,017	2,491,491	4,200,854	72.9
Federal grant/contract	14.8	8	283,554	283,554	168,823	101,784	115,167	271,981	415,441	477,626	9.6
Private donations and gifts	9.3	5	48,972	48,972	55,016	1,000	4,500	36,446	99,708	107,220	6.3
State appropriations	31.5	17	868,705	762,281	845,015	29,402	220,688	689,535	1,394,794	1,955,746	38.9
Tuitions and fees received directly by the program	59.3	32	3,134,773	2,971,789	2,985,403	168,083	745,432	2,473,202	4,003,816	8,850,363	74.2
Total		**54**	**3,347,418**	**3,167,163**	**2,665,486**	**1,110,310**	**1,686,735**	**2,488,983**	**3,749,982**	**8,630,892**	**100.0**
Non-Academic Health Center											
Endowment	71.8	94	1,661,780	1,372,715	1,992,987	232,186	617,685	1,338,798	2,024,475	2,838,354	85.9
Federal grant/contract	5.3	7	153,181	153,181	199,826	8,000	18,950	47,676	375,000	425,000	8.0
Private donations and gifts	12.2	16	213,185	213,185	257,436	8,500	39,538	86,172	326,389	719,500	11.0
State grant/contract (not appropriations)	13.0	17	35,798	35,798	61,845	1,158	1,530	10,000	61,404	110,200	6.9
Tuitions and fees received directly by the program	3.8	5	56,702	56,702	15,910	42,508	46,254	53,000	69,000	72,000	2.0
Endowment	47.3	62	2,448,186	2,272,996	2,061,693	95,059	446,458	2,292,347	3,367,813	5,176,118	7.4
Total		**131**	**2,480,661**	**2,141,757**	**2,474,354**	**343,290**	**1,116,523**	**1,730,654**	**2,950,387**	**4,661,815**	**100**

Note: Sources with fewer than 5 programs reporting dollar amounts were excluded.

TABLE 19. SOURCES OF FINANCIAL SUPPORT BY ADMINISTRATIVE HOUSING ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90	Mean % of Budget
College of Graduate and Professional Studies (n=8)										
Total	**7**	**3,242,389**	**3,242,389**	**1,903,736**	**70,943**	**2,175,684**	**3,177,000**	**3,407,482**	**4,841,429**	**100.0**
College/School of Medicine										
Budgeted funds from sponsoring institution	18	1,462,072	1,374,964	1,090,514	257,566	508,797	1,365,434	1,893,684	3,120,085	64.8
Tuitions and fees received directly by the program	20	3,466,391	3,051,611	2,987,302	288,328	1,541,131	3,148,074	4,062,411	8,924,321	75.9
Total	**30**	**3,418,473**	**2,926,080**	**2,728,248**	**1,216,479**	**1,695,156**	**2,373,469**	**3,844,065**	**8,895,218**	**100.0**
Department of PA Studies/ PA Program										
Budgeted funds from sponsoring institution	26	2,806,515	2,486,443	3,382,767	276,066	848,209	1,980,525	2,479,686	9,886,150	88.7
Tuitions and fees received directly by the program	20	2,695,781	2,414,624	2,333,067	309,196	1,683,974	2,285,567	2,979,412	5,975,178	80.5
Total	**41**	**3,231,951**	**2,888,476**	**3,146,487**	**343,290**	**1,696,066**	**2,131,400**	**3,348,020**	**9,485,624**	**100.0**
School of Allied Health/ Health Professions/ Health Sciences										
Budgeted funds from sponsoring institution	61	1,340,476	1,265,475	1,013,213	224,181	645,872	1,200,341	1,603,268	3,014,542	83.9
Tuitions and fees received directly by the program	43	2,215,009	1,986,341	2,220,202	48,670	250,000	1,917,340	3,302,806	5,531,770	69.4
Total	**88**	**2,289,069**	**2,014,184**	**2,159,475**	**330,735**	**1,087,428**	**1,649,823**	**3,049,472**	**4,008,514**	**100.0**

Note: Sources with fewer than 5 programs reporting dollar amounts were excluded.

PROGRAM EXPENSES

Programs were asked to report their total, non-itemized expenses for the 2020–2021 fiscal year. In addition, programs were asked to indicate itemized expenses incurred during the 2020–2021 fiscal year, from a list of 22 expense categories. Programs were then asked to report dollar amounts for each selected category. Programs could provide up to five "Other" sources, which were recoded into existing categories when possible. A total of 202 programs reported dollar amounts. "Total expenses" refers to the sum of each program's itemized expenses.

TABLE 20. PROGRAM EXPENSES ($)

	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
ARC-PA/Accreditation	85.6	173	29,664	16,751	115,447	15,000	15,000	15,000	15,000	24,321
Building expenses (e.g. lease, rent, furniture, renovations)	28.7	58	291,027	149,592	838,154	1,330	3,449	27,465	241,778	602,015
Education equipment/texts (not including simulation products)	58.9	119	33,029	21,743	68,458	994	2,344	15,000	33,891	59,829
Events (e.g. white coat ceremony, graduation)	70.3	142	9,999	5,560	26,694	1,000	2,000	3,500	7,930	16,245
Exam/testing (board review materials and test item banks)	71.3	144	28,018	20,845	42,723	4,667	9,800	15,100	24,520	44,460
Faculty development (e.g., CME, conferences, coursework, advanced degree)	83.2	168	17,802	12,834	30,408	1,595	3,530	9,400	20,175	36,948
Faculty fringe benefits	68.8	139	376,405	285,961	522,247	100,124	157,516	251,508	370,083	576,420
Faculty salaries (excluding fringe benefits)	89.1	180	1,130,712	949,495	1,213,129	498,491	663,261	898,026	1,200,886	1,602,861
Institution tax	13.9	28	637,439	551,781	809,247	3,852	23,122	522,307	872,444	1,330,045

TABLE 20 (CONTINUED). PROGRAM EXPENSES ($)

	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
IT (e.g. hardware, databases, clinical tracking, other software)	64.9	131	37,587	27,869	68,911	5,000	10,000	23,450	42,462	61,320
Laboratory supplies	69.8	141	49,866	17,753	329,802	2,000	5,852	12,500	25,010	46,000
Marketing and student recruitment	34.2	69	12,891	4,547	55,119	524	1,000	2,041	6,618	12,696
Office expenses (e.g., supplies, printing)	72.3	146	21,547	8,131	92,009	988	2,000	4,533	9,312	28,898
Payment for didactic instruction not included in faculty salaries	60.4	122	110,213	64,552	247,081	4,051	12,000	36,568	98,201	221,581
Payment for student housing and travel to remote clinical training sites	16.8	34	40,778	37,783	46,651	1,529	5,937	19,188	65,706	108,218
Payment for supervised clinical practice (sites and/or clinical preceptors)	50.0	101	218,823	170,421	305,466	8,000	35,000	112,000	295,200	450,000
Program membership/association fees and dues (including PAEA)	79.2	160	18,902	9,549	72,002	4,275	4,275	6,217	12,000	25,579
Simulation activities (excluding capital and standardized patients)	27.2	55	32,414	25,757	54,459	1,564	3,054	10,000	30,000	93,770
Staff fringe benefits	60.4	122	90,634	71,413	122,090	15,497	30,025	55,116	91,223	213,409
Staff salaries (excluding fringe benefits)	84.2	170	274,368	214,071	394,217	54,972	97,163	157,199	294,247	484,427
Standardized patients	44.6	90	24,125	13,687	66,566	2,374	5,000	8,530	20,000	37,783
Travel (not faculty development)	50.0	101	18,600	8,102	66,128	299	1,100	2,981	7,800	30,000
Other	32.7	66	342,027	177,106	915,488	5,340	19,909	47,564	166,189	540,201
Total expenses		**202**	**2,070,398**	**1,879,586**	**1,457,616**	**952,355**	**1,279,616**	**1,653,999**	**2,347,298**	**3,334,487**

Note: Sources with fewer than 5 programs reporting dollar amounts were excluded.

TABLE 21. PROGRAM EXPENSES AMONG PRIVATE AND PUBLIC PROGRAMS ($)

Public	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
ARC-PA/Accreditation	86.8	46	16,051	15,604	5,275	15,000	15,000	15,000	15,000	19,638
Building expenses (e.g. lease, rent, furniture, renovations)	35.8	19	159,409	159,409	313,992	1,394	2,541	7,802	141,125	469,032
Education equipment/texts (not including simulation products)	56.6	30	19,467	16,622	27,689	1,064	1,826	5,600	28,426	45,655
Events (e.g. white coat ceremony, graduation)	66.0	35	11,288	4,394	41,914	851	1,636	2,571	5,016	9,317
Exam/testing (board review materials and test item banks)	67.9	36	30,945	26,118	49,757	4,675	9,688	15,169	25,320	44,994
Faculty development (e.g., CME, conferences, coursework, advanced degree)	84.9	45	14,116	10,706	23,330	2,190	3,495	9,000	13,447	30,065
Faculty fringe benefits	73.6	39	324,974	316,328	222,931	130,756	188,580	254,381	370,083	739,973
Faculty salaries (excluding fringe benefits)	96.2	51	1,114,099	997,666	888,175	463,393	625,370	948,783	1,255,348	1,835,200
Institution tax	17.0	9	521,910	521,910	461,808	3,933	5,848	600,000	869,990	1,023,293
IT (e.g. hardware, databases, clinical tracking, other software)	66.0	35	48,917	33,664	102,680	4,100	10,000	23,450	44,691	83,505
Laboratory supplies	64.2	34	28,083	20,339	54,841	1,857	5,213	9,298	24,000	74,807
Marketing and student recruitment	30.2	16	31,074	31,074	111,756	538	1,000	2,120	5,000	9,369
Office expenses (e.g., supplies, printing)	67.9	36	24,530	17,150	58,330	1,409	2,679	6,688	15,790	35,223
Payment for didactic instruction not included in faculty salaries	47.2	25	54,068	45,713	75,938	3,709	8,750	27,200	61,356	131,305

TABLE 21 (CONTINUED). PROGRAM EXPENSES AMONG PRIVATE AND PUBLIC PROGRAMS ($)

Public	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
Payment for student housing and travel to remote clinical training sites	17.0	9	44,161	44,161	51,112	1,800	4,413	19,875	96,000	113,280
Payment for supervised clinical practice (sites and/or clinical preceptors)	28.3	15	227,835	227,835	436,353	5,024	9,038	44,999	202,025	565,564
Program membership/association fees and dues (including PAEA)	79.2	42	13,020	8,921	23,993	4,275	4,275	5,038	10,719	26,207
Simulation activities (excluding capital and standardized patients)	32.1	17	49,237	49,237	69,492	2,589	5,000	10,000	78,000	147,556
Staff fringe benefits	69.8	37	83,382	72,926	106,912	15,053	29,945	53,939	91,656	122,915
Staff salaries (excluding fringe benefits)	92.5	49	232,516	191,800	270,039	40,012	96,356	161,449	280,114	393,429
Standardized patients	34.0	18	41,131	41,131	131,297	2,868	4,201	6,381	10,632	36,412
Travel (not faculty development)	43.4	23	11,993	8,768	22,279	391	2,169	3,500	8,500	24,849
Other	41.5	22	187,357	111,678	409,919	5,043	18,444	30,127	144,570	424,854
Total expenses		**53**	**1,981,300**	**1,820,766**	**1,290,046**	**1,068,865**	**1,277,305**	**1,667,437**	**2,262,131**	**2,983,986**
Private	**% Reporting**	***n***	***M***	***M(T)***	***SD***	**P10**	**P25**	**P50 (*Mdn*)**	**P75**	**P90**
ARC-PA/Accreditation	89.7	105	37,405	17,895	147,316	15,000	15,000	15,000	19,275	30,000
Building expenses (e.g. lease, rent, furniture, renovations)	27.4	32	315,897	161,558	932,639	1,210	3,480	50,980	253,870	662,818
Education equipment/texts (not including simulation products)	58.1	68	31,721	21,770	66,017	617	4,679	16,897	33,722	58,536
Events (e.g. white coat ceremony, graduation)	77.8	91	8,726	6,377	13,884	1,000	2,175	4,000	8,577	19,638
Exam/testing (board review materials and test item banks)	82.1	96	28,654	22,532	42,376	4,830	10,278	15,340	25,000	59,978

TABLE 21 (CONTINUED). PROGRAM EXPENSES AMONG PRIVATE AND PUBLIC PROGRAMS ($)

Private	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
Faculty development (e.g., CME, conferences, coursework, advanced degree)	88.0	103	19,063	12,859	34,948	1,586	3,136	9,300	21,241	38,160
Faculty fringe benefits	71.8	84	350,943	267,291	495,529	100,000	146,728	253,137	358,789	483,255
Faculty salaries (excluding fringe benefits)	89.7	105	1,209,681	970,056	1,450,458	578,068	680,323	903,412	1,194,487	1,635,460
Institution tax	13.7	16	772,586	772,586	992,168	15,175	59,125	522,307	880,771	2,084,356
IT (e.g. hardware, databases, clinical tracking, other software)	67.5	79	33,123	26,622	54,824	6,189	10,000	22,990	38,407	57,031
Laboratory supplies	78.6	92	63,136	18,152	407,044	2,033	7,125	13,374	25,960	42,411
Marketing and student recruitment	37.6	44	8,294	5,298	16,750	551	1,250	2,498	9,001	16,050
Office expenses (e.g., supplies, printing)	78.6	92	22,305	7,168	109,583	611	1,736	4,377	8,025	22,576
Payment for didactic instruction not included in faculty salaries	71.8	84	117,189	73,104	234,555	5,246	19,680	40,200	116,794	218,735
Payment for student housing and travel to remote clinical training sites	19.7	23	42,639	38,220	46,722	2,400	10,819	26,361	64,237	103,248
Payment for supervised clinical practice (sites and/or clinical preceptors)	65.8	77	220,811	179,640	288,082	13,000	55,000	138,100	309,128	386,049
Program membership/association fees and dues (including PAEA)	84.6	99	20,953	10,644	86,306	4,275	4,568	7,053	13,168	24,246
Simulation activities (excluding capital and standardized patients)	26.5	31	24,893	18,257	48,629	1,330	2,600	8,975	18,930	56,497
Staff fringe benefits	62.4	73	98,129	79,236	134,507	20,568	42,795	58,579	88,588	213,170
Staff salaries (excluding fringe benefits)	83.8	98	286,447	241,369	346,592	65,381	113,004	163,876	322,464	568,599

TABLE 21 (CONTINUED). PROGRAM EXPENSES AMONG PRIVATE AND PUBLIC PROGRAMS ($)

Private	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
Standardized patients	54.7	64	20,818	14,638	38,558	2,409	5,375	9,619	20,382	40,534
Travel (not faculty development)	59.0	69	21,914	9,542	78,875	260	1,062	2,500	6,039	38,919
Other	32.5	38	471,300	361,061	1,154,942	5,432	17,958	49,350	253,815	1,176,685
Total expenses		**117**	**2,242,721**	**2,044,833**	**1,622,473**	**1,074,268**	**1,369,433**	**1,762,795**	**2,409,277**	**3,934,453**

TABLE 22. PROGRAM EXPENSES BY ACADEMIC HEALTH CENTER STATUS ($)

AHC	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
ARC-PA/Accreditation	78.7	48	18,498	15,726	19,769	15,000	15,000	15,000	15,000	19,572
Building expenses (e.g. lease, rent, furniture, renovations)	39.3	24	185,369	146,596	334,299	703	2,191	28,770	141,835	736,511
Education equipment/texts (not including simulation products)	52.5	32	22,481	14,142	53,432	188	1,000	3,500	20,784	44,196
Events (e.g. white coat ceremony, graduation)	63.9	39	13,776	7,761	39,805	1,599	2,146	4,000	9,265	27,984
Exam/testing (board review materials and test item banks)	68.9	42	25,630	19,585	35,013	7,280	11,408	15,900	24,345	37,405
Faculty development (e.g., CME, conferences, coursework, advanced degree)	77.0	47	14,700	12,537	17,959	2,435	3,812	9,000	14,500	39,898
Faculty fringe benefits	72.1	44	443,728	343,077	581,220	131,837	213,774	280,790	425,270	811,037
Faculty salaries (excluding fringe benefits)	86.9	53	1,265,999	1,162,220	837,659	630,452	826,035	1,139,028	1,394,279	1,857,120

TABLE 22 (CONTINUED). PROGRAM EXPENSES BY ACADEMIC HEALTH CENTER STATUS ($)

AHC	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
Institution tax	32.8	20	786,327	679,070	891,265	5,673	108,496	639,457	910,913	1,824,634
IT (e.g. hardware, databases, clinical tracking, other software)	62.3	38	51,480	37,641	99,018	4,550	10,000	28,330	52,453	97,967
Laboratory supplies	60.7	37	25,014	17,783	51,068	970	2,000	8,055	28,811	51,600
Marketing and student recruitment	36.1	22	27,104	7,313	95,267	600	1,002	1,775	9,050	22,839
Office expenses (e.g., supplies, printing)	67.2	41	33,328	23,395	65,468	1,000	4,109	7,757	20,390	121,990
Payment for didactic instruction not included in faculty salaries	50.8	31	81,744	77,026	88,297	3,138	9,250	55,000	112,438	223,004
Payment for student housing and travel to remote clinical training sites	21.3	13	55,438	55,438	54,628	3,527	15,264	39,032	74,119	123,120
Payment for supervised clinical practice (sites and/or clinical preceptors)	23.0	14	118,324	118,324	118,713	34,800	55,115	88,177	121,038	189,384
Program membership/association fees and dues (including PAEA)	75.4	46	11,939	8,422	22,371	4,275	4,275	5,638	10,300	24,725
Simulation activities (excluding capital and standardized patients)	34.4	21	50,213	43,561	65,936	1,330	3,037	13,770	78,000	130,815
Staff fringe benefits	63.9	39	96,302	87,110	102,702	19,777	39,126	69,034	97,299	211,741
Staff salaries (excluding fringe benefits)	78.7	48	353,584	273,190	537,530	51,230	128,905	200,247	333,332	628,991
Standardized patients	39.3	24	42,101	20,222	113,694	2,239	5,615	11,000	27,692	52,250
Travel (not faculty development)	29.5	18	50,609	50,609	142,625	195	1,031	4,000	24,686	72,838
Other	34.4	21	719,306	536,539	1,423,851	5,429	24,963	147,672	449,838	1,886,000
Total expenses		**61**	**2,682,262**	**2,447,577**	**1,989,934**	**1,083,853**	**1,582,352**	**2,115,687**	**3,006,302**	**4,168,726**

TABLE 22 (CONTINUED). PROGRAM EXPENSES BY ACADEMIC HEALTH CENTER STATUS ($)

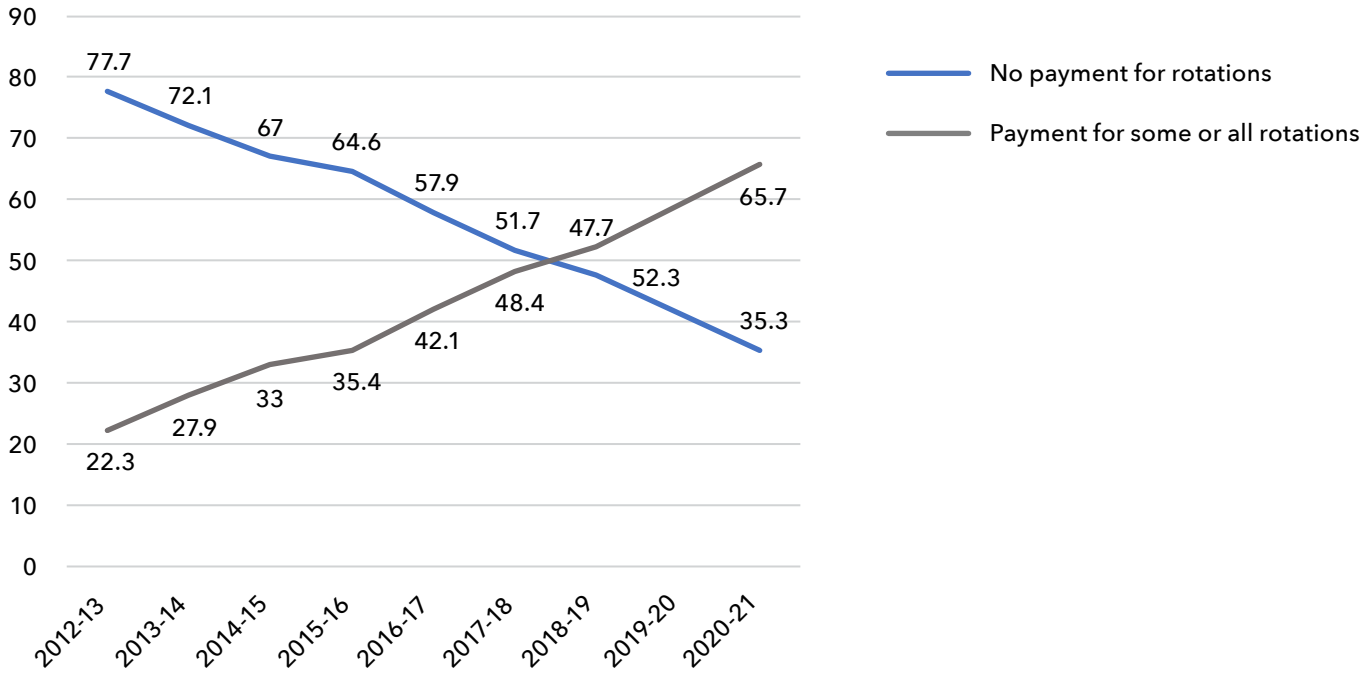
Non-AHC	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
ARC-PA/Accreditation	87.4	125	33,951	17304.85	135,174	15,000	15,000	15,000	16,330	25,000
Building expenses (e.g. lease, rent, furniture, renovations)	23.8	34	365,608	224,012	1,059,091	2,064	3,875	26,759	241,778	441,231
Education equipment/texts (not including simulation products)	60.8	87	36,909	24,618	73,107	1,383	4,553	18,546	37,939	60,000
Events (e.g. white coat ceremony, graduation)	72.0	103	8,569	4,920	19,677	1,000	1,710	3,182	7,500	12,900
Exam/testing (board review materials and test item banks)	71.3	102	29,001	21,360	45,643	4,629	8,450	15,005	24,775	44,820
Faculty development (e.g., CME, conferences, coursework, advanced degree)	84.6	121	19,006	12,949	34,029	1,500	3,495	9,744	22,320	35,526
Faculty fringe benefits	66.4	95	345,224	259,534	492,718	100,000	136,221	236,888	331,165	524,904
Faculty salaries (excluding fringe benefits)	88.8	127	1,074,253	866,038	1,337,996	465,346	647,070	797,930	1,058,218	1,403,754
Institution tax	5.6	8	265,221	265,221	384,957	2,771	17,276	46,748	406,026	872,935
IT (e.g. hardware, databases, clinical tracking, other software)	65.0	93	31,910	25,820	51,524	5,040	10,000	22,223	41,342	55,122
Laboratory supplies	72.7	104	58,707	18,317	382,922	3,034	8,843	12,561	24,645	42,093
Marketing and student recruitment	32.9	47	6,238	3,942	14,349	518	1,000	2,198	5,895	10,000
Office expenses (e.g., supplies, printing)	73.4	105	16,947	5,695	100,392	754	1,835	3,900	6,965	15,591
Payment for didactic instruction not included in faculty salaries	63.6	91	119,911	69,419	281,254	4,760	12,006	31,000	89,059	202,046
Payment for student housing and travel to remote clinical training sites	14.7	21	31,703	28,182	39,677	1,327	4,413	16,590	34,568	100,000

TABLE 22 (CONTINUED). PROGRAM EXPENSES BY ACADEMIC HEALTH CENTER STATUS ($)

Non-AHC	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
Payment for supervised clinical practice (sites and/or clinical preceptors)	60.8	87	234,996	184,114	323,203	5,036	32,486	138,050	309,564	503,600
Program membership/association fees and dues (including PAEA)	79.7	114	21,712	10,500	84,070	4,275	4,425	6,353	12,395	28,629
Simulation activities (excluding capital and standardized patients)	23.8	34	21,421	15,186	43,498	1,941	4,250	9,238	15,806	38,618
Staff fringe benefits	58.0	83	87,971	67,187	130,710	14,732	27,877	50,000	79,786	207,163
Staff salaries (excluding fringe benefits)	85.3	122	243,201	191,124	318,363	57,087	95,250	141,757	268,919	420,838
Standardized patients	46.2	66	17,588	11,804	36,476	2,449	5,000	8,038	17,250	29,927
Travel (not faculty development)	58.0	83	11,658	5,851	29,017	320	1,100	2,959	6,270	21,020
Other	31.5	45	165,963	71,059	465,798	5,354	19,288	39,670	110,183	252,845
Total expenses		**142**	**1,811,865**	**1,696,303**	**1,070,126**	**952,355**	**1,235,229**	**1,519,787**	**2,125,211**	**2,807,040**

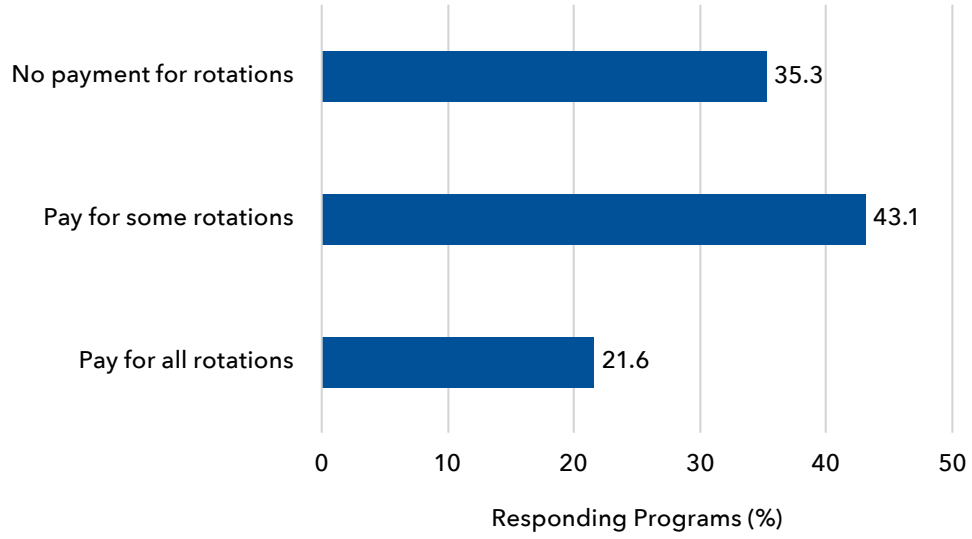
PAYMENT FOR CLINICAL SITES

FIGURE 7. TRENDS IN PAYMENT FOR CLINICAL SITES, 2012-2021



Note: Clinical payment site data were not collected for the 2019-2020 academic year.

FIGURE 8. PROGRAM PAYMENT FOR CLINICAL SITES



Continuing the trend first seen in 2019, more than half of responding programs again reported paying for some or all of rotations. Disruptions caused by the COVID-19 may be responsible for the increasing numbers of programs who now report paying for some or all of their clinical site rotations.

FIGURE 9. PAYMENT TO CLINICAL SITES AMONG PUBLIC AND PRIVATE PROGRAMS

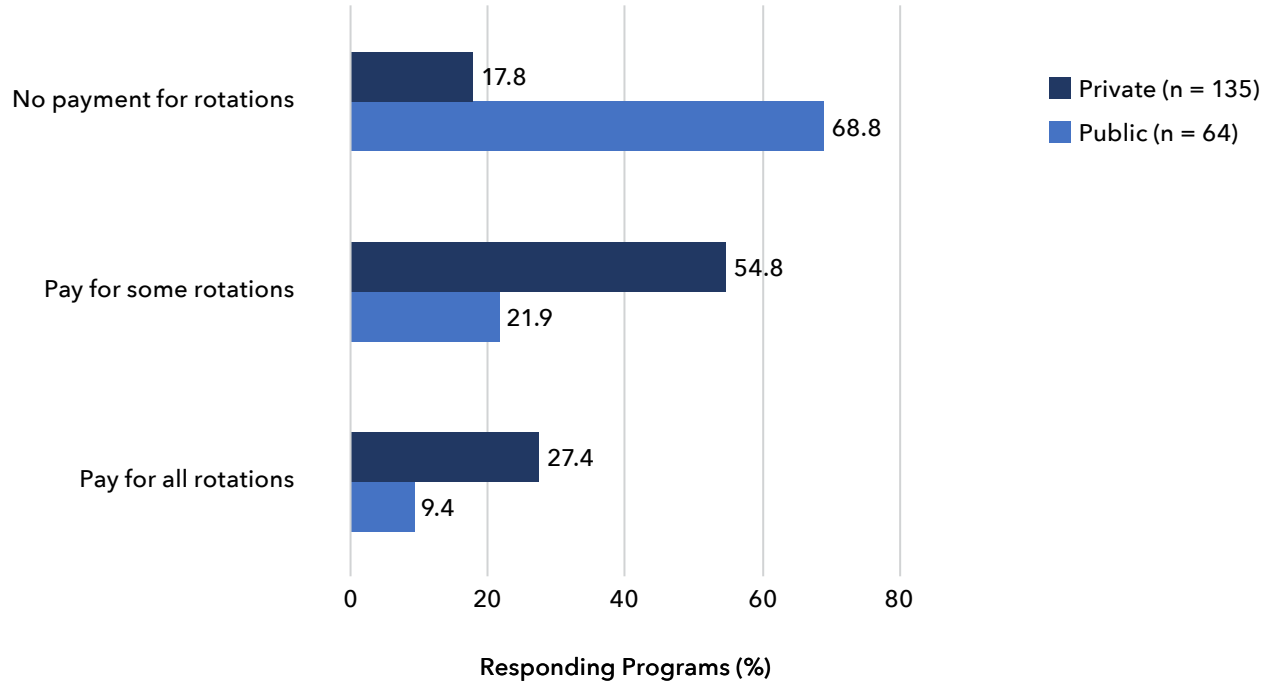


FIGURE 10. DIFFERENCES IN RATES OF PAYMENT TO CLINICAL SITES BY ACADEMIC HEALTH CENTER STATUS

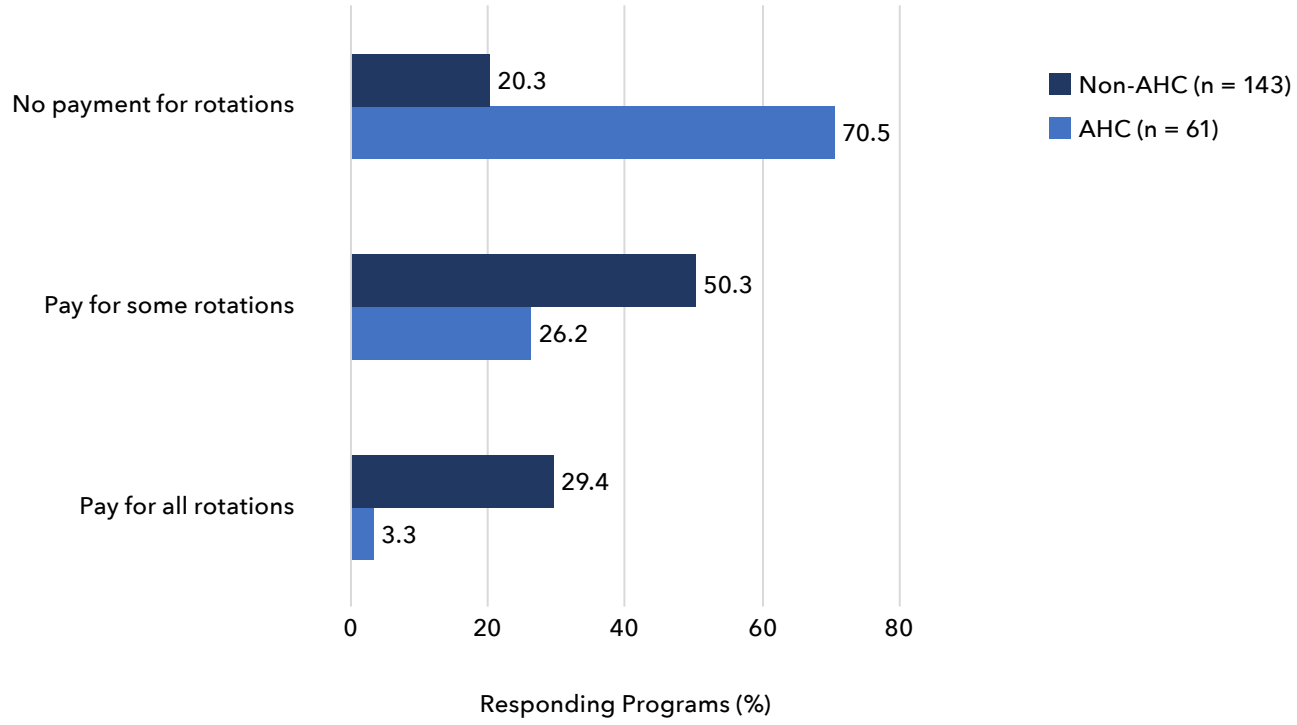


TABLE 23. PAYMENT FOR CLINICAL SITES BY GEOGRAPHIC LOCATION

	n	% Paying
Northeast Region		
New England Division	15	86.6
Middle Atlantic Division	40	75.0
Subtotal	45	78.2
Midwest Region		
East North Central Division	32	71.9
West North Central Division	19	36.8
Subtotal	51	58.8
South Region		
South Atlantic Division	42	57.2
East South Central Division	15	80.0
West South Central Division	15	20.0
Subtotal	72	54.2
West Region		
Mountain Division	11	81.9
Pacific Division	13	76.9
Subtotal	24	79.2
Total	**192**	**64.7**

Note: "n" represents the number of programs in each Census Region and Division that reported their clinical site payment arrangement. "% paying" represents the proportion of programs in that Census Region or Division that reported paying for some or all clinical rotations.

TABLE 24. RECIPIENTS OF CLINICAL ROTATION PAYMENTS

	n	%
Individual preceptor(s)	116	56.9
Clinic(s) or practice(s)	109	53.4
Hospital(s)	72	35.3
Hospital department(s) (e.g., Surgery, Pediatrics, OB, etc.)	47	23.0
Health systems	78	38.2
Hospital Department of Medical Education(s)	29	14.2

Note: Only programs that reported paying for some or all clinical sites and/or preceptors were asked to report the recipients of their payments. Percentages may sum to more than 100% because programs could indicate multiple recipients.

TABLE 25. AVERAGE COST PER STUDENT PER WEEK FOR CLINICAL SITES PAID BY PROGRAMS ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Type of institution									
Public	20	311	289	326	47	100	163	401	1,000
Private	111	307	216	694	85	100	176	250	500
Academic Health Center status									
AHC	18	263	233	247	24	97	188	433	586
Non-AHC	114	312	223	691	86	100	166	250	675
Overall	**132**	**306**	**227**	**648**	**81**	**100**	**171**	**250**	**582**

FIGURE 11. STUDENT PLACEMENTS AT REMOTE CLINICAL SITES

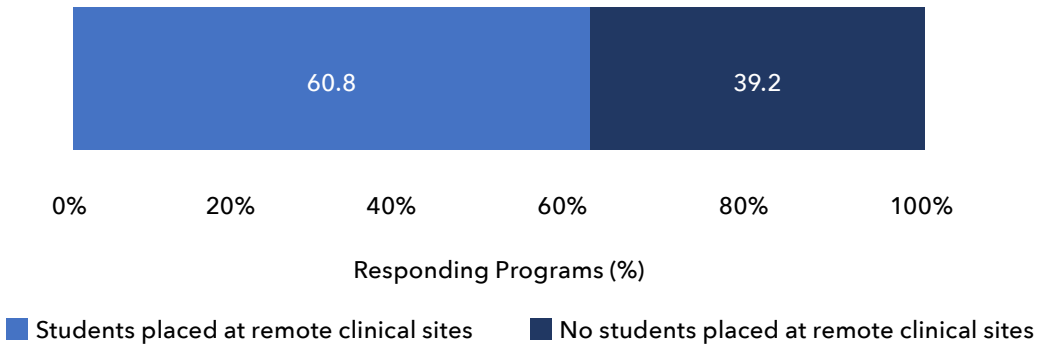


FIGURE 12. STUDENT PLACEMENTS AT REMOTE CLINICAL SITES AMONG PUBLIC AND PRIVATE PROGRAMS

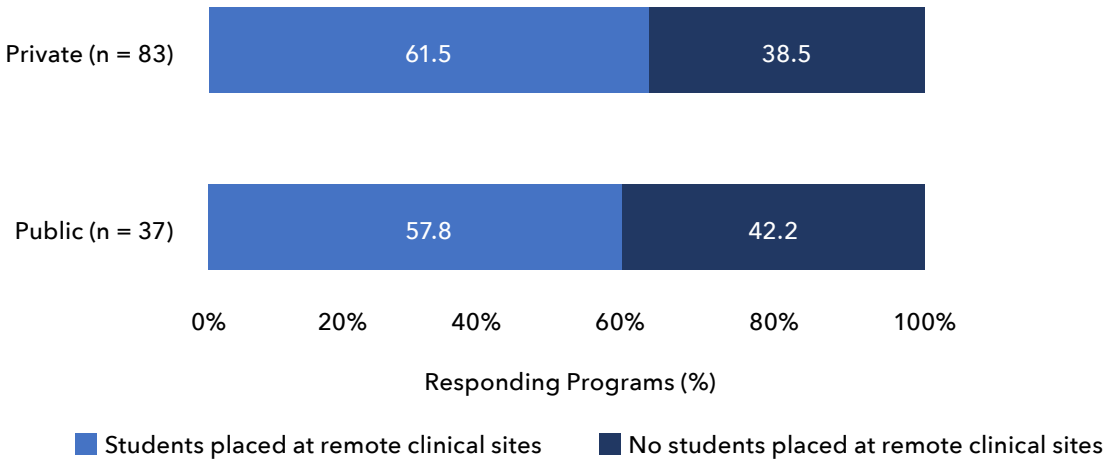


FIGURE 13. STUDENT PLACEMENTS AT REMOTE CLINICAL SITES BY ACADEMIC HEALTH CENTER STATUS

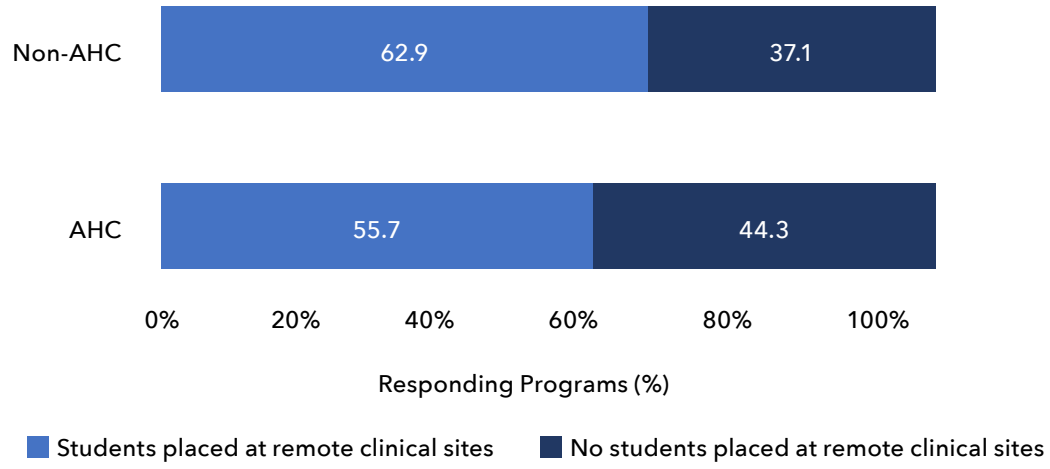


TABLE 26. STUDENTS' OUT-OF-POCKET EXPENSES FOR REMOTE CLINICAL SITES ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Type of institution									
Public	37	2,530	2,074	4,481	100	400	1,000	2,500	6,100
Private	81	4,045	3,149	7,781	200	821	2,000	4,426	9,906
Academic Health Center status									
AHC	33	2,276	1,745	4,692	70	200	600	2,000	5,568
Non-AHC	89	4,149	2,156	7,632	250	1,000	2,000	4,900	10,000
Overall	**122**	**3,642**	**2,587**	**6,992**	**178**	**500**	**1,500**	**3,125**	**9,371**

Programs were asked to report the average out-of-pocket housing expenses incurred by only those students placed at remote clinical sites. 1 additional program reported that they had students placed at remote clinical sites but reported $0 or $1 of out-of-pocket student expenses; this program was excluded from this table.

TUITION, STUDENT FEES & INCIDENTAL COSTS

In this section, tuition is defined as the "estimated current total tuition that each student will incur for the entire length of the graduate, professional phase of the PA program, excluding fees." One of the 131 private (0.8%) and 59 of the 69 public (85.5%) responding programs reported having separate tuition rates for resident and non-resident students. Therefore, resident and non-resident tuition are reported for public programs only and standard tuition is reported for private programs only.

TABLE 27. TUITION ($)

	n	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Public									
Resident/In-state tuition	55	57,955	57,159	18,586	36,661	44,608	56,718	70,420	81,141
Non-resident/Out-of-state tuition	55	96,171	94,653	25,328	70,167	79,870	88,168	106,586	135,715
Private									
Standard tuition	129	100,212	98,900	18,748	84,000	90,546	96,960	105,428	117,000

**Note: Based on the small sample size of private institutions reporting separate tuitions for resident and non-resident students, only standard tuition is reported for these institutions.*

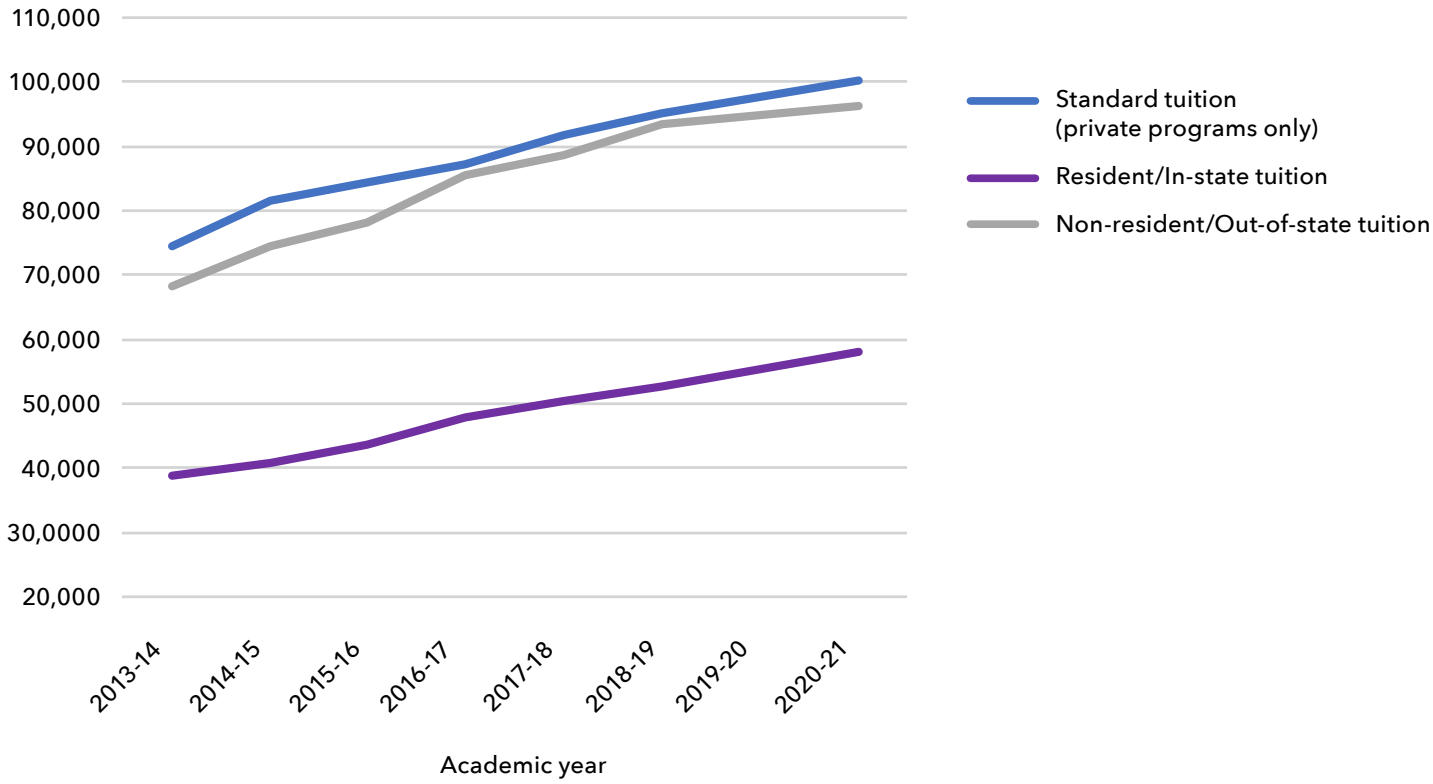
TABLE 28. TRENDS IN AVERAGE PA SCHOOL TUITION, 2013–2021

	2013-14		2014-2015			2015-2016			2016-2017		
	n	*M*($)	*n*	*M*($)	% Increase	*n*	M($)	% Increase	*n*	M($)	% Increase
Public											
Resident/In-state tuition	58	38,794	56	40,918	5.5	60	43,550	6.4	62	47,886	10.0
Non-resident/ Out-of-state tuition	58	68,311	56	74,607	9.2	60	78,214	4.8	62	85,401	9.2
Private											
Standard tuition	107	74,475	108	81,555	9.5	137	84,349	3.4	144	87,160	3.3

	2017-18			2018-2019			2020-2021		
	n	*M*($)	% Increase	*n*	M($)	% Increase	*n*	M($)	% Increase
Public									
Resident/In-state tuition	62	50,289	5.0	58	52,585	4.6	55	57,955	10.2*
Non-resident/ Out-of-state tuition	62	88,677	3.8	59	93,313	5.2	55	96,171	3.1
Private									
Standard tuition	160	91,630	5.1	154	95,058	3.7	129	100,212	5.4

**Note: "% increase" represents the percentage of increase in tuition from the previous academic year.*

FIGURE 14. TRENDS IN AVERAGE PA SCHOOL TUITION, 2013–2021



Note: Tuition data were not collected for the 2019-2020 academic year.

TABLE 29. ITEMIZED STUDENT FEES COLLECTED BY THE INSTITUTION/PROGRAM ($)

	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
ACLS/BLS/PALS/POCUS/ Simulation fees/etc.	34.2	64	411	313	587	113	174	250	418	646
Application and/or graduation fees	45.5	85	244	169	462	50	75	105	280	444
Background check	44.4	83	125	112	113	40	58	100	150	230
Clinical fee(s)	16.6	31	4,197	3,314	6,436	250	706	2,200	4,250	8,200
Clinical site costs/transportation	17.6	33	4,107	2,787	8,495	133	765	2,000	4,032	6,740
Computer/IT/software	39.6	74	1,568	1,235	2,706	256	443	1,153	2,000	2,514
Drug screening	34.8	65	83	75	72	26	37	50	100	180
Equipment (e.g. stethoscope, lab coat)	44.9	84	1,537	1,039	4,433	550	750	953	1,200	1,976
Fees for tests/assessments	19.3	36	580	439	950	95	240	420	653	785
Laboratory fee(s)	31.0	58	735	637	901	100	203	500	969	1,680
Liability insurance	11.2	21	148	134	157	15	32	82	200	385
Parking	24.6	46	378	317	452	60	91	200	530	768
Professional or association dues	23.5	44	136	132	62	75	95	125	150	225
Student health services	19.3	36	2,069	1,775	3,332	200	350	639	1,288	7,573
Student services fee(s)	31.6	59	1,569	1,430	1,733	143	330	980	2,258	3,547
Textbooks/Ebooks/Library resources	35.8	67	1,589	1,512	1,203	300	500	1,400	2,385	3,356
Other	31.0	58	2,849	2,314	4,392	130	306	936	3,770	7,959
Total fees		**187**	**7,914**	**6,645**	**8,976**	**1,123**	**2,450**	**5,239**	**9,906**	**14,526**

187 programs (91.6%) provided detailed, itemized student fees collected by their institution or program. "Total fees" represents the sum of all fees reported by these programs.

TABLE 30. ITEMIZED STUDENT FEES COLLECTED BY THE INSTITUTION/PROGRAM AMONG PUBLIC AND PRIVATE PROGRAMS ($)

Public	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
ACLS/BLS/PALS/POCUS/ Simulation fees/etc.	41.9	26	536	408	885	115	161	225	423	1,228
Application and/or graduation fees	51.6	32	245	133	665	50	54	92	115	294
Background check	46.8	29	87	86	48	40	51	79	110	151
Clinical fee(s)	9.7	6	4,099	4,099	5,331	351	798	2,495	4,275	9,450
Clinical site costs/transportation	19.4	12	1,685	1,685	1,504	103	333	1,250	2,846	3,932
Computer/IT/software	41.9	26	1,398	1,345	919	292	645	1,403	2,034	2,395
Drug screening	38.7	24	63	59	42	30	39	50	85	100
Equipment (e.g. stethoscope, lab coat)	46.8	29	1,133	1,109	566	630	850	1,000	1,300	2,000
Fees for tests/assessments	22.6	14	469	469	308	115	287	427	639	782
Laboratory fee(s)	32.3	20	686	646	589	96	208	525	1,009	1,231
Liability insurance	21.0	13	157	157	188	13	24	66	250	437
Parking	35.5	22	528	455	580	78	131	390	668	1,052
Professional or association dues	25.8	16	143	143	64	75	99	130	206	225
Student health services	32.3	20	705	596	721	183	244	442	920	1,265
Student services fee(s)	35.5	22	1,750	1,593	1,881	251	513	1,071	2,228	5,193
Textbooks/Ebooks/Library resources	40.3	25	2,027	1,975	1,308	500	1,000	1,700	2,700	4,000
Other	33.9	21	4,473	3,652	5,616	410	566	3,200	6,050	9,428
Total fees		**62**	**9,347**	**8,486**	**9,157**	**1,689**	**3,489**	**6,253**	**10,486**	**27,486**

TABLE 30 (CONTINUED). ITEMIZED STUDENT FEES COLLECTED BY THE INSTITUTION/PROGRAM AMONG PUBLIC AND PRIVATE PROGRAMS ($)

Private	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
ACLS/BLS/PALS/POCUS/ Simulation fees/etc.	30.9	38	325	309	197	118	226	300	409	508
Application and/or graduation fees	42.3	52	239	196	286	65	100	135	300	449
Background check	43.9	54	145	130	132	40	61	100	195	259
Clinical fee(s)	20.3	25	4,221	3,109	6,772	307	800	2,200	4,000	8,010
Clinical site costs/transportation	17.1	21	5,491	3,479	10,425	500	1,000	3,000	5,000	9,530
Computer/IT/software	38.2	47	1,642	1,140	3,335	230	430	1,099	1,825	2,630
Drug screening	33.3	41	95	85	83	25	37	60	140	200
Equipment (e.g. stethoscope, lab coat)	43.9	54	1,777	1,032	5,516	544	750	938	1,100	1,902
Fees for tests/assessments	17.9	22	651	419	1,196	91	240	420	626	776
Laboratory fee(s)	30.9	38	760	635	1,035	100	213	500	823	1,680
Liability insurance	6.5	8	133	133	94	58	79	91	185	236
Parking	19.5	24	241	226	227	56	79	128	433	528
Professional or association dues	22.0	27	130	127	63	75	90	125	150	200
Student health services	13.0	16	3,774	3,774	4,435	350	448	1,055	7,234	9,452
Student services fee(s)	29.3	36	1,499	1,382	1,664	120	340	915	2,239	2,850
Textbooks/Ebooks/Library resources	34.1	42	1,329	1,275	1,069	243	389	1,038	1,948	3,000
Other	30.1	37	1,927	1,587	3,256	117	150	519	1,700	5,830
Total fees		**123**	**7,335**	**5,897**	**9,069**	**1,049**	**2,284**	**5,004**	**9,088**	**12,153**

TABLE 31. ITEMIZED STUDENT FEES COLLECTED BY THE INSTITUTION/PROGRAM BY ACADEMIC HEALTH CENTER STATUS ($)

AHC	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 (*Mdn*)	P75	P90
ACLS/BLS/PALS/POCUS/ Simulation fees/etc.	37.3	22	361	313	339	151	166	240	441	676
Application and/or graduation fees	45.8	27	226	175	348	50	63	100	232	518
Background check	40.7	24	96	94	49	40	59	81	126	155
Clinical fee(s)	13.6	8	7,274	7,274	11,797	306	545	2,100	6,975	20,280
Clinical site costs/transportation	22.0	13	6,395	6,395	13,190	106	400	2,000	4,870	9,800
Computer/IT/software	47.5	28	2,362	1,654	4,171	311	750	1,500	2,350	2,824
Drug screening	33.9	20	61	59	35	25	39	53	86	101
Equipment (e.g. stethoscope, lab coat)	44.1	26	1,023	1,017	442	546	763	1,000	1,275	1,605
Fees for tests/assessments	20.3	12	438	438	264	105	248	401	682	750
Laboratory fee(s)	33.9	20	704	666	643	60	175	519	1,125	1,685
Liability insurance	18.6	11	128	128	161	12	20	32	186	385
Parking	32.2	19	585	585	606	87	113	480	730	1,173
Professional or association dues	23.7	14	134	134	55	75	96	130	184	200
Student health services	35.6	21	2,417	1,928	3,778	193	250	730	1,400	8,250
Student services fee(s)	40.7	24	1,415	1,297	1,483	146	258	1,120	1,964	2,878
Textbooks/Ebooks/ Library resources	42.4	25	2,017	1,974	1,376	500	900	1,790	2,800	4,000
Other	42.4	25	4,113	3,405	5,896	108	290	1,016	5,166	9,377
Total fees		**59**	**10,567**	**9,351**	**12,035**	**1,553**	**2,497**	**7,273**	**11,236**	**28,259**

TABLE 31 (CONTINUED). ITEMIZED STUDENT FEES COLLECTED BY THE INSTITUTION/PROGRAM BY ACADEMIC HEALTH CENTER STATUS ($)

Non-AHC	% Reporting	*n*	*M*	*M(T)*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
ACLS/BLS/PALS/POCUS/ Simulation fees/etc.	32.8	42	436	312	685	101	200	283	384	530
Application and/or graduation fees	45.3	58	253	176	509	50	92	125	279	411
Background check	46.1	59	137	123	129	40	58	100	165	256
Clinical fee(s)	18.0	23	3,127	2,996	2,751	322	1,154	2,200	4,000	7,639
Clinical site costs/transportation	15.6	20	2,620	2,375	2,398	465	941	1,500	4,008	5,070
Computer/IT/software	35.9	46	1,084	1,011	902	200	401	800	1,500	2,099
Drug screening	35.2	45	93	84	82	29	37	50	116	200
Equipment (e.g. stethoscope, lab coat)	45.3	58	1,768	1,076	5,325	550	763	938	1,100	2,150
Fees for tests/assessments	18.8	24	651	440	1,151	93	240	420	575	787
Laboratory fee(s)	29.7	38	751	625	1,019	118	220	500	825	1,605
Liability insurance	7.8	10	169	169	158	65	71	91	195	343
Parking	21.1	27	233	220	215	50	78	130	365	516
Professional or association dues	23.4	30	137	134	66	75	95	125	150	228
Student health services	11.7	15	1,582	1,582	2,634	308	350	500	1,055	3,591
Student services fee(s)	27.3	35	1,675	1,565	1,899	184	413	849	2,475	3,642
Textbooks/Ebooks/Library resources	32.8	42	1,335	1,282	1,022	255	449	1,138	1,900	3,000
Other	25.8	33	1,891	1,677	2,468	132	354	850	1,940	5,740
Total fees		**128**	**6,692**	**5,761**	**6,862**	**1,114**	**2,459**	**5,067**	**8,612**	**11,669**

SECTION 3. PROGRAM PERSONNEL

TABLE 32. FULL-TIME FACULTY HEADCOUNTS

	n(P)	*n(F)*	*Min*	*Max*	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Assigned ONLY or PRIMARILY to the didactic phase of the program	179	943	1	25	5.3	2.9	3.0	3.0	5.0	6.0	9.0
Assigned ONLY or PRIMARILY to the clinical phase of the program	152	283	1	13	1.9	1.4	1.0	1.0	1.0	2.0	3.0
Assigned to BOTH the didactic and clinical phases of the program	140	455	1	16	3.2	2.9	1.0	1.0	2.0	5.0	8.0
All full-time faculty	**203**	**1,681**	**3**	**3**	**8.3**	**3.5**	**5.0**	**6.0**	**8.0**	**10.0**	**13.0**

Note: "n (P)" represents the number of reporting programs. "n (F)" represents the total faculty headcount across all reporting programs. Faculty with .5 or more FTE were considered to be full-time. Zeroes were excluded.

Programs were asked to provide full-time faculty headcounts; however, some appear to have reported FTEs instead. Because full-time faculty were defined as those with .5 or greater FTE, any decimal under .5 was rounded down and any decimal .5 or above was rounded up to approximate a headcount of full-time faculty.

FIGURE 15. FULL-TIME FACULTY ASSIGNMENTS

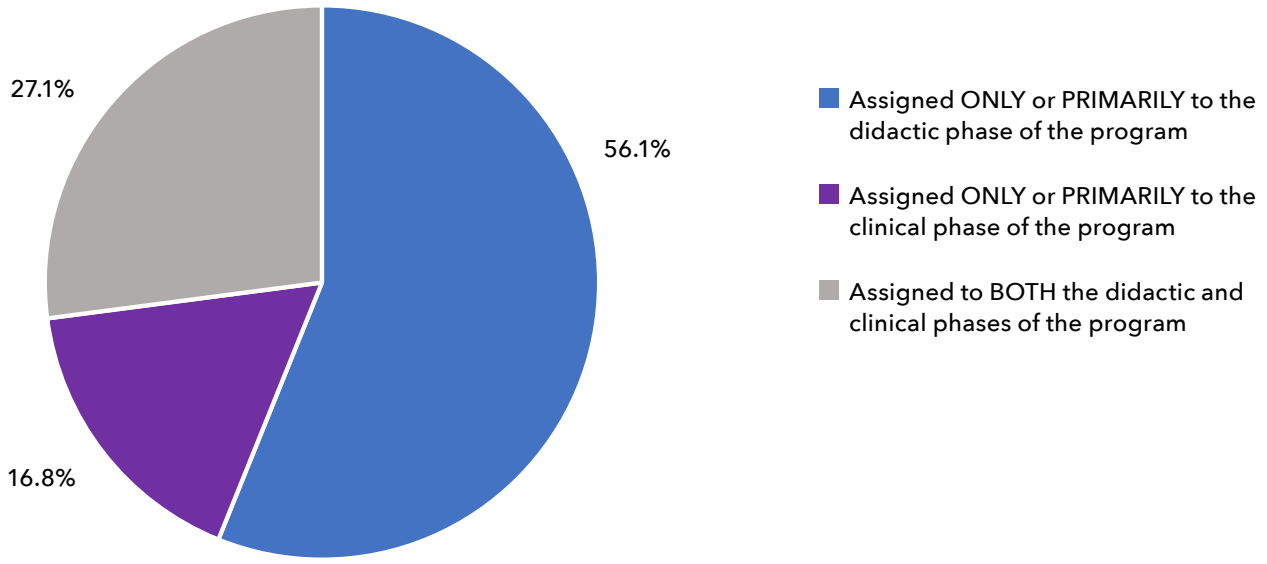


TABLE 33. PART-TIME FACULTY AND GUEST LECTURERS

	n(P)	*n(F)*	*Min*	*Max*	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Part-time faculty											
Headcount	136	577	1.0	70	4.2	6.9	1.0	1.0	2.0	4.8	11.0
FTE	142	359.3	0.1	130	2.5	11.4	0.2	0.3	0.7	1.3	3.9
Guest lecturers											
Headcount	191	8,558	1	350	44.8	62.2	6.0	11.0	22.0	50.0	108.0

Note: "n (P)" represents the number of reporting programs. "n (F)" represents the total headcount or FTE across all reporting programs. Faculty with less than .5 FTE were considered to be part-time.

TABLE 34. PERCENTAGE OF DIDACTIC CURRICULUM TAUGHT BY CORE FACULTY (%)

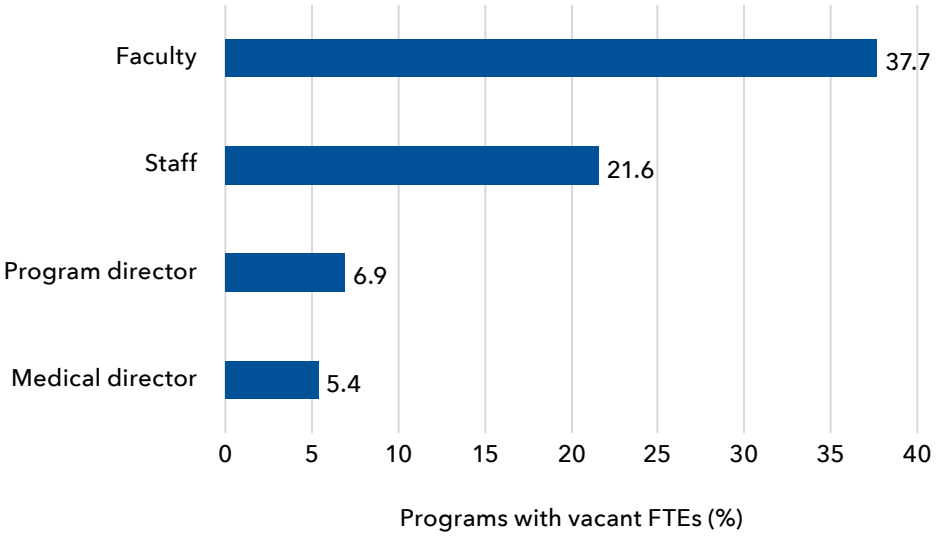
	n	*Min*	*Max*	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Taught directly by your program's core/ principal faculty	199	18.0	100.0	71.3	18.9	40.0	60.0	75.0	85.0	93.0
Taught by others but actively coordinated by your program's core/principal faculty (e.g., arranging schedules, selecting topics, course mastering)	185	2.0	73.0	22.8	16.4	5.0	10.0	20.0	30.0	50.0
Taught directly by non-program personnel (e.g., faculty from biology department) with minimal input from program core/ principal faculty	106	1.0	52.0	14.0	12.2	5.0	5.0	10.0	20.0	31.8

TABLE 35. CAPACITY, FILLED, AND VACANT FTE

	n(P)	*n*(FTE)	*Min*	*Max*	*M*	SD	P10	P25	P50 *(Mdn)*	P75	P90
Capacity											
Faculty	204	1576.2	1.0	31.9	7.7	3.9	4.1	5.0	7.0	9.0	12.0
Staff	204	717.0	1.0	19.3	3.5	2.3	1.5	2.0	3.0	4.0	6.0
Program director	204	204.1	0.6	2.0	1.0	0.1	1.0	1.0	1.0	1.0	1.0
Medical director	204	125.1	0.0	3.0	0.6	0.4	0.1	0.2	0.5	1.0	1.0
Filled											
Faculty	203	1,440.4	0.8	26.8	7.1	3.6	4.0	5.0	6.0	8.5	11.4
Staff	203	667.7	1.0	19.3	3.3	2.2	1.0	2.0	3.0	4.0	5.2
Program director	199	199.1	0.6	2.0	1.0	0.1	1.0	1.0	1.0	1.0	1.0
Medical director	202	121.8	0.0	3.0	0.6	0.4	0.1	0.2	0.5	1.0	1.0
Vacant											
Faculty	77	105.5	0.2	5.1	1.4	0.9	1.0	1.0	1.0	1.5	2.0
Staff	44	57.3	0.5	6.0	1.3	1.0	0.5	1.0	1.0	1.0	2.0
Program director	14	14.0	1.0	1.0	1.0	0.0	1.0	1.0	1.0	1.0	1.0
Medical director	11	7.2	0.1	1.0	0.7	0.4	0.2	0.2	1.0	1.0	1.0

Note: "n (P)" represents the number of reporting programs. "n (FTE)" represents the total FTE across all reporting programs. Zeroes were excluded.

FIGURE 16. PROGRAMS WITH VACANT FTES



RECRUITMENT & RETENTION

Data were collected in 2021, during the COVID-19 pandemic. Reports published by PAEA during the pandemic indicate that staffing was affected at many programs.

TABLE 36. OPEN POSITIONS

	n(P)	*n*(O)	Max	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Faculty All open positions	153	281	8	1.8	1.2	1.0	1.0	1.0	2.0	3.0
Staff All open positions	84	112	3	1.3	0.6	1.0	1.0	1.0	2.0	2.0

Note: "n (P)" represents the number of reporting programs. "n (O)" represents the total number of open positions available across all reporting programs. Zeroes were excluded.

163 (79.9%) programs reported seeking to hire new faculty or staff in the 2020-2021 academic year, Some programs appear to have reported FTE instead of headcounts. All decimals were rounded up to the nearest integer to approximate headcounts.

TABLE 37. BARRIERS TO HIRING NEW FACULTY (%)

	n	Not at all a Barrier	Slight Barrier	Moderate Barrier	Serious Barrier
Salary	201	15.4	21.9	32.8	29.9
Lack of qualified candidates	201	20.9	22.9	28.4	27.9
Location	201	45.3	27.4	18.4	9.0
Candidates' lack of teaching experience	199	21.1	29.6	40.7	8.5
Area cost of living	200	64.0	16.0	12.0	8.0
Degree requirements	201	71.6	20.4	6.0	2.0
Lifestyle	201	64.7	22.9	10.4	2.0

Note: Table rows are sorted from most serious barrier to least.

TABLE 38. REASONS FOR FACULTY DEPARTURES

	n(P)	*n*(F)	%(F)
Job change: Return to clinical practice	45	56	25.8
Job change: Accepted position at another PA program	37	43	19.8
Personal reason	31	36	16.6
Retirement	27	34	15.7
Job change: Other reason	13	14	6.5
Dismissal due to performance issues	10	10	4.6
Dismissal due to professionalism issues	8	10	4.6
Medical/disability/death	6	6	2.8
All faculty departure	**135**	**217**	**100.0**

Note: "n (P)" represents the number of reporting programs. "n (F)" represents the total number of faculty departures across all reporting programs. "% (F)" represents the percentage of all faculty departures that occurred for each reason.

135 (66.2%) programs reported that at least one faculty member had left in the 2020-2021 academic year.

STUDENT-TO-FACULTY RATIO

Each program's student-to-faculty ratio (SFR) was calculated in two ways. For Table 39, SFR was calculated by dividing each program's total number of enrolled students by their full-time faculty headcount. For Table 40, SFR was calculated by dividing each program's total number of enrolled students by the sum of their filled faculty, program director, and medical director FTEs.

TABLE 39. STUDENT-TO-FACULTY RATIO: FULL-TIME FACULTY HEADCOUNT

	n	*Min*	*Max*	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Overall	**197**	**2.3**	**26**	**12.8**	**4.8**	**7.1**	**9.7**	**12**	**16**	**19.1**
Public vs. private										
Private	133	2.7	26	12.8	4.8	6.9	9.7	12.1	16	19.0
Public	59	2.3	24.9	12.8	5	6.5	9.2	11.8	16.4	20.7
Academic Health Center status										
AHC	60	3.7	24.9	13.1	4.9	6.6	9.4	12.2	16.5	20.6
Non-AHC	137	2.3	26	12.7	4.8	7.1	9.7	11.9	15.9	18.7
Administrative Housing										
College of Graduate and Professional Studies	7	6.5	16.7	12.2	3.4	6.5	10.6	11.5	15.8	16.2
College/School of Medicine	32	4.2	23	13.2	4.3	8.5	10.1	12.9	16.5	19.0

TABLE 39 (CONTINUED). STUDENT-TO-FACULTY RATIO: FULL-TIME FACULTY HEADCOUNT

	n	*Min*	*Max*	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Department of PA Studies/PA Program	39	4.4	24.6	11.9	4.1	6.7	9	11.8	14.7	17.0
School of Allied Health/Health Professions/Health Sciences	98	2.29	25.5	13.1	5.3	6.3	9.7	12.3	17.5	20.4
Satellite campuses										
Program does not have satellite campus	182	2.3	26	12.7	4.8	7.2	9.7	12	15.9	19.0
Program has satellite campus	15	6.3	24.6	14.1	5.2	6.4	9	14.2	17.7	22.2
Enrolled classes										
First-year only	12	2.3	6.7	4.7	1.6	2.4	3.1	4.9	6.2	6.6
First-and second year only	71	3.7	19	11.1	3.1	7.5	9.1	10.9	12.6	16.0
First-,second-, and third-year students	114	5	26	14.7	4.6	9.2	11.5	14.2	18	21.4
Census Regions and Divisions										
Northeast Region										
New England Division	15	8.3	23.6	14.5	4.7	8.5	10	14	16.8	22.2
Middle Atlantic Division	36	3	25.5	12.7	5.3	6.1	8.5	12.3	15.9	20.7
Subtotal	51	3	25.5	13.2	5.1	6.6	9.5	12.9	16.5	21.1
Midwest Region										
East North Central Divison	31	4.4	21.7	12.1	4.3	6.3	9.2	11.8	15.6	17.7
West North Central Division	19	3.7	20.7	13.3	4.9	7.1	9.7	12.8	18	20.0
Subtotal	50	3.7	21.7	12.6	4.5	6.6	9.4	12	16.1	19.0
South Region										
South Atlantic Division	42	2.3	21.8	12.6	4.5	6	9.7	12.5	16.3	18.3
East South Central Division	15	3.3	24.9	13.7	6.8	5.2	9.7	11.7	20.5	24.7
West South Central Division	14	9	23	13.9	4.1	9.4	10.7	12.6	17.3	21.3
Subtotal	71	2.3	24.9	13.1	4.9	6.8	9.9	12	17	19.8
West Region										
Mountain Division	10	6	26	12.9	5.4	6.4	10.1	11.6	14.1	25.2
Pacific Division	13	2.7	18.9	10.8	3.8	5	8.8	10.8	12.9	17.1
Subtotal	23	2.7	26	11.7	4.6	7	9	11.2	12.9	18.4

Note: Programs with other categories of administrative housing were excluded due to low frequencies.

TABLE 40. STUDENT-TO-FACULTY RATIO: FTE

	n	*Min*	*Max*	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Overall	**195**	**2.3**	**28.6**	**12.2**	**4.8**	**5.7**	**9.2**	**11.6**	**14.7**	**18.4**
Public vs. private										
Private	131	2.3	25.4	12	4.7	5.6	9.1	11.6	14.6	18.1
Public	60	2.7	28.6	12.6	5.1	6.2	9.7	11.6	16.4	19.1
Academic Health Center status										
AHC	58	2.8	28.6	12.8	5.1	6.9	9.4	12	16.8	19.2
Non-AHC	137	2.3	27.1	11.9	4.6	5.5	9.2	11.6	14.5	17.6
Administrative Housing										
College of Graduate and Professional Studies	7	6.5	13.6	11	2.6	6.5	8.6	11.6	13	13.6
College/School of Medicine	33	4.6	21	12.8	4.2	6.6	9.6	12.7	16.8	18.4
Department of PA Studies/PA Program	39	4.1	27.1	11.7	4.7	4.9	9.1	11.5	14.3	17.5
School of Allied Health/Health Professions/Health Sciences	95	2.3	28.6	12.4	5.2	5.5	9.5	11.6	15.5	19.3
Satellite campuses										
Program does not have satellite campus	180	2.3	27.1	11.9	4.7	5.6	9.2	11.6	14.4	18.2
Program has satellite campus	15	6.5	28.6	14.7	5.4	8	9.7	15.5	17.2	22.7
Enrolled classes										
First-year only	12	2.3	28.6	6	7.2	2.4	2.8	4.3	4.9	21.7
First-and second year only	69	2.8	27.1	10.5	3.6	6.1	8.7	10.1	12	14.1
First-,second-, and third-year students	114	4	25.4	13.8	4.2	8.9	10.7	13.2	16.8	19.4
Census Regions and Divisions										
Northeast Region										
New England Division	15	7.5	23.5	13.5	4.8	8.1	9.7	12.9	15.6	22.0
Middle Atlantic Division	36	2.9	28.6	12.3	5.6	5.1	9.2	12	15.5	19.5
Subtotal	51	2.9	28.6	16.7	5.4	5.7	9.6	12.7	15.6	20.3
Midwest Region										
East North Central Divison	30	4.4	20.8	11.3	4.4	4.8	7.7	11.3	14.1	18.1
West North Central Division	19	2.8	27.1	13.6	6.2	6.9	9.1	13	17.3	24.6
Subtotal	49	2.8	27.1	12.2	5.2	5.7	8.7	11.6	14.6	18.9

TABLE 40 (CONTINUED). STUDENT-TO-FACULTY RATIO: FTE

	n	*Min*	*Max*	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
South Region										
South Atlantic Division	41	2.7	18.6	12	4	5.4	9.9	12.3	15.3	17.2
East South Central Division	15	2.7	21.5	12.8	5.9	4.1	9.1	11.5	19.0	20.6
West South Central Division	14	7.6	19	16.1	3.3	8.3	9.6	10.8	14.2	18.0
Subtotal	70	2.7	21.5	12.2	4.3	5.6	9.8	11.9	15.4	18.5
West Region										
Mountain Division	10	5.4	17.3	11.8	3.6	5.7	9.9	10.8	15.5	17.2
Pacific Division	13	2.3	18.1	10.2	4.1	3.2	8.6	10	12.8	16.6
Subtotal	23	2.3	18.1	10.9	3.9	4.8	9.1	10.6	14.2	16.8

Note: Programs with other categories of administrative housing were excluded due to low frequencies.

SECTION 4. STUDENTS

CAPACITY & ENROLLMENT

"Maximum capacity" refers to programs' capacity as approved by ARC-PA. "Current enrollment" refers to enrollment at the time that programs responded to the survey, which does not necessarily reflect day-one student enrollment. For example, if a program has a third-year cohort for part of the academic year but survey administration does not coincide with that period, that program may report zero third-year enrollment. Therefore, discrepancies between capacity and enrollment do not necessarily reflect unfilled seats.

"First-year" students were defined as didactic-phase students, and "second-year" students as clinical-phase students. "Third-year" students were defined as "end-of-clinical-phase students who, when present, may overlap with second-year clinical phase students; this may be typical in programs that are longer than two years.

TABLE 41. STATUS OF INAUGURAL CLASSES IN PROVISIONALLY ACCREDITED PROGRAMS

	n	%
Graduated	25	54.3
Enrolled in the first year	13	28.3
Enrolled in the second year	7	15.2
Enrolled in the third year	1	2.2
Total	**46**	**100.0**

47 programs (23.0%) were provisionally accredited.

FIGURE 17. ENROLLED COHORTS

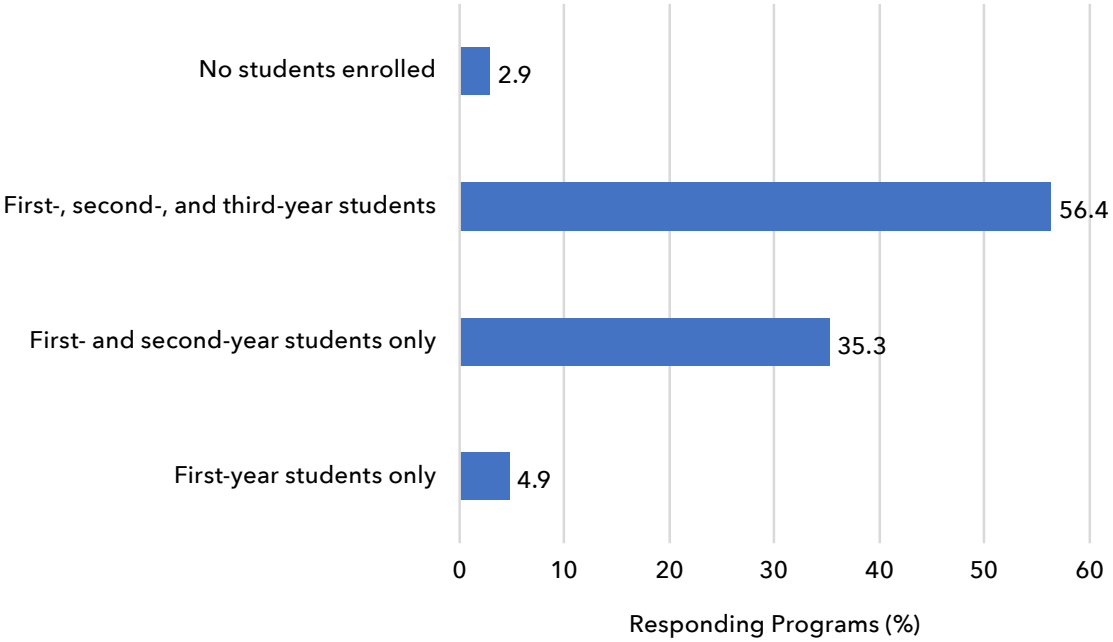


TABLE 42. STUDENT MAXIMUM CAPACITY AND CURRENT ENROLLMENT

	n(P)	*n*(S)	Min	Max	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Maximum capacity											
First-year (didactic phase)	197	9,534	20	170	48.4	23.7	27.6	32.0	40.0	58.5	80.0
Second-year (clinical phase)	187	9,122	17	156	48.8	23.3	29.6	33.0	40.0	60.0	80.0
Third-year (end-of-clinical phase)	111	5,082	1	156	45.8	22.8	26.4	32.0	40.0	50.0	74.0
Total	**198**	**23,738**	**20**	**468**	**120**	**65.7**	**60.0**	**78.0**	**108.0**	**144.3**	**194.1**
Current enrollment											
First-year (didactic phase)	196	8,875	13	169	45.3	21.8	25.0	30.0	40.0	54.8	74.3
Second-year (clinical phase)	184	3,424	15	138	44.4	20.4	25.0	30.0	39.0	53.8	72.5
Third-year (end-of-clinical phase)	95	3,768	1	123	39.7	17.9	24.2	29.0	35.0	46.0	62.8
Total	**198**	**16,067**	**16**	**430**	**105.1**	**54.2**	**50.9**	**67.8**	**97.0**	**130.3**	**172.2**

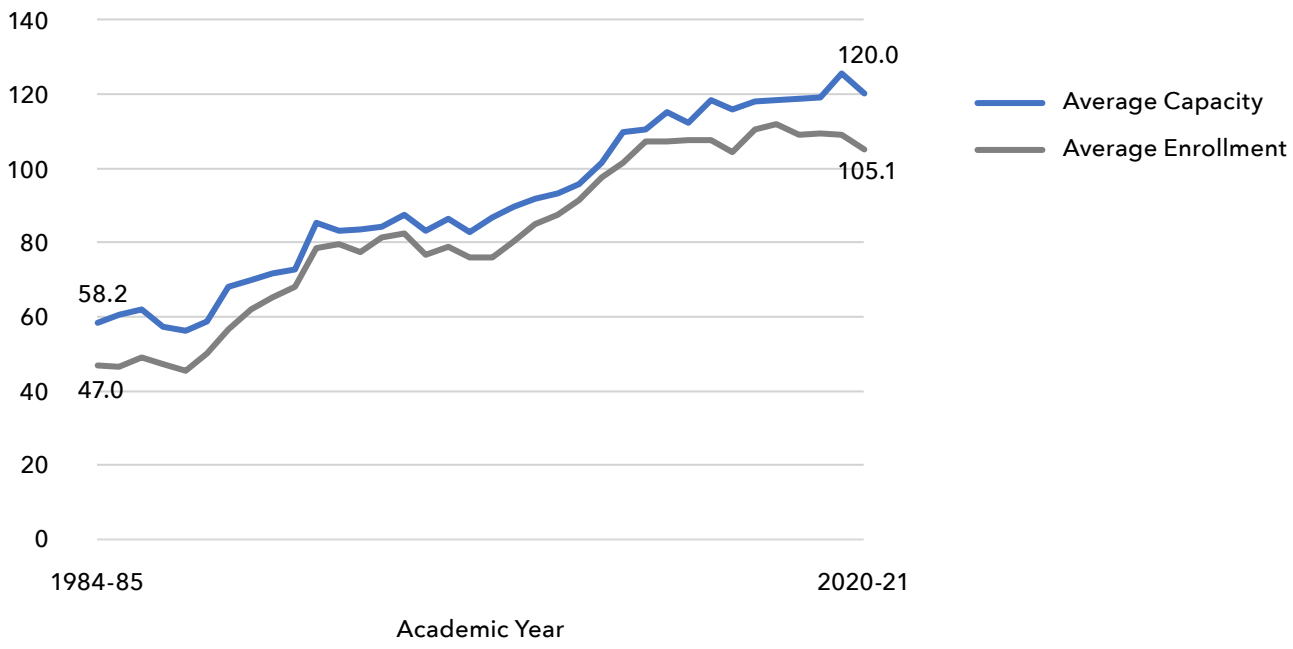
Note: Zeroes were excluded. "n (P)" refers to the number of reporting programs.
"n (S)" refers to the number of students reported by the programs.

TABLE 43. DAY-ONE ENROLLMENT OF MOST RECENTLY ADMITTED CLASS

	n(P)	*n*(S)	Min	Max	*M*	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Type of institution											
Private	133	6,113	17	125	46.0	19.5	26.4	31.0	40.0	55.0	75.0
Public	59	2,506	17	140	42.5	19.6	24.0	30.0	40.0	50.0	60.0
Academic Health Center status											
AHC	59	2,906	22	140	49.3	22.7	25.0	35.0	44.0	60.0	86.0
Non-AHC	138	6,037	17	125	43.7	18.5	25.9	30.0	40.0	50.0	75.0
Overall	**197**	**8,943**	**17**	**140**	**45.4**	**19.9**	**25.0**	**30.0**	**40.0**	**54.5**	**75.0**

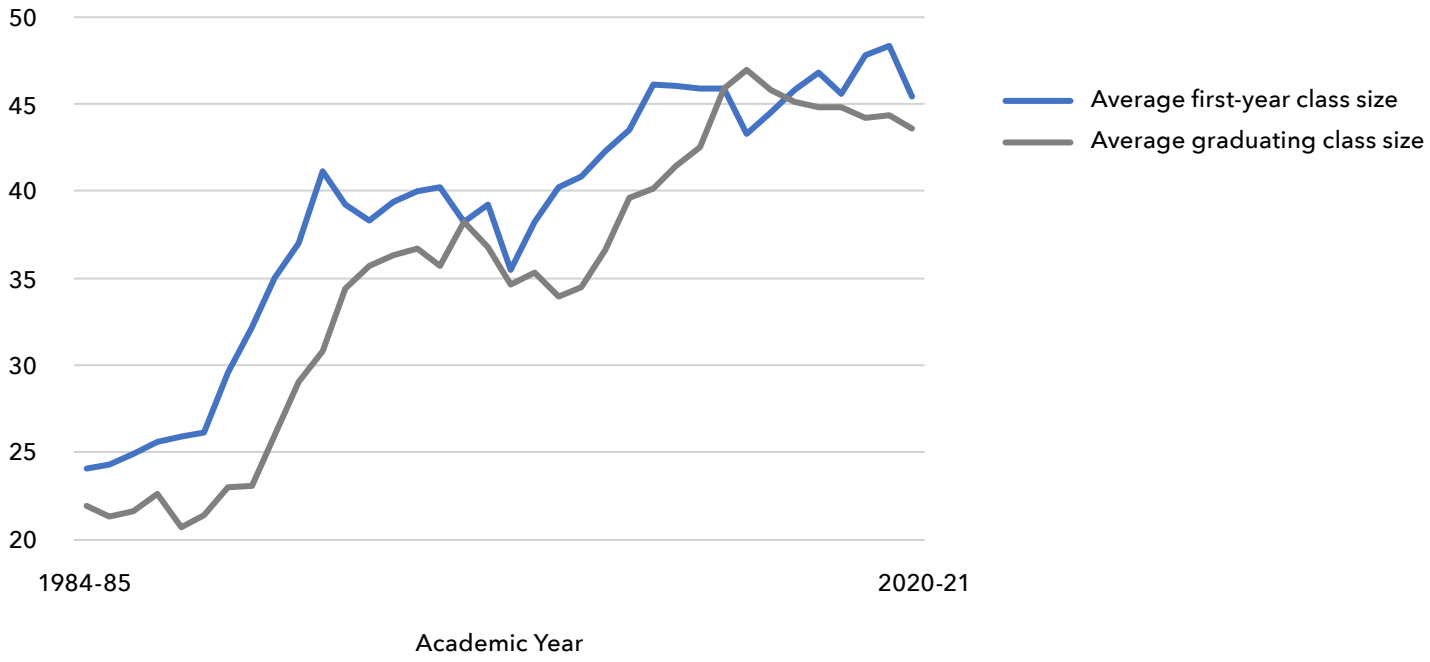
Based on programs' reports of their ARC-PA-approved first-year capacity and the day-one enrollment of their most recently admitted class, 27 programs reported a total of 268 unfilled seats (M = 9.9, SD = 17.1, Mdn = 4.0). This number differs from the difference of total first-year capacity reported in Table 42 and overall day one enrollment because programs that reported greater day-one enrollment than capacity, or that reported first-year capacity but not day-one enrollment, were excluded.

FIGURE 18. AVERAGE PROGRAM ENROLLMENT AND CAPACITY, 1985–2021



***Note: This data was not collected for the 2019-2020 academic year. In addition, these numbers reflect the data provided by the 204 participating respondents and are not reflective of the full population of students enrolled in member programs during the 2020-2021 academic year.*

FIGURE 19. AVERAGE FIRST-YEAR AND GRADUATING CLASS SIZES 1985–2021



Note: Prior to 2016's Program Report 31, the number of graduates depicted in this figure was calculated based on the size of the graduating cohort at matriculation. From 2016 onwards, the figure reports only those students who have or will graduate on time.

This data was not collected for the 2019-2020 academic year. In addition, these numbers reflect the data provided by the 204 participating respondents and are not reflective of the full population of students enrolled in member programs during the 2020-2021 academic year.

FIRST-YEAR CLASS

This section refers to students who began or were in their first year at the time of the survey administration.

TABLE 44. EXAMS REQUIRED FOR ADMISSION

	n	%
GRE	87	42.6
TOEFL	63	30.9
None	48	23.5
CASPer	19	9.3
GRE or MCAT	16	7.8
IELTS	6	2.9
PA-CAT	5	2.5
SAT	4	2.0
ACT	2	1.5
MCAT	1	0.5
Total	**156**	

*Note: Percentages will not sum to 100% because programs could report more than one required exam. * Indicates that the exam was recoded from programs' write-in "Other" responses.*

TABLE 45. FIRST-YEAR CLASS: GRE SCORES

	n	*M*	*SD*	*Mdn*
Verbal reasoning	76	153.1	2.7	153
Quantitative reasoning	76	152.7	2.8	152.4
Analytical	65	4.1	0.3	4.1

Note: Programs that required the GRE were asked to report their first-year students' average GRE scores. Although zeroes are technically valid analytic writing scores, they were excluded from this table.

TABLE 46. FIRST-YEAR CLASS: UNDERGRADUATE GRADE-POINT AVERAGES

	n	*M*	*SD*	*Mdn*
Science	194	3.5	0.2	3.6
Non-science	187	3.6	0.3	3.7
CASPA biology, chemistry, physics (BCP)	192	3.5	0.2	3.5
Overall	**195**	**3.6**	**0.1**	**3.6**

Note: Zeroes were excluded.

TABLE 47. FIRST-YEAR CLASS: HEALTH CARE EXPERIENCE HOURS

	n	Min	Max	*M*	*M*(T)	*SD*	P10	P25	P50 *(Mdn)*	P75	P90
Patient contact experience	134	30	12,700	3,235	3,125	1,988	1,147	1,977	2,928	4,000	5,575
Health care shadowing	76	8	1,185	157	130	202	19	58	120	179	259
Community service/volunteering	68	10	1,580	432	430	366	96	200	314	568	880
Other health care experience	51	50	9,962	1,470	1,360	1,552	113	600	1,069	2,072	2,569
Other work experience	27	10	6,181	1,966	1,952	1,394	50	1,000	1,936	2,506	3,832

Note: Zeroes were excluded.

153 programs (75.0%) reported that they collected data on their first-year class's average number of hours of health care experience (HCE) or work/volunteer experience.

FIRST-YEAR CLASS DEMOGRAPHICS

This section details the enrollment of first-year PA students by demographic factors (i.e., gender, ethnicity, and race). Omissions and imprecisions in programs' reporting of student demographic data make it difficult to provide a complete and accurate picture of the PA student body. This is also why cohort sample sizes differ across demographic tables. For example, programs that do not collect or have access to student race data may be reporting all students as "other" or "unknown" race. PAEA is exploring new ways to collect this information but would like to underscore the importance of member programs gathering and accurately reporting detailed student demographic data. Beginning with 2018's Program Report 33, statistics in this section were calculated using a different method from prior years. Therefore, data in these tables will be very different from previous Program Reports. Please see "Report Enhancements" (p. 2) for more details.

A total of 195 programs (95.6%) reported having a first-year class enrolled in the 2020-2021 academic year and/or reported first-year demographic data. This is accounted for by the fact that a small number of provisionally accredited programs had not matriculated their first student cohort.

For Tables 49-51:

- **"*n* (P)"** refers to the number of programs reporting at least one student of that demographic (e.g., in Table 49, 194 programs reported having at least one female first-year student).
- **"% (P)"** refers to the proportion of programs reporting at least one student of that demographic, out of the 228 that either reported having a first-year class enrolled and/or reported first-year demographic data (e.g., in Table 49, 99.0 % of the 195 programs with a first-year class reported having at least one female first-year student).
- **"*n* (S)"** refers to the number of students reported by the n (P) programs who belonged to each demographic (e.g., in Table 49, 194 programs reported a total of 6,936 female first-year students).
- **"% (S)"** refers to the proportion of all students reported across programs who belonged to each demographic (e.g., in Table 49, of the 9,121 reported first-year students, 76.0% were female).
- **"Mean % (S)"** refers to the average proportion of students belonging to each demographic among the n (P) reporting programs (e.g., in Table 49, of the 194 programs that reported at least one female student, an average of 79.6% of their students were female).
- ***M*, *SD*, and *Mdn*** were calculated using data from the *n* (P) reporting programs and were not reported when fewer than 5 programs reported data.

TABLE 48. FIRST-YEAR CLASS: PROGRAMS WITH MISSING DEMOGRAPHIC INFORMATION

	n	%
Missing gender information	2	1.0
Missing ethnicity information	12	6.1
Missing race information	13	6.6

The percent of programs missing demographic information was calculated by dividing the number of programs that did not report demographic information, or reported all "Do not know," by the 197 programs that reported having a first-year class enrolled and/or reported demographic data on their first-year students. Three programs reported that they had a first year class enrolled but did not provide first-year student demographics.

TABLE 49. FIRST-YEAR CLASS: GENDER

	n(P)	% (P)	*n (S)*	% (S)	Mean % (S)	*M*	*SD*	*Mdn*
Female	194	99.0	6,936	76.0	79.6	35.8	17.7	30.5
Male	194	99.0	2,182	23.9	25.4	11.2	7.3	9.0
Unknown gender	3	1.5	3	0.0	43.3	1.0	0.0	1.0
Total	**195**	**99.5**	**9,121**	**100.0**	**100.0**	**47.3**	**22.8**	**40**

TABLE 50. FIRST-YEAR CLASS: ETHNICITY

	n(P)	% (P)	*n (S)*	% (S)	Mean % (S)	*M*	*SD*	*Mdn*
Hispanic, Latino, or Spanish in origin	160	81.6	829	9.5	11.5	5.2	6.8	3.0
Not Hispanic, Latino, or Spanish in origin Male	171	87.2	7,204	82.9	93.0	42.1	21.6	37.0
Unknown ethnicity	36	18.4	659	7.6	36.5	18.3	25.7	5.0
Total	**191**	**97.4**	**8,692**	**100.0**	**100.0**	**45.5**	**24.3**	**40**

Of the 185 programs that reported some ethnicity information (excluding those that only reported "Do not know") for their first-year class, 21 (11.4%) reported no Hispanic students.

TABLE 51. FIRST-YEAR CLASS: RACE

	n(P)	% (P)	*n (S)*	% (S)	Mean % (S)	*M*	*SD*	*Mdn*
American Indian or Alaskan Native	30	15.3	42.0	0.5	3.8	1.4	1.0	1.0
Asian	157	80.1	927.0	10.5	12.8	5.9	4.7	5.0
Black or African American	144	73.5	432.0	4.9	7.0	3.0	2.6	4.0
Multiracial	76	38.8	270.0	3.1	7.9	3.6	3.5	2.0
Native Hawaiian or Pacific Islander	14	7.1	16.0	0.2	3.1	1.1	0.4	1.0
White	179	91.3	6162.0	69.8	76.9	34.4	17.3	30.0
Other	55	28.1	232.0	2.6	9.7	4.2	3.9	3.0
Unknown race	54	27.6	746.0	8.5	27.1	13.8	22.4	3.0
Total	**191**	**97.4**	**8827**	**100.0**	**100.0**	**46.2**	**21.4**	**40**

Of the 184 programs that reported some race information (excluding those that only reported "Other" or "Do not know") for their first-year class, 3 (1.6%) reported no non-White students.

TABLE 52. FIRST-YEAR CLASS: AGE

	n	*M*	*SD*	*Mdn*
Average age of first-year class	187	24.9	1.8	25
Age of youngest matriculant	183	21.3	1.3	21
Age of oldest matriculant	183	38.5	4.4	38

2021 COHORT

This section refers to the 2021 cohort, or the group of students who entered a PA program expecting to graduate in 2021. For most programs, this group of students matriculated in 2019. 184 programs (90.2%) reported that they had graduated or would be graduating a 2021 cohort of PA students.

For Table 53:

- "*n* (P)" refers to the number of programs reporting at least one student of that status (e.g., in Table 53, 72 programs reported at least one student who was dismissed for academic reasons).
- "% (P)" refers to the proportion of programs reporting at least one student of that status, out of the 184 programs that reported graduating a 2021 cohort of students (e.g., in Table 53, of the 184 programs with a 2021 cohort, 39.1% reported at least one student who was dismissed for academic reasons).
- "*n* (S)" refers to the number of students of each status as reported by the n (P) programs (e.g., in Table 53, 72 programs reported 120 students who were dismissed for academic reasons).
- "% (S)" refers to the proportion of all students reported across programs of each status (e.g., in Table 53, of 8,827 total students, 1.4% were dismissed for academic reasons).
- "Mean % (S)" refers to the average proportion of students of each status among the n (P) reporting programs (e.g., in Table 53, of the 72 programs that reported at least one student who was dismissed for academic reasons, an average of 3.8% of their 2021 cohort was dismissed for academic reasons).
- *M*, *SD*, and *Mdn* are calculated using data from the n (P) reporting programs.

TABLE 53. 2021 COHORT: STUDENT STATUS AT GRADUATION

	***n*(P)**	**% (P)**	***n (S)***	**% (S)**	**Mean % (S)**	***M***	***SD***	***Mdn***
Graduated, or expect to graduate, on time	184	100.0	8,015	94.1	94.2	43.6	19.1	38.0
Academic dismissal	72	39.1	120	1.4	3.8	1.7	1.0	1.0
Non-academic dismissal (e.g., professionalism sanction)	14	7.6	15	0.2	2.9	1.1	0.3	1.0
Withdrew: Medical reason(s)	23	12.5	36	0.4	3.1	1.6	0.9	1.0
Withdrew: Personal reason(s)	57	31.0	97	1.1	3.8	1.7	1.1	1.0
Decelerated: Short term (graduated less than one year late)	46	25.0	107	1.3	5.1	2.3	1.9	1.5
Decelerated: To next cohort	61	33.2	124	1.5	3.9	2.0	1.6	1.0
Total	**184.0**	**100.0**	**8,514.0**	**100.0**	**100.0**	**46.8**	**20.8**	**40.0**

2021 COHORT DEMOGRAPHICS

The following section details the graduation, deceleration, and withdrawal status of the 2021 cohort of PA students by demographic factors (i.e., gender, ethnicity, and race). Omissions and imprecisions in programs' reporting of student demographic data make it difficult to provide a complete and accurate picture of the PA student body. This is also why cohort sample sizes differ across demographic tables. For example, programs that do not collect or have access to student race data may be reporting all students as "other" or "unknown" race.

Demographic breakdowns are presented in two ways, in the "A" and "B" tables. The two types of tables present the same information in two different but complementary ways, giving further insight into the demographic makeup and statuses of the 2021 cohort.

In the "A" tables, we report student demographics by their status (i.e., graduation, dismissal, withdrawal, and deceleration rates). The "% (S)" column in the "A" tables can be interpreted as "Within each demographic category, what percentage of students had that status?" The "% (All S)" column of the "A" tables can be interpreted as "Of all students reported by demographics and status, how many students were of that demographic and status?" For example, Table 55A shows that, among female students, 94.7% graduated, and female graduates comprised 66.5% of all reported students in the 2021 cohort.

The "B" tables report student statuses by demographics. The interpretation of the percentages in the "B tables" is "Within each status, what percentage of students belonged to each demographic?" For example, Table 55B shows that 74.0% of all graduates in the 2021 cohort were female.

For all "A" tables:

- "*n* (P)" refers to the number of programs reporting at least one student of that demographic and status (e.g., in Table 55A, 49 programs reported at least one female student who was dismissed for academic reasons).
- "% (P)" refers to the proportion of programs reporting at least one student of that demographic and status, out of the 208 programs that reported graduating a 2021 cohort of students (e.g., in Table 55A, of the 182 programs with a 2021 cohort, 26.9% reported at least one female student who was dismissed for academic reasons).
- "*n* (S)" refers to the number of students of each demographic who had each status (e.g., in Table 55A, programs reported a total of 78 female students who were dismissed for academic reasons).
- "% (S)" refers to the proportion of all students within a demographic who had each status (e.g., in Table 55A, of 6,103 total female students, 1.3% were dismissed for academic reasons).
- "% (All S)" refers to the proportion of all students who belonged to a demographic and who had each status (e.g., in Table 55A, of 8,284 total students, 0.9% were female students who were dismissed for academic reasons).
- *M*, *SD*, and *Mdn* were calculated using data from the n (P) reporting programs and were not tabled when there were fewer than 5 reporting programs. Instead, they are labeled "NR."

TABLE 54. 2021 COHORT: PROGRAMS WITH MISSING DEMOGRAPHIC INFORMATION

	n	%
Missing gender information	3	1.6
Missing ethnicity information	19	10.3
Missing race information	15	8.2

The percent of programs missing demographic information was calculated by dividing the number of programs that did not report demographic information, or reported all "Do not know," by the 184 programs that reported that they would be graduating a 2021 cohort of students.

TABLE 55A. 2021 COHORT: GENDER BY STUDENT STATUS

	n(P)	% (P)	*n* (S)	% (S)	% (All S)	*M*	*SD*	*Mdn*
Female								
Graduated, or expect to graduate, on time	175	96.2	5,779	94.7	66.5	33.0	15.2	30.0
Academic dismissal	49	26.9	78	1.3	0.9	1.6	0.9	1.0
Non-academic dismissal (e.g., professionalism sanction)	10	5.5	11	0.2	0.1	1.1	0.1	1.0
Withdrew: Medical reason(s)	17	9.3	21	0.3	0.2	1.2	0.4	1.0
Withdrew: Personal reason(s)	38	20.9	58	1.0	0.7	1.5	1.0	1.0
Decelerated: Short term (graduated less than one year late)	35	19.2	74	1.2	0.9	2.1	1.3	2.0
Decelerated: To next cohort	49	26.9	82	1.3	0.9	1.7	1.2	1.0
Subtotal	182	100.0	6,103	100.0	70.2	34.3	16.6	31.0
Male								
Graduated, or expect to graduate, on time	175	96.2	1,854	92.7	21.3	10.6	6.3	9.0
Academic dismissal	36	19.8	41	2.0	0.5	1.1	0.5	1.0
Non-academic dismissal (e.g., professionalism sanction)	8	4.4	8	0.4	0.1	1.0	0.0	1.0
Withdrew: Medical reason(s)	7	3.8	7	0.3	0.1	1.0	0.0	1.0
Withdrew: Personal reason(s)	36	19.8	39	1.9	0.4	1.1	0.3	1.0
Decelerated: Short term (graduated less than one year late)	16	8.8	22	1.1	0.3	1.4	0.7	1.0
Decelerated: To next cohort	25	13.7	30	1.5	0.3	1.2	0.5	1.0
Subtotal	178	97.8	2,001	100.0	23.0	11.2	6.8	10.0
Unknown gender								
Graduated, or expect to graduate, on time	3	1.6	173	96.1	2.0	NR	NR	NR
Academic dismissal	1	0.5	4	2.2	0.0	NR	NR	NR
Non-academic dismissal (e.g., professionalism sanction)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Medical reason(s)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Personal reason(s)	2	1.1	2	1.1	0.0	NR	NR	NR
Decelerated: Short term (graduated less than one year late)	0	0.0	0	0.0	0.0	NR	NR	NR
Decelerated: To next cohort	1	0.5	1	0.6	0.0	NR	NR	NR
Subtotal	3	1.6	180	100.0	2.1	NR	NR	NR

TABLE 55A (CONTINUED). 2021 COHORT: GENDER BY STUDENT STATUS

	n(P)	% (P)	*n* (S)	% (S)	% (All S)	*M*	*SD*	*Mdn*
Total								
Graduated, or expect to graduate, on time	178	96.7	7,806	89.8	89.8	43.9	19.0	38.5
Academic dismissal	71	38.6	123	1.4	1.4	1.7	1.2	1.0
Non-academic dismissal (e.g., professionalism sanction)	17	9.2	19	0.2	0.2	1.1	0.3	1.0
Withdrew: Medical reason(s)	23	12.5	28	0.3	0.3	1.2	0.4	1.0
Withdrew: Personal reason(s)	60	32.6	99	1.1	1.1	1.7	1.0	1.0
Decelerated: Short term (graduated less than one year late)	42	22.8	96	1.1	1.1	2.3	1.7	2.0
Decelerated: To next cohort	63	34.2	113	1.3	1.3	1.8	1.4	1.0
Total	**182**	**100.0**	**8,284**	**100.0**	**100.0**	**45.5**	**28.7**	**40.0**

TABLE 55B. 2021 COHORT: STUDENT STATUS BY GENDER (%)

	n (S)	Female	Male	Unknown Gender
Total				
Graduated, or expect to graduate, on time	7,806	74.0	23.8	2.2
Academic dismissal	123	63.4	33.3	3.3
Non-academic dismissal (e.g., professionalism sanction)	19	57.9	42.1	0.0
Withdrew: Medical reason(s)	28	75.0	25.0	0.0
Withdrew: Personal reason(s)	99	58.6	39.4	2.0
Decelerated: Short term (graduated less than one year late)	96	77.1	22.9	0.0
Decelerated: To next cohort	113	72.6	26.5	0.9
Total	**8284**	**70.2**	**23.0**	**2.1**

TABLE 56A. 2021 COHORT: ETHNICITY BY STUDENT STATUS

	n(P)	% (P)	*n* (S)	% (S)	% (All S)	*M*	*SD*	*Mdn*
Hispanic, Latino, or Spanish in origin								
Graduated, or expect to graduate, on time	128	73.1	587	94.1	7.7	4.6	5.8	3.0
Academic dismissal	9	5.1	11	1.8	0.1	1.2	0.4	1.0
Non-academic dismissal (e.g., professionalism sanction)	1	0.6	1	0.2	0.0	1.0	0.0	1.0
Withdrew: Medical reason(s)	0	0.0	0	0.0	0.0	0.0	0.0	0.0
Withdrew: Personal reason(s)	5	2.9	6	1.0	0.1	1.2	0.4	1.0
Decelerated: Short term (graduated less than one year late)	7	4.0	8	1.3	0.1	1.1	0.4	1.0
Decelerated: To next cohort	8	4.6	11	1.8	0.1	1.4	0.7	1.0
Subtotal	131	74.9	624	100.0	8.2	4.8	5.9	3.0
Not Hispanic, Latino, or Spanish in origin								
Graduated, or expect to graduate, on time	137	78.3	5,540	93.9	72.5	40.4	18.9	36.0
Academic dismissal	53	30.3	88	1.5	1.2	1.7	1.1	1.0
Non-academic dismissal (e.g., professionalism sanction)	12	6.9	14	0.2	0.2	1.2	0.4	1.0
Withdrew: Medical reason(s)	18	10.3	22	0.4	0.3	1.2	0.4	1.0
Withdrew: Personal reason(s)	47	26.9	74	1.3	1.0	1.6	0.8	1.0
Decelerated: Short term (graduated less than one year late)	37	21.1	89	1.5	1.2	2.4	1.9	2
Decelerated: To next cohort	46	26.3	71	1.2	0.9	1.5	1.0	1.0
Subtotal	153	87.4	5,898	100.0	77.2	38.5	22.5	35.0
Unknown ethnicity								
Graduated, or expect to graduate, on time	35	20.0	1,082	96.8	14.2	30.9	26.5	28.0
Academic dismissal	4	2.3	9	0.8	0.1	NR	NR	NR
Non-academic dismissal (e.g., professionalism sanction)	4	2.3	7	0.6	0.1	NR	NR	NR
Withdrew: Medical reason(s)	2	1.1	2	0.2	0.0	NR	NR	NR
Withdrew: Personal reason(s)	5	2.9	10	0.9	0.1	2.0	1.2	2.0
Decelerated: Short term (graduated less than one year late)	1	0.6	2	0.2	0.0	NR	NR	NR
Decelerated: To next cohort	3	1.7	6	0.5	0.1	NR	NR	NR
Subtotal	38	21.7	1,118	100.0	14.6	29.4	27.4	30.0

TABLE 56A (CONTINUED). 2021 COHORT : ETHNICITY BY STUDENT STATUS

	n(P)	% (P)	*n* (S)	% (S)	% (All S)	*M*	*SD*	*Mdn*
Total								
Graduated, or expect to graduate, on time	173	98.9	7,209	94.4	94.4	41.9	22.2	38.0
Academic dismissal	62	35.4	108	1.4	1.4	1.7	1.1	1.0
Non-academic dismissal (e.g., professionalism sanction)	17	9.7	22	0.3	0.3	1.3	0.8	1.0
Withdrew: Medical reason(s)	20	11.4	24	0.3	0.3	1.2	0.4	1.0
Withdrew: Personal reason(s)	55	31.4	90	1.2	1.2	1.6	0.9	1.0
Decelerated: Short term (graduated less than one year late)	40	22.9	99	1.3	1.3	2.5	1.9	2.0
Decelerated: To next cohort	53	30.3	88	1.2	1.2	1.7	1.2	1.0
Subtotal	175	100.0	7,640	100.0	100.0	44.4	29.2	39.5

TABLE 56B. STUDENT STATUS BY ETHNICITY (%)

	n (S)	Hispanic, Latino, or Spanish in Origin	Not Hispanic, Latino, or Spanish in Origin	Unknown Ethnicity
Graduated, or expect to graduate, on time	7,209	7.7	72.5	14.2
Academic dismissal	108	0.1	1.2	0.1
Non-academic dismissal (e.g., professionalism sanction)	22	0.0	0.2	0.1
Withdrew: Medical reason(s)	24	0.0	0.3	0.0
Withdrew: Personal reason(s)	90	0.1	1.0	0.1
Decelerated: Short term (graduated less than one year late)	99	0.1	1.2	0.0
Decelerated: To next cohort	88	0.1	0.9	0.1
Total	**7,640**	**8.2**	**77.2**	**14.6**

TABLE 57A. 2021 COHORT: RACE BY STUDENT STATUS

	n(P)	% (P)	*n* (S)	% (S)	% (All S)	*M*	*SD*	*Mdn*
American Indian or Alaska Native								
Graduated, or expect to graduate, on time	25	14.1	40	97.6	0.5	1.6	1.2	1.0
Academic dismissal	0	0.0	0	0.0	0.0	NR	NR	NR
Non-academic dismissal (e.g., professionalism sanction)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Medical reason(s)	1	0.6	1	2.4	0.0	NR	NR	NR
Withdrew: Personal reason(s)	0	0.0	0	0.0	0.0	NR	NR	NR
Decelerated: Short term (graduated less than one year late)	0	0.0	0	0.0	0.0	NR	NR	NR
Decelerated: To next cohort	0	0.0	0	0.0	0.0	NR	NR	NR
Subtotal	26	14.7	41	100.0	0.5	1.6	1.2	1.0
Asian								
Graduated, or expect to graduate, on time	132	74.6	722	94.0	9.0	5.5	4.5	4.0
Academic dismissal	8	4.5	8	1.0	0.1	1.0	0.0	1.0
Non-academic dismissal (e.g., professionalism sanction)	2	1.1	2	0.3	0.0	NR	NR	NR
Withdrew: Medical reason(s)	3	1.7	3	0.4	0.0	NR	NR	NR
Withdrew: Personal reason(s)	9	5.1	10	1.3	0.1	1.1	0.3	1.0
Decelerated: Short term (graduated less than one year late)	11	6.2	15	2.0	0.2	1.4	0.7	1.0
Decelerated: To next cohort	7	4.0	8	1.0	0.1	1.1	0.4	1.0
Subtotal	135	76.3	768	100.0	9.6	5.7	4.7	4.0
Black or African American								
Graduated, or expect to graduate, on time	104	58.8	249	85.9	3.1	2.4	1.6	2.0
Academic dismissal	12	6.8	12	4.1	0.2	1.0	0.0	1.0
Non-academic dismissal (e.g., professionalism sanction)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Medical reason(s)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Personal reason(s)	10	5.6	11	3.8	0.1	1.1	0.3	1.0
Decelerated: Short term (graduated less than one year late)	8	4.5	9	3.1	0.1	1.1	0.4	1.0
Decelerated: To next cohort	9	5.1	9	3.1	0.1	1.0	0.0	1.0
Subtotal	112	63.3	290	100.0	3.6	2.6	1.8	2.0

TABLE 57A (CONTINUED). 2021 COHORT: RACE BY STUDENT STATUS

	n(P)	% (P)	*n* (S)	% (S)	% (All S)	*M*	*SD*	*Mdn*
Multiracial								
Graduated, or expect to graduate, on time	63	35.6	165	95.9	2.1	2.6	2.5	2.0
Academic dismissal	2	1.1	2	1.2	0.0	NR	NR	NR
Non-academic dismissal (e.g., professionalism sanction)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Medical reason(s)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Personal reason(s)	1	0.6	1	0.6	0.0	NR	NR	NR
Decelerated: Short term (graduated less than one year late)	0	0.0	0	0.0	0.0	NR	NR	NR
Decelerated: To next cohort	3	1.7	4	2.3	0.1	NR	NR	NR
Subtotal	65	36.7	172	100.0	2.2	2.6	2.5	2.0
Native Hawaiian or Pacific Islander								
Graduated, or expect to graduate, on time	17	9.6	19	86.4	2.4	1.1	0.3	1.0
Academic dismissal	1	0.6	1	4.5	0.1	NR	NR	NR
Non-academic dismissal (e.g., professionalism sanction)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Medical reason(s)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Personal reason(s)	0	0.0	0	0.0	0.0	NR	NR	NR
Decelerated: Short term (graduated less than one year late)	1	0.6	1	4.5	0.1	NR	NR	NR
Decelerated: To next cohort	1	0.6	1	4.5	0.1	NR	NR	NR
Subtotal	19	10.7	22	100.0	2.8	1.2	0.5	1.0
White								
Graduated, or expect to graduate, on time	155	87.6	5,231	95.0	65.5	33.7	15.8	29.0
Academic dismissal	43	24.3	62	1.1	0.8	1.4	0.7	1.0
Non-academic dismissal (e.g., professionalism sanction)	11	6.2	13	0.2	0.2	1.2	0.4	1.0
Withdrew: Medical reason(s)	15	8.5	18	0.3	0.2	1.2	0.4	1.0
Withdrew: Personal reason(s)	38	21.5	55	1.0	0.7	1.4	0.7	1.0
Decelerated: Short term (graduated less than one year late)	31	17.5	66	1.2	0.8	2.1	1.4	2.0
Decelerated: To next cohort	40	22.6	62	1.1	0.8	1.6	1.1	1.0
Subtotal	158	89.3	5,507	100.0	68.9	34.9	16.9	30.5

TABLE 57A (CONTINUED). 2021 COHORT: RACE BY STUDENT STATUS

	n(P)	% (P)	*n* (S)	% (S)	% (All S)	*M*	*SD*	*Mdn*
Other								
Graduated, or expect to graduate, on time	45	25.4	160	92.5	2.0	3.6	2.8	2.0
Academic dismissal	3	1.7	3	1.7	0.0	NR	NR	NR
Non-academic dismissal (e.g., professionalism sanction)	0	0.0	0	0.0	0.0	NR	NR	NR
Withdrew: Medical reason(s)	1	0.6	1	0.6	0.0	NR	NR	NR
Withdrew: Personal reason(s)	0	0.0	0	0.0	0.0	NR	NR	NR
Decelerated: Short term (graduated less than one year late)	3	1.7	4	2.3	0.1	NR	NR	NR
Decelerated: To next cohort	5	2.8	5	2.9	0.1	1.0	0.0	1.0
Subtotal	50	28.2	173	100.0	2.2	3.5	3.0	2.0
Unknown race								
Graduated, or expect to graduate, on time	51	28.8	972	95.4	12.2	19.1	24.9	4.0
Academic dismissal	7	4.0	13	1.3	0.2	1.9	1.1	2.0
Non-academic dismissal (e.g., professionalism sanction)	3	1.7	3	0.3	0.0	NR	NR	NR
Withdrew: Medical reason(s)	2	1.1	2	0.2	0.0	NR	NR	NR
Withdrew: Personal reason(s)	8	4.5	14	1.4	0.2	1.8	1.0	1.5
Decelerated: Short term (graduated less than one year late)	2	1.1	3	0.3	0.0	NR	NR	NR
Decelerated: To next cohort	5	2.8	12	1.2	0.2	2.4	0.9	3.0
Subtotal	58	32.8	1,019	100.0	12.8	22.9	25.9	4.0
Total								
Graduated, or expect to graduate, on time	175	98.9	7,558	94.6	94.6	43.2	20.2	38.0
Academic dismissal	62	35.0	101	1.3	1.3	1.6	1.0	1.0
Non-academic dismissal (e.g., professionalism sanction)	17	9.6	18	0.2	0.2	5.2	17.0	1.0
Withdrew: Medical reason(s)	20	11.3	25	0.3	0.3	1.3	0.4	1.0
Withdrew: Personal reason(s)	55	31.1	91	1.1	1.1	1.7	1.0	1.0
Decelerated: Short term (graduated less than one year late)	41	23.2	98	1.2	1.2	2.4	1.8	2.0
Decelerated: To next cohort	60	33.9	101	1.3	1.3	1.7	1.3	1.0
Total	**177**	**100.0**	**7,992**	**100.0**	**100.0**	**47.0**	**30.0**	**40.0**

TABLE 57B. 2019 COHORT: STUDENT STATUS BY RACE (%)

	n(S)	American Indian or Alaskan Native	Asian	Black or African American	Multiracial	Native Hawaiian or Pacific Islander	White	Other Race	Unknown Race
Other									
Graduated, or expect to graduate, on time	7,558	0.5	9.6	3.3	2.2	0.3	69.2	2.1	12.9
Academic dismissal	101	0.0	7.9	11.9	2.0	1.0	61.4	3.0	12.9
Non-academic dismissal (e.g., professionalism sanction)	18	0.0	11.1	0.0	0.0	0.0	72.2	0.0	16.7
Withdrew: Medical reason(s)	25	4.0	12.0	0.0	0.0	0.0	72.0	4.0	8.0
Withdrew: Personal reason(s)	91	0.0	11.0	12.1	1.1	0.0	60.4	0.0	15.4
Decelerated: Short term (graduated less than one year late)	98	0.0	15.3	9.2	0.0	1.0	67.3	4.1	3.1
Decelerated: To next cohort	101	0.0	7.9	8.9	4.0	1.0	61.4	5.0	11.9
Total	**7,992**	**0.5**	**9.6**	**3.6**	**2.2**	**0.3**	**68.9**	**2.2**	**12.8**

Of the 162 programs that reported some race information (excluding those that only reported "Other" or "Do not know") for their 2021 graduating cohort, 6 (3.7%) reported no non-White graduates.

SECTION 5. SPECIALIZED SUPERVISED CLINICAL PRACTICE EXPERIENCE

This section details additional information about supervised clinical practice experiences (SCPEs), including the utilization of Veterans Affairs (VA) and community health centers (CHCs). These questions were asked for the first time on the 2020-2021 Program Survey and will be included in future Curriculum Surveys (Didactic, Clinical). In addition, programs were also surveyed on waiver training for medication assisted treatments for substance use disorders (MAT).

TABLE 58. MAT WAIVER TRAINING

	n	%
Provided	132	64.7
Required	112	54.9

TABLE 59. MAT WAIVER TRAINING HOURS RECOMMENDED/REQUIRED BY PROGRAMS

	n	Min	Max	*M*	*SD*	*Mdn*
Number of hours	108	2.0	41.0	19.2	7.5	24.0

TABLE 60: PERCENTAGE OF PROGRAMS REPORTING ACTIVE PRECEPTORS BY PROFESSION (%)

Profession	*n*	%	Min	Max	*M*	SD	P10	P25	P50 (*Mdn*)	P75	P90
Advanced Practice Nursing (APN; Nurse Practitioner)	170	83.3	1.0	33.0	7.8	6.1	2.0	4.0	5.0	10.0	15.0
Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO)	202	99.0	8.0	94.0	54.2	18.5	30.0	42.0	51.3	70.0	15.0
Physician Assistant/ Associate (PA)	203	99.5	5.0	95.0	39.4	17.7	16.0	27.0	40.0	50.0	60.0
Other	21	10.3	0.1	100.0	7.2	21.3	0.6	1.0	2.0	5.0	5.0

Note: Other professions include, but were not limited to: clinicians who hold other doctoral degrees (PhD, PsyD), as well as psychologists, licensed behavioral health counselors, physical therapists, and occupational therapists.

TABLE 61: USAGE OF VETERANS AFFAIRS (VA) AND COMMUNITY HEALTH CENTERS (CHCS) FOR CLINICAL ROTATIONS

			# of Students		
Type of Facility	***n***	**%**	***Mn***	***SD***	***Mdn***
Veteran Affairs (VA) facilities	122	59.8	14.7	16.8	9.5
Community Health Centers (CHCs)	121	59.3	17.6	20.0	12.5

Note: "n" denotes number of programs.

TABLE 62: OBSTACLES OR BARRIERS TO USAGE OF VA AND CHCS FOR CLINICAL ROTATIONS

Obstacles or Barriers to Placement	Veterans Affairs (VA)		Community Health Center (CHCs)	
	n	%	*n*	%
Placing students at remote sites is financially prohibitive to the program and/or students	9	4.4	12	5.9
The local facility administrators preferentially give slots not already reserved for medical students to students from other non-PA health professions (e.g., APRN)	35	17.2	35	17.2
The local facility administrators only give slots to medical students	30	14.7	20	9.8
There are no sites of this type within the vicinity of my program	3	1.5	4	2.0
The local facilities do not use advanced practice clinicians	3	1.5	4	2.0
Other barriers	67	32.8	47	23.0
N/A: My program has placed students in this type of facility with no obstacles or barriers	66	32.4	66	32.4
N/A: My program has not attempted to place students at this type of facility	20	9.8	30	14.7

Other barriers listed by programs for both VA and CHC placement include the COVID-19 pandemic and competition with other PA programs. In addition, programs noted the onboarding process/administrative barriers and difficulties with obtaining affiliation agreements as barriers specific to VA facilities while high staff/provider turnover, lack of experienced preceptors, and the overburdened nature of CHCs as barriers to placing students at those facilities.

From: Beverly Shelton on behalf of Humayun Chaudhry
To: Beverly Shelton
Subject: Retatrutide Letter to FSMB
Date: Wednesday, April 2, 2025 9:08:14 AM
Attachments: image002.png

Dear Executive Directors,

I wanted to alert you to a letter sent to the FSMB from the U.S. Food and Drug Administration (FDA) with information related to compounded drug products containing retatrutide, an investigational drug that is similar to (but not the same as) GLP-1 agonists. Some of these drug products claim to treat chronic weight management, diabetes, and related conditions. The FDA has asked us to share this information with our member medical boards to make licensees aware of the current regulatory status of compounded retatrutide. The FDA recommends that consumers not purchase unapproved products containing retatrutide and they encourage health care providers to discuss the risks of unapproved compounded products with their patients.

The full FDA letter to FSMB on this matter can be found here. If you have questions about any issues related to drug compounding, the FDA encourages you to reach out to the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,
Hank

Humayun "Hank" Chaudhry, DO, MACP, FRCP
President and Chief Executive Officer

Federation of State Medical Boards
1775 Eye Street NW | Suite 410 | Washington, DC 20006
o. 817-868-4044 | hchaudhry@fsmb.org | www.fsmb.org

Quarterly FSMB Update on USMLE®

March 2025, Vol. 6, No. 1

State Board Members Chair USMLE Governance Committees

For the first time in United States Medical Licensing Examination® (USMLE®) history, the governing bodies for the USMLE program – the Composite Committee and the Management Committee – are chaired by state board members! We asked Dr. Walker-McGill and Dr. Anderson to provide a few words about their service on the USMLE committees and the importance of having state medical board representatives serve on the program.

Cheryl Walker-McGill, MD (North Carolina), Chair of the USMLE Composite Committee

"As Past Chair of the Federation of State Medical Boards (FSMB) and Past President of the North Carolina Medical Board, it is my profound privilege to serve as Chair of the USMLE Composite Committee. I am proud to contribute to our shared mission of ensuring patient access to quality healthcare and upholding the highest standards of patient safety — shaping the future of medical practice for the benefit of all Americans."

Andrea Anderson, MD, (District of Columbia), Chair of the USMLE Management Committee

"My involvement with the USMLE program on all levels, from item writing to item review, content policy, and governance has absolutely been one of the highlights of my state medical board and FSMB service. I was first introduced when I attended the USMLE Orientation at the NBME headquarters. I was immediately hooked! As a medical school faculty member, the opportunity to volunteer for the USMLE combines my love of medical education with my medical regulation expertise. State board members are especially useful with regards to assessment of ethics and professionalism topics. I am honored to serve and urge interested state board members to get involved as well. USMLE service is directly related to our charge of public protection by prioritizing and assessing the areas important to creating a competent and well-trained physician workforce."

On behalf of FSMB and the state medical board community, we extend a huge thank you to Dr. Walker-McGill and Dr. Anderson for their long-standing commitment and service to USMLE! We owe a debt of gratitude to them and to all state board members who volunteer their time with the USMLE program.

USMLE Orientation for State Board Members

L-R: Alex Mechaber, MD (NBME staff); David Johnson (FSMB staff); Ramanathan Raju, MD (New York); Dawn Walker, DO (Arizona Osteopathic); Karen Domino, MD (Washington Medical); Jill Shaw, DO (Oregon); Milton Bond, Jr. (Wisconsin); and Suzanne McEllhenney (NBME staff).

On March 14, 2025, FSMB and NBME hosted a special state board members only USMLE Orientation at FSMB's office in Euless, Texas. A total of 11 individuals from 8 different boards participated in-person and remotely:

- Dawn Walker, DO - Arizona Board of Osteopathic Examiners in Medicine and Surgery
- Mohammed Jameel, MD - Illinois State Medical Board
- Richard Bradbury, DPM - Kansas State Board of Healing Arts
- Ramanathan Raju, MD - New York State Board for Medicine (Licensure)
- Jill Shaw, DO - Oregon Medical Board
- Amanda Barner Welch, MD - Virginia Board of Medicine
- Charlie Browne, MD - Washington Medical Commission
- Karen Domino, MD, MPH - Washington Medical Commission
- Milton Bond, Jr - Wisconsin Medical Examining Board
- Kris Ferguson, MD - Wisconsin Medical Examining Board
- Gregory Schmeling, MD - Wisconsin Medical Examining Board

During the meeting, attendees learned about the history of licensing examinations, the USMLE program, how test items are developed, and opportunities for participating in USMLE, such as item writing and review, standard setting panels, governance committees and special workgroups. We appreciate and thank everyone who joined us!

The annual USMLE Orientation for State Board Members and Staff will be held in the fall (dates TBD) at FSMB's Texas office. **Board members and staff interested in participating in the fall orientation can contact Frances Cain, FSMB Director of Assessment Services, at fcain@fsmb.org.**

USMLE Predictive Validity Research

Since its introduction in 1992, the USMLE has provided the medical licensing community with a high-quality assessment tool ensuring that licensed physicians are held to a rigorous and reliable standard. Passing USMLE Step 1, Step 2 Clinical Knowledge (CK), and Step 3 ensures that physicians have demonstrated they understand and can apply medical knowledge and clinical reasoning to provide safe and effective patient care.

USMLE has administered more than three million Step exams since 1992—providing much of the groundwork for an extensive research program that continues to produce numerous peer-reviewed contributions to the professional literature of medical licensing, education and training.

Staff at NBME and FSMB working on the USMLE program have assembled a collection of key recent articles evaluating the predictive validity of USMLE. Predictive validity involves studying how the exam scores are associated with relevant future outcomes and thus can provide strong evidence that the exam truly measures competencies related to safe and effective practice. Extensive research has focused on USMLE performance and its correlation with other key measures, such as performance on other professional assessments, residency outcomes, disciplinary actions by state medical boards, and, most importantly, patient outcomes.

These studies augment the validity evidence from the rigorous exam development, scoring, and standard setting practices that collectively support the validity of licensing decisions informed, in part, by requiring successful completion of USMLE Step 1, Step 2 CK and Step 3. These key articles were shared in their entirety or with citation and brief summary in a January 22, 2025, email to all state board executive directors.

USMLE and patient outcomes:
Typically regarded as the most important form of predictive validity research in medical assessment is that which explores the association with patient outcomes. Such research can be difficult to construct and execute given the statistical complexity of connecting exam performance to future patient outcomes. Yet, this evidence remains the "gold standard" for predictive validity research. A pair of studies from 2024 and 2014 spotlight USMLE performance and patient outcomes involving treatment for common inpatient diagnoses, length of in-hospital stay and in-hospital mortality. Both studies identified a correlation between USMLE performance and improved patient outcomes in the specified areas after accounting for various other relevant factors.

USMLE and state board disciplinary actions:
Multiple studies have explored the association between USMLE performance and subsequent likelihood of disciplinary action by a state medical board. The findings indicate that higher performance on each USMLE examination relates to a lower likelihood of disciplinary action. Another study exploring this outcome revealed that more attempts on USMLE Step exams were associated with an increased likelihood of subsequent disciplinary action.

USMLE and performance in residency training:
The introduction of competency "milestones" by the Accreditation Council for Graduate Medical Education (ACGME) into residency training has provided another point for comparison with USMLE performance. It is not unreasonable to expect performance measures and milestones to align with competencies assessed on USMLE. A 2021 study provides one example of this, showing incremental validity evidence for support of Step 1 and Step 2 CK scores with emergency medicine milestones.

USMLE and other professional examinations:
One of the most common forms of predictive validity evidence explores the relationship between an exam and other assessments within that field. Thus, another line of research has explored the relationship between USMLE and other medical education examinations, such as board certification exams. These studies typically use USMLE as a control to account for prior knowledge before the specialties in-training examination. However, the studies often reveal that USMLE performance also strongly relates to the certification exam.

For example, a 2020 study published in Academic Medicine explored the correlation between performance on USMLE Step exams, the in-training exam of the American College of Physicians, and the American Board of Internal Medicine's (ABIM) certifying examination. This study showed that while no individual USMLE Step score was as strongly predictive of the ABIM certifying exam score as the internal medicine in-training exam score, the combined relative contribution of all three USMLE Step scores was similar to that of the in-training score.

Comparable research has been done and published for numerous other specialties, including infectious disease (2015), adult rheumatology (2015), hematology and medical oncology (2016), cardiology (2017) and nephrology (2018).

The research spotlighted here shows a consistent positive relationship between USMLE performance and key external outcomes—precisely what one should expect of a high-stakes examination for medical licensure. The studies noted here provide a compelling basis for the continued validity of the licensing decisions based, in part, on the successful completion of the USMLE Step sequence.

We will continue to share relevant literature supporting medical boards' continued utilization of the USMLE as the primary assessment tool in the decision to issue a full, unrestricted medical license.

Questions about these studies or interpretations of this data may be directed to Daniel Jurich, PhD, NBME Associate Vice President for USMLE, at djurich@nbme.org. If you would like a copy of any of the studies referenced here, or would like the January 22, 2025, email resent to you, please contact Frances Cain, FSMB Director of Assessment Services, at fcain@fsmb.org.

2025 USMLE Meetings	
March	Committee for Individualized Review: March 5-6
April	Management Committee: April 1-2 Budget Committee: April 17
May	Committee for Individualized Review: May 6-7
June	Composite Committee: June 3

From: Jasmyn Brown <jbrown@nationalstaff.com>
Sent: Tuesday, April 15, 2025 7:17 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Nurse Practitioner/Physician Assistant Opportunity for New Graduates or Established Providers

Dear Alaska State Medical Board,

I hope this email finds you well. I am reaching out to share an exciting General Medical opportunity that might be of interest to recent graduates with NP, APRN or PA qualifications.

There is a clinic in Anchorage, AK & Wasilla, AK in need of a Full-time Provider to perform Compensation and Pension exams for Veterans. This is a Monday-Friday opportunity that offers consistent scheduling, a low stress environment & weekly pay.

This role is designed to support Veterans and offer new Nurse practitioners & Physician Assistant's the chance to develop their careers in a flexible and supportive environment. If possible, I would appreciate it if you could share this opportunity with your network of recent graduates or any relevant parties who may find it beneficial.

If additional details are needed or if there's a formal process for sharing job opportunities, please let me know. I would be happy to provide more information or follow your guidelines.

Thank you for your time and assistance.

Sincerely,

Jasmyn Brown | Advanced Practice Recruiter | National Staffing Solutions

O: 407.961.6649 | C: 904-474-9809 | F: 866.683.4613

925 S. Semoran Blvd, #110A, Winter Park, FL 32792

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April 1, 2025

Natalie Norberg
Executive Administrator
Alaska State Medical Board
333 Willoughby Ave., 9th FL
Juneau, Alaska 99801

Re: Mounjaro® and Zepbound® and Continued Patient Safety Concerns

Dear Ms. Norberg,

I write on behalf of Eli Lilly and Company ("Lilly") to alert the Alaska State Medical Board (the "Board") regarding a recent development related to tirzepatide, the active ingredient in Lilly's Mounjaro® and Zepbound® medicines. As you may be aware, tirzepatide was removed from the Food and Drug Administration's ("FDA") drug shortage list last year. A Texas federal court denied an attempt to block FDA's decision, holding that "Lilly regains its statutory exclusivity over tirzepatide products" and all other sellers "must cease production of their versions of the drugs." See Attachment. Then, on March 10, 2025, FDA announced that it would immediately begin enforcing the essentially-a-copy prohibition in section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA").[1]

Nevertheless, it appears that some telehealth providers and associated physicians have continued to mass prescribe and mass produce unapproved, untested compounded tirzepatide, putting patients across Alaska at risk. We are writing to alert you to these patient safety concerns and request your help in protecting the public from the dangers of large-scale marketing and sale of copies Lilly's FDA-approved medicines.

Lilly's FDA-Approved Medicines

Lilly's Mounjaro® and Zepbound® medicines are FDA approved to treat serious medical conditions. Mounjaro® is indicated in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Zepbound® is indicated, in addition to diet and exercise, for adults with obesity or those who are overweight and also have at least one weight-related additional condition, such as hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease, to lose weight.

The active pharmaceutical ingredient ("API") in both Mounjaro® and Zepbound® is called tirzepatide. Lilly is the only lawful supplier of FDA-approved tirzepatide and does not provide tirzepatide API to compounding pharmacies, other manufacturers, or anyone else. Because these

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1 FDA, "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize," (March 10, 2025), https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

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+1.317.276.2000
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medicines are sterile injectables, Lilly manufactures Mounjaro® and Zepbound® under strict controls. Lilly only sells Mounjaro® and Zepbound® through authorized channels, such as licensed pharmacies authorized by the state to dispense FDA-approved medicines prescribed by a healthcare provider. And we own the intellectual property rights related to Mounjaro® and Zepbound®.

Mounjaro® and Zepbound® should only be used when prescribed by a licensed healthcare professional. Lilly does not promote or encourage use of Mounjaro®, Zepbound®, or any other Lilly medicine outside of the medicine's FDA-approved indication.

Unlawful Sale and Prescription of Tirzepatide Knockoffs Risks Harming Patients

Numerous entities are currently marketing and selling illegal copycat versions of Lilly's tirzepatide. These illegal sellers are purporting to offer "compounded" drugs. Drug compounding is a practice where a pharmacist combines, mixes, or alters ingredients to create a drug tailored to the unique needs of an individual patient. Compounding is permitted only in very limited circumstances, such as when an FDA-approved drug is not commercially available or where a particular patient's "medical needs cannot be met by commercially available drug products."[2]

Entities previously claimed they were permitted to compound tirzepatide because FDA deemed Lilly's FDA-approved medicines in "shortage" for a period of time. But Mounjaro® and Zepbound® have now been out of shortage for months. In October 2024, FDA announced that the shortage of tirzepatide injection had been resolved. On December 19, 2024, FDA re-confirmed that decision, concluding that Lilly's supply of its medicines Mounjaro® and Zepbound® were sufficient to meet demand. And, as noted, a Texas federal court recently denied an attempt to block FDA's decision, upholding Lilly's "statutory exclusivity over tirzepatide products" and making clear that compounders must "cease production of their versions of the drugs." See Attachment. And FDA subsequently announced that immediately begin enforcing the essentially-a-copy prohibitions in the FDCA.[3]

FDA has repeatedly cautioned that these compounded products are "risky for patients."[4] That's because compounded drugs do not have to meet the same stringent safety regulations that FDA-approved medications do. Compounded tirzepatide is not studied in clinical trials, and is never FDA-approved, which means that FDA does not review the product to evaluate it for the safety, efficacy, or quality American patients expect and deserve. Compounding pharmacies do not have to register or list their products with FDA, are not required to meet FDA's "Good Manufacturing Practices," and do not have to report adverse events. While some falsely equate compounded products with

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2 21 U.S.C. § 353a(b)(1)(D).

3 https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

4 https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

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U.S.A.
+1.317.276.2000
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generic medicines, generics are FDA-approved and must be manufactured according to the same rigorous standards as branded medicines like Mounjaro® and Zepbound®—compounded drugs are neither.

As reported in JAMA Health Forum, most websites selling compounded GLP-1 drugs exclude important safety information and many mislead consumers about the safety and efficacy of their products.[5] The Obesity Action Coalition explained, "using a compounded medication is like playing a guessing game with your health. You don't know what you're getting, and if something goes wrong, it's hard to know why."[6] The American Diabetes Association recommended that patients avoid compounded products "due to uncertainty about their content, safety, quality, and effectiveness."[7]

Federal regulators, 37 State Attorneys General, and State Drug Task Forces have all warned the public about the dangers of these unsafe and unapproved products, including compounders using "non-sterile ingredients" and taking "no steps to sterilize them."[8] FDA recently warned a tirzepatide mass compounder for violating federal law by producing drugs in unsanitary conditions and using active ingredients from an unregistered entity.[9] And Lilly continues to discover compounded tirzepatide with critical safety, sterility, and efficacy problems, including products infected with dangerous bacteria and endotoxins.[10]

Continued Prescriptions of Unlawfully Compounded Drugs

We are concerned that even with tirzepatide out of shortage and fully available to meet patients' needs, some physicians are continuing to prescribe compounded tirzepatide that is illegally compounded and risky for patients. We are similarly concerned that decisions to compound, market, sell, and prescribe these compounded drugs are driven by financial considerations in a way that may not be in the best interests of patient health.

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5 https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225.

6 https://www.obesityaction.org/why-compounded-glp-1-medications-arent-the-answer/.

7 https://nclnet.org/the-national-consumers-league-urges-the-public-to-heed-warnings-about-unregulated-versions-of-glp-1-weight-loss-drugs/; https://diabetes.org/sites/default/files/2024-12/24.11.8%20compounding%20statement%20press%20release_FINAL.pdf.

8 https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/; https://www.nbcnews.com/health/health-news/tennessee-woman-accused-selling-fake-weight-loss-drugs-counterfeit-con-rcna184154; https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

9 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prorx-llc-696742-12202024.

10 *Complaint for False Advertising and Deceptive Trade Practices, Eli Lilly v. Thrive Health*, Case No. 25-cv-00104, Dkt. No. 1 (D. Colo. January 13, 2025).

Lilly

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Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
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When an FDA-approved product is not in shortage, federal law permits compounding a drug only when it differs from the FDA-approved medicine in a way that makes a "significant difference" for a specific patient. A classic example is when a patient is allergic to an inactive ingredient in an FDA-approved medicine, such as gluten; a compounded product without the inactive ingredient—e.g., a gluten-free version—is permitted because it produces a "significant difference" for that specific patient.

Tirzepatide does not contain any common allergen. Yet under the pretext of offering "personalized care," certain telehealth providers and drug compounders are mass-producing and mass-marketing tirzepatide with manipulated ingredients, doses, or route of administration, and providers are prescribing them without regard to patient need. These manipulated products have never been clinically tested or proven to be safe and effective, and a product that is mass produced and prescribed in the same manipulated formulation to many patients clearly is not designed to meet any specific patient's individual needs. None of these schemes is allowed, and all of them put patients at risk.

- *Additives.* Some physicians are prescribing compounded tirzepatide with added ingredients like B-3, B-6, B-12, or glycine. Compounders cannot simply add an ingredient to avoid legal restrictions against knockoff FDA-approved medicines that are not in shortage. There is no clinical evidence that adding these other ingredients to tirzepatide works better than tirzepatide alone or that there is a clinical need for any particular patient.

- *Altered Doses.* The FDA-approved labels for Mounjaro® and Zepbound® recommend 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, and 15mg doses with a four-week titration schedule (for slowly increasing dosage). Some physicians are prescribing new, different doses under the pretext of providing "personalized" care. There is no clinical evidence that would support adjusting the FDA-approved dosing regimen—and certainly not routinely prescribing an unapproved dosing regime for all patients.

- *Oral Versions.* Some physicians are prescribing what compounders claim are pill, under-the-tongue, or other oral versions of tirzepatide. There are no clinical trials or other human studies involving any oral tirzepatide product, meaning these physicians are experimenting on unsuspecting patients. Anyone claiming that oral tirzepatide products are safe or effective is doing so without clinical support.

We are also concerned about the troubling relationship between certain prescribing physicians, telehealth companies, and compounding pharmacies, which appear to work hand in glove to direct patients exclusively to untested, unapproved, illegally mass-produced compounded drugs. The routine—sometimes exclusive—prescribing of compounded tirzepatide, including tirzepatide with altered formulas, manipulated doses, or untested and unapproved routes of administration, when Lilly's FDA-approved products are available suggests that some physicians are not prioritizing patient health when prescribing tirzepatide products. Not only does this practice risk patient health, it may also put a physician malpractice insurance in jeopardy. As one senior risk consultant for a medical

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

malpractice insurer recently observed: "Some compounders . . . may believe the FDA enforcement manpower is so weak that the FDA won't be enforcing the prohibition that closely. . . . Physicians need to be aware of that. From a risk standpoint, I don't think they'd want to be associated with a compounder that's in violation of the law."[11]

Preventing Prescriptions of Unlawfully Compounded Tirzepatide

In light of the above, Lilly requests the Board's continued help to protect Alaska patients from the risks of unlawfully compounded prescription drugs. Specifically, Lilly requests that the Board:

- Inform Alaska physicians of FDA's December 19, 2024 Declaratory Order and the Texas federal court's ruling, attached to this letter, upholding FDA's removal of Lilly's medicines from the drug shortage list and confirming that compounding of tirzepatide must stop; and FDA's confirmation that it will immediately "take action against compounders for violations of the FD&C Act" related to tirzepatide as of March 19[12];

- Issue guidance to Alaska physicians concerning compounded tirzepatide, making clear that prescribing tirzepatide with added substances (like vitamin B-6 or B-12), in untested and unapproved oral formulations, or with altered doses intended to create the appearance of "personalization" is unlawful; and

- Work with your state board of pharmacy and board of medicine, together with any relevant state health and consumer protection regulators, and the FDA, in any investigation or enforcement action related to improper compounding of tirzepatide or improper prescriptions.

We appreciate your attention to these issues.

Sincerely,

Jillian V. Fuhs

Jillian V. Fuhs, JD, PharmD
Associate Vice President, Global Regulatory Affairs - Americas
Eli Lilly and Company

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11 https://www.medscape.com/viewarticle/end-compounded-glp-1s-what-physicians-need-know-2025a100063o?form=fpf.

12 https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL.,

Plaintiffs,

v. **No. 4:24-cv-0953-P**

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants.

OPINION & ORDER

Before the Court is Plaintiffs Outsourcing Facilities Association's and North American Custom Laboratories LLC Partners' (collectively "Plaintiffs") Motion for Preliminary Injunction and Stay (ECF No. 64). Having considered the briefing and applicable legal authorities, the Court will **DENY** Plaintiffs' Motion.

BACKGROUND

A. Regulatory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA") generally prohibits the introduction of a "new drug" into interstate commerce without the United States Food and Drug Administration's (the "FDA") approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer generally must submit a new drug application ("NDA"). *Id.* § 355(b)(1). The FDA adjudicates such applications and approves them only if it finds, based on the evidence before it, that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the new drug generally must comply with "current good manufacturing practice[s]" ("cGMP"), which "assure[s] that such drug meets the requirements of this chapter as to safety and has the identity

and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B); *see* 21 C.F.R. Pts. 210, 211.

In order to protect patients and ensure efficacy, the FDA's approval process is demanding. Each drug seeking the FDA's approval must be evaluated through three increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials. The sponsor must detail every ingredient and component in its application to the FDA. 21 U.S.C. § 355(b)(1)(A)(i)–(viii). The FDA conducts inspections to ensure compliance with cGMP, *id.* § 351(a)(2)(B), reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings and contraindications, *id.* § 352(f)(1)–(2), and monitors advertising and promotion to ensure it is not misleading, *id.* §§ 321(n), 352(a)(1), 352(n). The FDA also requires manufacturers to track and trace each finished product, *id.* § 360eee-1, to promptly report all adverse events, *id.* § 355(k), and to conduct further post-approval studies, *id.* § 355(o). Because of the FDA's rigorous requirements, "[o]n average, it takes 10-15 years and costs $2.6 billion to develop one new medicine."[1]

Despite the difficulties in getting new drugs approved, companies regularly invest in the research and development of new drugs due to the incentives created by Congress. Relevant here, new chemical entity exclusivity is earned whenever the FDA approves a new medicine for the first time. 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii). This statutory exclusivity means that for five years the FDA is prohibited from approving another manufacturer's application for any drug using the same active moiety. *Id.*

In addition to subjecting all new drugs to the NDA process, the FDCA regulates when drug compounding is permitted. Drug compounding is "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Thompson v. W. States*

[1]PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://tinyurl.com/5eecdtm9.

Med. Ctr., 535 U.S. 357, 360–61 (2002) (internal citation omitted). For example, the FDCA allows licensed pharmacists and physicians to compound a version of an FDA-approved product to address patient-specific needs, such as creating a liquid version of a medication for a patient who has trouble swallowing solids. *See* 21 U.S.C. § 353a.

Compounding pharmacies and physicians whose drugs meet the conditions of 21 U.S.C. § 353a (hereinafter "503A compounders") are not required, *inter alia*, to follow cGMP. On the other hand, outsourcing facilities (hereinafter "503B compounders") are subject to cGMP, registration, and product reporting requirements. *Id.* § 353b. Regardless of who produces them, compounded drugs are not subject to the safety requirements that apply to FDA-approved drugs because they do not undergo the FDA's premarket review for safety, effectiveness, and quality. Due to this reduced oversight, Congress has generally prohibited compounders from producing products that "are essentially copies of a commercially approved drug." *Id.* §§ 353a(b)(1)(D); 353b(a)(2)(A)(ii). Nonetheless, this prohibition is temporarily lifted when a drug is placed on the "shortage list."

The FDCA defines "shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c. Further, the FDCA requires the FDA to "maintain an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." *Id.* § 356e(a). For every drug the FDA adds to its shortage list under this provision, it is required to identify "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the shortage as determined by the [FDA]." *Id.* § 356e(b)(1)–(4). When a drug is placed on the FDA's shortage list, Congress permits 503A compounders to compound copies of the drug and 503B compounders to compound from that drug's active ingredient—which is otherwise prohibited—including by compounding drugs that are "essentially a copy" of an approved drug. *See Id.* §§ 353b(a)(2)(A)(ii), (a)(5), (d)(2)(A). Because, as discussed above, compounders are subject to less oversight

than drug manufactures, the FDCA permits this type of compounding only while a shortage persists.

B. Factual and Procedural Background

The drugs relevant to this case are Mounjaro® and Zepbound® (collectively the "Lilly Drugs"). The FDA approved the Lilly Drugs pursuant to Intervener Eli Lilly and Company's ("Lilly") marketing applications in 2022 and 2023, respectively. The Lilly Drugs contain a complex molecule called tirzepatide, which targets hormone receptors (called GIP and GLP-1). The FDA approved Mounjaro® for adults with type 2 diabetes mellitus seeking to improve their glycemic control. And the FDA approved Zepbound® for adults with obesity, weight-related medical problems, and moderate to severe obstructive sleep apnea. Given the groundbreaking nature of these drugs, Lilly experienced unprecedented demand, which it was unable to meet. As a result, the FDA placed the Lilly Drugs on its drug shortage list.

The Lilly Drugs remain protected by statutory exclusivity, meaning that the FDA is prohibited by law from accepting an NDA or abbreviated NDA for any tirzepatide product from any company other than Lilly until June 2027. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2), (b)(3). However, as discussed above, this exclusivity is suspended while the drugs remain on the FDA's shortage list. Thus, until the drugs are removed from the shortage list, compounders can legally produce similar products to help satisfy the demand not filled by Lilly.

In an effort to regain its exclusive right to produce and sell tirzepatide products—by having the Lilly Drugs removed from the FDA's shortage list—Lilly spent roughly $23 billion to build, expand, acquire, or obtain internal and external manufacturing facilities in the United States and Europe. Additionally, in August 2024, Lilly obtained supplemental FDA approvals authorizing the sale of the Lilly Drugs in single-use vials—on top of addition to the already approved auto-injector devices—allowing Lilly to more readily supply doses of the drugs. As a result of Lilly's efforts, the FDA updated the shortage list to reflect that "[a]ll doses of Mounjaro® and Zepbound® [were] available." Two

months after that announcement, on October 2, 2024, the FDA announced that the tirzepatide shortage was over and that the Lilly Drugs would be removed from the shortage list.

Five days later, on October 7, 2024, Plaintiffs filed this lawsuit. On October 11, 2024, the FDA filed an unopposed motion to remand and stay the case so that the FDA could "reevaluate the decision at issue in this case." The Court granted the motion, and the FDA reconsidered its decision. On December 19, 2024, the FDA issued a "Delisting Action" reaffirming its decision to remove the Lilly Drugs from the shortage list. The Delisting Action was memorialized in two documents. The first, titled the "Decision," presented the evidence considered by the FDA and its reasoning. The second, titled the "Order," summarized the FDA's rationale and provided that the FDA would exercise its enforcement discretion to delay the enforcement of its decision.

Thereafter, on January 1, 2025, Lilly filed its Motion to Intervene, which the Court granted on January 6, 2025. On January 2, 2025, Plaintiffs and the FDA filed a Joint Motion to Reopen the Case and Enter Scheduling Order. After holding a hearing on January 14, 2024, the Court reopened the case and set a briefing schedule for the present Motion. The Parties, and *Amici Curiae*, have filed their respective briefs and the Motion is ripe for determination.

LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy" and will be granted only if the movants carry their burden on four requirements. *Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). The movants must show: "(1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) the threatened injury to the movant outweighs the threatened harm to the party sought to be enjoined; and (4) granting the injunctive relief will not disserve the public interest." *City of Dall. v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017) (cleaned up). "The decision to grant or deny a preliminary injunction is discretionary with the district court." *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ANALYSIS

The Court begins with Plaintiffs' likelihood of success on the merits for their claims against Defendants. For the reasons stated *infra*, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of their claims, which is the most important (and usually decisive) factor. *See Tesfamichael v. Gonzales*, 411 F.3d 169, 176 (5th Cir. 2005); *Baird v. Bonta*, 81 F.4th 1036, 1041 (9th Cir. 2023). While the Court's analysis could end there, in an abundance of caution, the Court will briefly address the other preliminary injunction elements.

A. Likelihood of Success on the Merits

Plaintiffs' Amended Complaint raises six claims for why the FDA's Delisting Action should be set aside. *See generally* ECF No. 68. Plaintiffs, in their Motion for Preliminary Injunction, do not address their fifth cause of action—unlawful interpretation of the statute under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). *Id.* at 22. Thus, because Plaintiffs did not raise it as a basis for injunctive relief, the Court's analysis focuses on the other five claims, which are addressed in Plaintiffs' Motion.

Those claims are: (1) rulemaking without conducting notice and comment; (2) failure to consider the statutory factors; (3) facially contradictory findings that undermine the basis of the agency action; (4) failure to consider countervailing evidence; and (5) failure to publish a rule in the federal registry. ECF No. 68 at 17–24. Because claims one and five are both predicated on the Delisting Action being a rule, the Court considers them together. Similarly, Plaintiffs' remaining three claims are considered together as they all involve whether the Delisting Action was arbitrary and capricious.

1. Notice-and-Comment and Failure to Publish Claims

For the Court to determine Plaintiffs' likelihood of success on the merits on their notice-and-comment and failure to publish claims, the Court must first determine how to categorize the Delisting Action. The Parties do not dispute that the Delisting Action is a final agency action subject to judicial review under the Administrative Procedures Act

("APA"). However, the Parties do dispute how to classify the FDA's Delisting Action. Plaintiffs assert that the Delisting Action is a substantive rule. ECF No. 64 at 8. On the other hand, Lilly and the FDA (collectively the "FDA Defendants") claim that the Delisting Action is an informal adjudication. ECF Nos. 83 at 16; 90 at 17–18. If the Delisting Action is a substantive rule, as Plaintiffs urge, then then the FDA was required to comply with the APA's stringent notice-and-comment requirements and that process is reviewed under the arbitrary and capricious standard. But if the Delisting Action is an informal adjudication, as the FDA Defendants urge, then the Court simply reviews the decision under the arbitrary and capricious standard.

As best the Court can tell, the question of how to classify the FDA's removal—or addition—of a drug from its shortage list has never been raised or answered. In fact, the regulatory scheme is seemingly silent as to what procedure the FDA must use to make its shortage determinations. Plaintiffs argue that the Delisting Action is a substantive rule under the APA because it "changed the law by establishing a new prohibition." ECF No. 64 at 8. Specifically, Plaintiffs assert that the Delisting Action "creates law by prohibiting all compounding of tirzepatide by Section 503B outsourcing facilities and compounding drugs that are essentially copies of branded tirzepatide products by Section 503A pharmacies" because "there is no difference between" the FDA explicitly declaring "that 'compounding of tirzepatide is prohibited' and removing it from the shortage list." *Id.*

In contrast, the FDA Defendants argue that the Delisting Action is not a substantive rule and was properly issued through adjudication for two reasons. *First*, the FDA simply resolved a factual dispute according to an established statute rather than promulgating a policy-like standard or new interpretation of a statute. *See* ECF No. 83 at 16. And *second*, the FDA has discretion to choose whether to proceed through adjudication or rulemaking because the statutory framework does not explicitly provide what procedure the FDA must use. *See* ECF No. 83 at 16–17.

In reviewing whether an agency action was a rulemaking or an adjudication, courts consider two things. "First, we consider the agency's

characterization of its own action. Second, we must examine the ultimate product of the agency action." *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). The Court will first address whether the FDA had the discretion to proceed through adjudication before turning to whether the Delisting Action is in effect an adjudication or substantive rule.

a. The FDA's discretion

When a statutory scheme is silent as to what procedure an agency must use to act, an agency has discretion to proceed through either rulemaking or adjudication. *McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981) ("[T]he Supreme Court held that the decision to make new law through rulemaking or adjudication 'is one that lies primarily in the informed discretion of the administrative agency.'") (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)). An agency's decision to proceed through rulemaking or adjudication is reviewed under an abuse of discretion standard, and the agency's judgment "is entitled to great weight." *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *see also Neustar, Inc. v. Fed. Commc'ns Comm'n*, 857 F.3d 886, 894 (D.C. Cir. 2017) (internal citations omitted) ("[A]s a general matter, '[i]n interpreting and administering its statutory obligations under [an] Act, [an agency] has very broad discretion to decide whether to proceed by adjudication or rulemaking."). Here, the FDA Defendants argue that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication because: (1) Congress requires the shortage list to be "up-to-date" and rulemaking is incompatible with that mandate; (2) engaging in a meaningful notice-and-comment process was not possible given the confidential materials involved; and (3) Congress permits the FDA to withhold confidential information, including the very existence of a shortage. ECF No. 83 at 17–18.[2] Having reviewed the Parties' arguments and the applicable law, the Court finds that the FDA did not

[2]Because the Court finds that the FDA did not abuse its discretion to proceed through adjudication because of the requirement that the list be up-to-date and the issues presented by the confidential data, the Court declines to address the third argument—that the FDA is allowed to withhold information.

abuse its discretion by choosing to proceed through adjudication because notice-and-comment rulemaking is incompatible with Congress's mandate to keep an up-to-date list.[3]

Congress has tasked the FDA with "maintain[ing] an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." 21 U.S.C. § 356e(a). Merriam-Webster defines "up-to-date" as "extending up to the present time: including the latest information." *Up-to-date*, Merriam-Webster's Collegiate Dictionary (11th ed. 2003). If the FDA had chosen to proceed through rulemaking, as Plaintiffs urge, it would have been required by the APA to provide adequate "opportunity to participate in the rule making through submission of written data, views, or arguments. . . ." 5 U.S.C. § 553(c). Generally, for an agency to give adequate opportunity for notice and comment, the APA "requires . . . a minimum thirty-day comment period." *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 779 (5th Cir. 2023). An agency is then required to review the comments, respond to "significant" comments, and make any appropriate changes before officially promulgating a rule. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Thus, even if the FDA expeditiously participated in notice-and-comment rulemaking, the process would take well over a month. Given the constant fluctuation in national supply and demand numbers for a given drug, a rule based on data that is more than a

[3]Additionally, and in the alternative, the Court finds that the FDA did not abuse its discretion due to the issues presented in achieving meaningful notice and comment while maintaining Lilly's confidentiality. Plaintiffs argue that the Delisting Action is invalid because, *inter alia*, the FDA did not post it in the federal registry for notice and comment before issuing it. However, a simple review of the redacted version of Plaintiffs' Brief in Support of its Motion evidences the difficulty—if not the impossibility—of giving sufficient notice of the data that the FDA relied upon in drafting the proposed "rule," and allowing for meaningful comment on it. *See* ECF No. 66 at 14–19. The redacted data in the above reference section of Plaintiffs' Brief was not even made available to them through the issuance of the Delisting Action. Rather, Plaintiffs were not allowed to see the data until, as a part of this lawsuit, the Court signed and entered an agreed confidentiality agreement. Requiring the FDA to do the same with everyone who wishes to participate in the notice-and-comment process is unattainable and unenforceable.

month old cannot be said to be based on "the latest information" available.

Moreover, the APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez*, 575 U.S. at 101 (internal citation omitted); *Texas v. Biden*, 646 F. Supp. 3d 753, 771 (N.D. Tex. 2022); *Ctr. for Biological Diversity v. Regan*, 691 F. Supp. 3d 1, 8 (D.D.C. 2023). Consequently, if the FDA is required to participate in notice-and-comment rulemaking to remove a drug from its shortage list, then it is required to do the same to add a drug to the shortage list. Requiring the FDA to participate in a lengthy rule-making process to add and remove drugs from the shortage list—based on stale information—cannot be said to be congruent with Congress's mandate for the FDA to maintain an "up-to-date list of drugs . . . in shortage in the United States." 21 U.S.C. § 356e(a)

To emphasize this point, the Court proposes the following scenario. Company A creates a breakthrough drug and is unable to supply enough of the drug to meet an unprecedented national demand. Company A reports its inability to meet demand, as required, and a couple months later the FDA, after going through notice-and-comment rulemaking, places the drug on the shortage list. Company A, understanding the value of its drug, invests tens-of-billions of dollars to ramp up production in order to meet demand. Company A's investment pays off, and it is able to supply enough of the drug to meet the national demand. The FDA, based on the data provided by Company A, engages in notice-and-comment rulemaking, and a couple of months later removes the drug from the shortage list. The day after the rule is final, the demand numbers for the preceding month come in, and due to an unexpected spike, Company A's supply capabilities no longer meet the national demand. Not only did the FDA remove a drug that is in a shortage based on stale information, but it must now once again participate in a lengthy rulemaking process to allow compounders to fill the unmet demand. In contrast, through informal adjudication the FDA can act in a matter of days not months. And while efficiency may not always be the benchmark for agency action, Congress's explicit

command to keep the shortage list up-to-date makes efficiency important here. This example demonstrates why the Court finds that the FDA did not abuse its discretion in choosing to proceed through an informal adjudication rather than notice-and-comment rulemaking.

Based on the foregoing, the Court agrees with the FDA Defendants that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication. However, the label the FDA has attached to the Delisting Action is not dispositive of whether the action should be classified as such. *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017) ("An agency may not escape the requirements of § 553 by labeling its rule an 'adjudication'"). If the FDA properly exercised its discretion to proceed though adjudication, but the Delisting Action is a substantive rule in effect, then the APA requires that it be subject to notice-and-comment rulemaking. Therefore, the Court now turns to whether the Delisting Action is an adjudication or substantive rule in its effect.

b. Substantive rule or informal adjudication in effect

As a preliminary matter, it appears to the Court that this issue is a "lose-lose scenario" for Plaintiffs. As discussed above, the APA requires the FDA to use the same procedure to add a drug to the shortage list that it uses to remove a drug from the list. Thus, if the FDA's removal of the Lilly Drugs from the shortage list required notice and comment, then so did the FDA's addition of the Lilly Drugs to the list. It is undisputed that Plaintiffs are only able to compound their versions of the Lilly Drugs because of the FDA's placement of the Lilly Drugs on the shortage list. Consequently, if Plaintiffs are correct and the FDA's removal of the Lilly Drugs from the shortage list is invalid because it violated the APA's notice-and-comment requirements, then the FDA's listing of the Lilly Drugs without notice and comment is similarly invalid and Plaintiffs should not have been allowed to compound their versions of the drugs. But, if Plaintiffs are wrong, and the Delisting Action is an adjudication, then both the addition and removal of the Lilly Drugs were proper, and Plaintiffs can no longer compound their versions

of the drugs.[4] Nevertheless, the Court turns to the Parties' arguments regarding whether in effect the Delisting Action is a substantive rule or informal adjudication.

Plaintiffs assert that the Delisting Action is a substantive rule because it created law and is "no different in its force and effect than if Congress had enacted a statute prohibiting" the compounding of tirzepatide. ECF No. 65 at 7–11. Additionally, Plaintiffs argue that the Delisting Action cannot be an adjudication because it does not resolve a factual dispute between two parties, but, rather, is generally applicable to an entire industry. *Id.* The Court will begin with the latter before addressing the former.

i. Broad impact argument

Plaintiffs first argue that the Delisting Action cannot be an adjudication because of its broad impact. While "[a]djudications typically 'resolve disputes among specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals,'" "[i]t is true that an agency need not be presented with a specific dispute between two parties in order to" proceed through adjudication "because § 554 does not limit an agency's use of declaratory rulings to terminating controversies between parties." *City of Arlington, Tex.*, 668 F.3d at 242–43. This is the case because "[j]ust as a class action can encompass the claims of a large group of plaintiffs without thereby becoming a legislative proceeding, an adjudication can affect a large group of individuals without becoming a rulemaking." *Goodman v. F.C.C.*, 182 F.3d 987, 994 (D.C. Cir. 1999) (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 292 (1974) (explaining that an agency may "promulgate a new standard that would govern future conduct" of non-parties in an adjudication)); *see also Neustar, Inc.*, 857 F.3d at 894 ("The fact that an order rendered in an adjudication 'may affect agency policy and have general prospective application,' does not make it rulemaking

[4]Plaintiffs argue that the FDA adding a drug to the shortage list is less legally consequential than removing a drug from the list. The Court finds the opposite to be true. An agency action that suspends statutory exclusivity and allows for a statutorily prohibited action to be temporarily performed is a greater "change" in law than restoring the statutory norms.

subject to APA section 553 notice and comment."); *Nat'l Biodiesel Bd. v. Env't Prot. Agency*, 843 F.3d 1010, 1018 (D.C. Cir. 2016) (internal citation omitted) ("[T]he fact that an agency action applies to a 'large number of [parties]' 'carr[ies] [little] weight' in [the Court's] analysis.").

As pointed out by the FDA Defendants, the FDA routinely conducts adjudications that affect large numbers of third parties: the new drug approval process. *See* 21 U.S.C. §§ 355(d)–(g). The FDA's approval of an NDA triggers numerous effects on potential competitors, such as: (1) prohibiting the FDA from approving a competitor's NDA for any drug containing the same active moiety; and (2) triggering statutory restrictions on compounding drugs that are essentially copies of the approved drug. *Id.* §§ 353b(a)(5), (d)(2)(A); *id.* § 355(c)(3)(E)(ii).[5] The Supreme Court has endorsed the FDA's use of informal adjudications to approve NDAs and remove unsafe drugs from the market, despite those adjudications triggering broad sweeping effects on "several persons or manufacturers." *See, e.g., Weinberger v. Hynson, Westcott & Dunning Inc.*, 412 U.S. 609, 624–26 (1973). Consequently, the Court is unpersuaded by Plaintiffs' broad impact argument.

ii. Creates new law argument

Turning now to Plaintiffs' argument that the Delisting Action is a substantive rule in effect because it creates law, Plaintiffs rely on a series of cases in which an agency listing action was considered a rule.

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[5]In their Reply, Plaintiffs attempt to distinguish the FDA's approval of an NDA from an FDA's shortage determination by arguing that an NDA application involves a specific party while a shortage determination does not. *See* ECF No. 98 at 3–4. The Court is unpersuaded by this argument. To approve an NDA, the FDA reviews data submitted by a company and determines whether it satisfies a set of requirements. If the FDA approves an NDA, it triggers statutory exclusivity for the submitting company as well as a statutory prohibition against compounding the drug. Similarly, to make a shortage determination, addition or removal, the FDA reviews data submitted by a company to determine whether supply is greater than demand over a period of time. If, for example, the FDA finds that a shortage no longer exists, it reinstates the same statutory exclusivity and prohibitions that the FDA's approval of that drug's NDA put into place. And those statutory provisions apply to the same company and compounders that were affected by the NDA adjudication. Thus, Plaintiffs argument that one affects specific parties and the other does not, is unpersuasive.

ECF No. 65 at 8–10. Of the cases cited by Plaintiffs, they rely most heavily on *Safari Club*. 878 F.3d 316. Because that case is demonstrative and dispositive of Plaintiffs' other cited authorities, the Court will focus its analysis on *Safari Club*.

The "basic distinction between" an adjudication and rulemaking is that adjudications are "proceedings designed to adjudicate disputed facts in particular cases," whereas rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *See United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 244–45 (1973); *see also* 5 U.S.C. §§ 551(4) (defining "rule"), 551(6) ("order"), 551(7) ("adjudication"). The "line between" adjudication and rulemaking "is frequently a thin one. . . ." *Gen. Am. Transp. Corp. v. Interstate Com. Comm'n*, 883 F.2d 1029, 1030 n.2 (D.C. Cir. 1989). While it can be difficult to decipher where courts draw the thin line between adjudication and rulemaking, courts generally find that an agency action is an adjudication when it involves "concrete and narrow questions of law the resolutions of which would have an immediate and determinable impact on specific factual scenarios." *City of Arlington, Tex.*, 668 F.3d at 243. Rulemaking, on the other hand, is identifiable when the application of the action "will only become clear after adjudication of the dispute in a court of competent jurisdiction." *Id.*

This distinction can be seen in *Safari Club*. In *Safari Club*, the United States Fish and Wildlife Service (hereinafter the "Service") issued findings providing that it lacked sufficient information to make a positive finding that the sport-hunting of elephants would enhance the survival of the species. 878 F.3d at 323. The Service's findings also "temporarily banned imports of sport-hunted trophies of elephants." *Id.* The plaintiffs filed a lawsuit challenging the findings and argued, *inter alia*, that the findings were substantive rules despite the Service's insistence that they were adjudications. *Id.* at 331–34. The United States Court of Appeals for the District of Columbia agreed and held that the Service's findings could not be adjudications because, unlike the denial of "an application for an import permit," they had "no immediate legal consequences for any specific parties." *Id.* at 334–35. Rather, the D.C. Circuit held that the findings were substantive rules because they

"established a standard binding on the agency . . . to be applied to future requests" and were "only meant to bind hunters in future permitting adjudications and enforcement actions." *Id.* at 334.

Applying the principle that "adjudications immediately bind parties" while rules have "only future effect" to this case, the Court finds that the Delisting Action is an adjudication for two reasons. *First*, the Delisting Action undoubtably has immediate legal consequences for specific parties. The immediate consequences of the Lilly Drugs being removed from the shortage list are, *inter alia*, that Lilly regains its statutory exclusivity over tirzepatide products, and that 503A and 503B Compounders, like Plaintiffs, must cease production of their versions of the drugs. Plaintiffs seemingly concede the immediate effect the Delisting Action has on them as they argue that the removal of the Lilly Drugs from the shortage list will force their tirzepatide products "off the market," causing them irreparable harm. ECF No. 65 at 2, 23. In contrast, the Service's findings in *Safari Club*, did not cancel any prior but unfulfilled importation approvals, they only served to govern the Service's consideration of future applications. *See Safari Club*, 878 F.3d at 333 ("[T]he Service's ban on imports was only meant to bind hunters in future permitting adjudications and enforcement actions . . . ."). Thus, unlike *Safari Club*, where the findings had no immediate impact on a specific party, the Delisting Action triggered statutory provisions, immediately restoring Lilly's exclusivity and requiring compounders to stop compounding tirzepatide.

And *second*, the Delisting Action does not promulgate a new policy-type rule or standard that will govern the FDA's future actions. Instead, it made a specific factual determination based on the statutory definition of shortage. The Delisting Action did not change or interpret the statutory definition of shortage. It simply fulfilled the FDA's mandate to determine whether tirzepatide products are in shortage. Put another way, unlike *Safari Club*, where the Service's findings "implement[ed] and interpret[ed] [a rule's] enhancement requirement" to make a policy like judgment about what level of protection elephants needed to be afforded to enhance their chance of survival; the FDA's Delisting Action simply looked at the evidence presented and made a

factual determination on whether one number was bigger than another. 878 F.3d at 334 (internal quotations omitted). While it is true that the FDA's numerical determination had the immediate effect of prohibiting Plaintiffs from continuing to compound tirzepatide products, that prohibition did not come by way of a new agency interpretation, but rather by operation of an existing statute.

This distinction is further evidenced by the difference in the prospective effect of the respective agency actions. In *Safari Club*, the Service's findings determined that a ban on the future importation of elephant parts was appropriate until further notice to protect the species. This new standard served as a guide for the Service's consideration of future importation applications. In contrast, rather than creating a standard by which the FDA will consider future compounding applications,[6] the Delisting Action immediately reinstated, as discussed above, statutory protections and prohibitions. In fact, the Delisting Action provides no guidance for any future shortage determination the FDA must make, as every shortage determination—even potentially one involving tirzepatide—must be made on a case-by-case basis. Such case-by-case factual determinations have been found by courts to be adjudications. *See, e.g., Vanda Pharms., Inc. v. FDA*, 436 F. Supp. 3d 256, 270 n.4 (D.D.C. 2020) (rejecting the argument that the FDA's analysis of scientific literature in an adjudication applied to future cases such that it was a legislative rule, and noting that, unlike in *Safari Club*, the agency's analysis was "in the context of 'adjudicating a particular set of disputed facts'").

The FDA's Delisting Action made a factual determination about whether from [redacted] to [redacted], and projecting forward through [redacted], the supply of the Lilly Drugs was equal to or greater than the demand. It did not make a policy-like determination. Therefore, the Court finds that the Delisting Action was an informal adjudication—not a rule. And as a result, the FDA was not required to submit the Delisting Action to notice and comment or publish it in the

[6]In fact, the statutory exclusivity that Lilly immediately regained upon the issuance of the Delisting Action explicitly prohibits the FDA from even considering an application. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

Federal Registry. Accordingly, Plaintiffs are unlikely to succeed on their notice-and-comment and failure to publish claims.

2. Arbitrary and Capricious Claims

The Court now turns to whether Plaintiffs demonstrate a likelihood of success on the merits because the FDA's actions were arbitrary and capricious. Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 120 F.4th 494, 504 (5th Cir. 2024) (citing *Medina Cnty. Env't Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). "If the agency articulates a rational relationship between the facts found and the choice made it does not act arbitrarily or capriciously." *Joseph v. Dir. of Texas Serv. Ctr., U.S. Citizenship & Immigr. Servs.*, No. 24-40249, 2025 WL 458001, at *3 (5th Cir. Feb. 11, 2025) (internal quotation and citation omitted). The "focal point" of that review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And "[j]udicial review under that standard is deferential, a[s] a court may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While courts "may not supply a reasoned basis for the agency's action that the agency itself has not given," courts are to "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Tex. Med. Ass'n,* 120 F.4th at 504 (citing *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (quotations omitted)).

Here, Plaintiffs assert that the Delisting Action is arbitrary and capricious because: (1) it does not sufficiently identify or analyze the key parameters of the shortage determination; (2) it is facially incoherent and inconsistent; and (3) it improperly ignored countervailing evidence. *See* ECF No. 68 at 19–22; *see also* ECF No. 65 at 13–23. The Court will address each in turn.

a. Identification of key parameters[7]

Plaintiffs first argue that the Delisting Action is arbitrary and capricious because it fails to identify what time period the FDA looked at to make its shortage determination. ECF No. 68 at 19–20; ECF No. 65 at 14–19. Plaintiffs assert that the Delisting Action's failure to state a specific time frame is fatal because it is inconsistent with the statutory language and it "blinded [the] FDA to Lilly's inconsistent temporal presentations that concealed shortages." ECF No. 65 at 14. The Court need not spill much ink on this argument as it plainly fails.

Even assuming without deciding that the FDA was required to explicitly provide what period of time on which it based its shortage determination, the FDA satisfied that burden. On multiple occasions, the Delisting Action clarifies that it considered the previously produced supply and demand numbers for [redacted] to [redacted], as well as the recently released [redacted] numbers and the projected numbers through [redacted]. *See* ECF No. 65-1 at 1, 7, 8, 9, 10, 14, 15. This time period was seemingly evident to Plaintiffs as, in the same section of their brief, they take issue with the specific period of time used and argue that the Delisting Action is arbitrary because it failed to consider evidence from outside that time period. ECF No. 65 at 15–16 (asserting that the FDA erred because it did not consider past deficits or surplusages in its analysis as it started [redacted]" and looked at the numbers through [redacted]). Thus, in one breath, Plaintiffs assert that the FDA failed to identify a specific time frame and in another that the FDA's time frame was erroneous. While the Delisting Action occasionally references narrower time frames, the decision as a whole focuses on a set of data and projected data from a specific time frame—[redacted] to [redacted].

Thus, the Court finds that the FDA sufficiently identified what time period it considered in making the shortage determination. Further, the Court finds that because it is tasked to determine whether a shortage

[7]The Court does its best to separate out Plaintiffs' first two arbitrary and capricious claims as they intermingle them in their brief. *See* ECF No. 65 at 14–19.

exists over a specific period of time, the FDA did not err in failing to consider evidence from outside that time frame. Therefore, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of this claim.

b. Facially incoherent and inconsistent

Before turning its attention to Plaintiffs arguments for why the Delisting Action is facially incoherent and inconsistent, the Court finds it prudent to begin by briefly summarizing the FDA's decision.

i. Summary of the Delisting Action

The Delisting Action concluded that the tirzepatide shortage was over because the data demonstrated "that Lilly's supply is currently meeting or exceeding demand for these drug products, and that Lilly has developed reserves that it now holds in its finished product inventory, plus significant units of semi-finished product." ECF No. 65-1 at 1. Additionally, the FDA noted that Lilly received approval to produce doses in vials, and that it has scheduled substantial additional production over the coming months. *Id.* [redacted]

In making its determination, the FDA reviewed:

> [D]etailed information and data regarding its production and inventory of these drug products at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of these drug products; cumulative quantities supplied to and demanded by its customers in the year 2024; projected demand and supply in future months; and wholesaler inventory data, among other information.

Id.[8]

The data reviewed by the FDA is best summarized by two tables contained within the Delisting Action, as shown below:

[8]"[A]mong other information" includes numerous information submitted by Plaintiffs and others to demonstrate the existence of a shortage. Because that is the basis for Plaintiffs' third arbitrary and capricious claim, the Court does not discuss that information in this section.

Table 4. Lilly-reported cumulative demand and cumulative supply of tirzepatide single-dose pens for [redacted] (thousands of doses)[31]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Table 6. Lilly-reported projected cumulative demand and cumulative supply of tirzepatide single-dose pens [redacted] (thousands of doses)[58]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Id. at 10, 15.

These tables summarize Lilly's reported and projected supply and demand numbers beginning in [redacted] and concluding in [redacted]. The tables are constructed in a cumulative fashion with each month building on the previous month(s). This means that each month's column shows the total supply and demand numbers from [redacted] to the specified month. As a consequence, the numbers for [redacted] appear astronomically larger than those for [redacted].

The FDA determined that the shortage had concluded based on the fact that: (1) from [redacted] to [redacted], Lilly's total supply

([redacted]) outpaced total demand ([redacted]); (2) at least through [redacted], the shortage would not return based on the projections that Lilly's total supply ([redacted]) would continue to outpace total demand [redacted]; and (3) the information provided by wholesalers "further indicate[d] that nationwide supply for [Lilly's] products is exceeding demand." ECF No. 65-1 at 10–15. Furthermore, the FDA noted that its determination was bolstered by: (1) the months-long production of data by Lilly to the FDA; (2) Lilly's supply of over [redacted] units of semi-finished syringe products (products that have already completed sterile manufacturing and are awaiting labeling and packaging); (3) the recent approval of Lilly's vial versions of the drugs, which allows Lilly to supply more product than currently projected; and (4) Lilly's investment into additional production facilities that will soon be in operation. *Id.* After reviewing the other evidence provided by Plaintiffs, and others, the FDA determined that the nationwide shortage had ended and reaffirmed its decision to remove the Lilly Drugs from the shortage list. *Id.* at 16–23.

ii. Plaintiffs' arguments

Plaintiffs seemingly insist that the Delisting Action needed to be perfect. It did not. Rather, it needed only to "articulate[] a rational relationship between the facts found and the choice made." *Joseph*, 2025 WL 458001, at *3. Thus, the Court need not confuse the trees for the leaves. The question before the FDA was, for "a period of time" did "the demand or projected demand for the [Lilly] drug[s] within the United States exceed the supply of the [Lilly] drug[s]." 21 U.S.C. § 356c(h)(2). The FDA answered that question in the negative and therefore found that the shortage had ended. Consequently, the question before the Court is whether the FDA's decision, that supply of the Lilly drugs outpaced demand for a period of time, was reasonable in light of the evidence before it. For the reasons set out *infra*, the Court answers that question in the affirmative.

The crux of Plaintiffs' argument that the Delisting Action is incoherent and inconsistent is that "Lilly's use of cumulative figures misled or at least confused [the] FDA." ECF No. 65 at 15. Plaintiffs claim that this confusion obfuscated the fact that the shortage still persists

and created an unreasonable reliance on Lilly's statements. *Id.* at 15–19. Specifically, Plaintiffs argue that the Delisting Action is facially incoherent and inconsistent because: (1) the FDA looked at the total supply and demand data for the relevant period rather than at "monthly snapshots;" (2) the FDA [redacted], but then did not [redacted]; (3) the "FDA made no finding of demand under any consistently defined time period" as "[o]nly cumulative tables report demand, and each month has a different baseline;" and (4) the Delisting Action "turns on" Lilly's unsupported statement that it can supply over [redacted] a month. *Id.*

Plaintiffs' first argument, that the Delisting Action should not have considered cumulative data, fails. It is axiomatic that to consider something for a period of time requires considering it for the entire period of time. Yet, Plaintiffs argue that the FDA's decision is without reason because there were data points from shorter periods of time, within the overall time frame, that could lead to a different result. The real and "detailed data" considered by the FDA shows that for the period of [redacted] to [redacted], Lilly supplied some [redacted] more than were demanded ([redacted] supplied - [redacted] demanded). The FDA, relying on projected data,[9] found that for the period of [redacted] to [redacted], Lilly would be capable of supplying at least [redacted] more than would be demanded [redacted] supplied - [redacted] demanded).

Plaintiffs insist that the FDA should have considered the data on a month-to-month basis, rather than through cumulative numbers, and point out that there was more demand than supply produced for individual months. However, this argument ignores the fact that even if

[9]There is no evidence to show that the FDA's reliance on the projections was unreasonable as they provided that Lilly's [redacted] " ECF No. 65-1 at 14. Further, [redacted]

the charts were based on each individual month's numbers, the FDA would have had to add them together to get the total numbers for the relevant period of time. Thus, the result would have been the same as surplus carries over[10] and every month ([redacted]) ended with a net total surplus. *See* ECF No. 65-1 at 10, 15. Consequently, Plaintiffs are unlikely to succeed on the basis that the FDA fatally erred by considering cumulative numbers.

Plaintiffs next argue that the Delisting Action is arbitrary because the FDA [redacted]. In addition, Plaintiffs argue that the FDA erred by [redacted]. Plaintiffs claim that the FDA had no reason to [redacted], because doing so ignores the fact that surpluses/shortages carry over. While true, it ignores the fact that a period of time requires a starting and ending point. Thus, it was not unreasonable for the FDA to [redacted], as it was the beginning of the relevant time period.[11] Additionally, for the same reason Plaintiffs' cumulative numbers argument fails so does their assertion that the FDA should have [redacted]. In evaluating data for a period of time, one looks at the whole not just part. Therefore, Plaintiffs are unlikely to succeed on the basis that the FDA arbitrarily started [redacted], and [redacted].

Plaintiffs third argument, that the FDA "made no finding of demand under any consistently defined time period" fails for the same reasons. The FDA considered total demand for the relevant time period based on actual and projected data. The argument that the cumulative demand numbers were based on different lengths of time ignores the fact that the supply numbers were based on the same lengths of time. Additionally, just as above, even if they were broken down by month, the FDA would have still been required to total the months up to

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[10]Each dose can be stored for up to 24 months. ECF No. 90 at 12.

[11]Plaintiffs do not, and cannot, argue that the FDA was required to look at numbers all the way back to the approval of the Lilly drugs. As Plaintiffs do argue, the FDA was required to choose a time period for its analysis. The FDA did and it looked at the actual and projected numbers for that time frame. The statute does not require more of the FDA and neither does this Court.

evaluate if the total demand outpaced total supply for the time period being considered. Thus, Plaintiffs are unlikely to prevail on their demand calculation argument.

Finally, Plaintiffs assert that the Delisting Action is arbitrary because it "turns on" Lilly's unsupported representation that it can now supply over [redacted] a month. This argument also fails. Even assuming without deciding that Lilly's [redacted] a month estimate is unsupportable, Plaintiffs cannot show that the FDA's determination has no reasonable relationship to the facts presented for two reasons. *First*, Plaintiffs statement is a mischaracterization, as the FDA considered significantly more information than Lilly's explicit [redacted] estimate. *See* ECF No. 35-1 at 1. And *second*, even if the monthly estimate is unsupportable by the data, that does not negate the fact that the actual numbers show that total supply outpaced demand for the relevant period. *Id.* at 10, 15. Thus, even if the FDA was never presented with Lilly's estimate, the actual supply and demand numbers provide the FDA with a reasonable basis for determining that the Lilly Drugs are no longer in shortage. Accordingly, because the FDA was not required to be perfect, Plaintiffs are unlikely to succeed on their claim that the Delisting Action is incoherent and inconsistent.

c. Countervailing evidence

Finally, Plaintiffs assert that the Delisting Action "arbitrarily waved away all evidence of shortage." ECF No. 65 at 19–23. Specifically, Plaintiffs claim that the FDA reviewed all of the evidence provided by them, and others, with "hyper-skepticism."[12] *Id.* Plaintiffs, and others, provided four categories of evidence to the FDA: (1) screenshots of pharmacy wholesalers websites; (2) patient reports; (3) news reports; and (4) compounding numbers. *Id.* Plaintiffs argue that all of this evidence shows that the FDA unreasonably relied on Lilly's assertions and should not have been waved away. *Id.* The Court will address each

[12]As a preliminary matter, the Court notes that the FDA also scrutinized and rejected some of Lilly's evidence based on the same standards it applied to the countervailing evidence. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53. If nothing else, this shows that the FDA did not blindly rely on Lilly's assertions and evidence.

set of evidence to determine if the FDA's finding that it did not outweigh or undermine the evidence provided by Lilly was reasonable in light of the facts before it.

First, Plaintiffs point to the screenshots of wholesalers' webpages showing that on certain days some tirzepatide products were unavailable. *Id.* at 19–20. The FDA reviewed the screenshots and found that the evidence did not "undermine[] or outweigh[] the information provided by Lilly . . . with respect to availability of product to wholesalers and retailers" because: (1) Lilly provided data from the wholesalers showing that Lilly is meeting or exceeding wholesaler demand for the Lilly Drugs; (2) of supply chain dynamics; (3) most of the screenshots were undated; (4) Lilly [redacted] and (5) some localized and temporary supply issues do not demonstrate a national shortage. ECF No. 65-1 at 19–21.

Plaintiffs take issue with all of the FDA's explanations, but most notably argue that "[d]elay in shipping of the drug" is a statutory indicator of a shortage. ECF No. 65 at 20 (citing 21 U.S.C. § 356e(b)(3)(F)). While a significant delay in shipping could affect supply on a national level, it was reasonable for the FDA to conclude that a "[redacted]" delay for a specific dose of tirzepatide on a specific retailer's website does not rise to the level of a national shortage. Similarly, the Court finds that the FDA's review and explanation of the data related to screenshots of wholesalers' websites was not unreasonable in light of the additional data provided and supply chain dynamics.

Second, Plaintiffs claim that the FDA unreasonably found that Lilly's evidence was not outweighed by the "tens of thousands" of "reports of patients" not being able to obtain tirzepatide. ECF No. 65 at 20. Plaintiffs, and others, submitted website "survey data" where people responded in the affirmative to a question asking if they have had "an inability to access name brand GLP-1s." *Id.* at 20; ECF No 65-1 at 17. The FDA reviewed the submissions and found that they did not undermine Lilly's evidence that the shortage was over because: (1) there is no way to verify how many individuals actually filled out the reports,

when they filled out the reports, or when their inability to obtain the drugs occurred; (2) the prompt does not define "inability to access" so some may be reporting that a pharmacy was out of stock and others that their doctor did not prescribe them the medication; (3) of business decisions made by pharmacies as well as their limited storage capacities; and (4) some localized and temporary supply issues do not demonstrate a national shortage. ECF No 65-1 at 16–19. Given the issues with the evidence as articulated by the FDA, the Court finds that the FDA did not unreasonably determine that Lilly's evidence is not outweighed by the patient survey reports.[13]

Third, Plaintiffs assert that the FDA "ignored" news coverage of the shortage situation. ECF No. 65 at 21. With regard to this evidence, the FDA stated:

> FDA reviewed various articles and blog posts submitted by various groups, as well as other news coverage. While these pieces discussed various aspects of the shortage situation, FDA did not find them to contain probative evidence relevant to the analysis FDA must conduct to determine whether a shortage has resolved. While some of these sources contained personal accounts of inability to get a particular product at a particular time, like the evidence discussed in sections II.B.1.i and ii above, those individual accounts do not undermine or outweigh the more specific, reliable, comprehensive, and current information that has been provided by Lilly demonstrating its ability to supply enough product to meet demand.

ECF No. 65-1 at 21.

The Court finds that it was not unreasonable for the FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly, than news reports and blog posts from sources who may have had ulterior motives and lacked the same detailed data presented to the FDA. Consequently, the Court finds that the FDA did not arbitrarily wave away the news coverage of the shortage situation.

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[13]As previously noted, the FDA found some of Lilly's evidence to be unpersuasive [redacted]. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53.

Fourth, and finally, Plaintiffs argue that the "FDA erred" by "disregarding the '[] sales volume of compounded tirzepatide' as evidence of demand." ECF No. 65 at 21–23. Specifically, Plaintiffs claim that FDA "erroneously deemed compounded products irrelevant," "disregard[ed] demand for compounded products because they beat Lilly's on price," failed to take into account the correct volume of compounding, and incorrectly assumed that some patients were using compounded tirzepatide for off-label uses. *Id.*

Plaintiffs' first point, that the FDA deemed compounded products irrelevant, fails. The FDA stated that the number of compounded products has "minimal relevance" on the current demand of the Lilly Drugs, but that it is relevant to projected demand—after the compounded drugs are removed from the market. ECF No. 65-1 at 22–23. On that basis, the FDA considered whether Lilly would be able to fill the demand hole that would be left after the compounded drugs were removed. *Id.* at 23–28. After a lengthy discussion, the FDA found that based on the projections Lilly would be able to meet the projected demand. *Id.*

Plaintiffs' second and fourth arguments similarly fail. In essence, Plaintiffs take issue with the FDA's statements that demand for compounded drugs does not translate one-for-one to demand for the Lilly Drugs because of price considerations and patients' current off-label use. ECF No. 65 at 21–23. Lilly did not zero out the projections of demand based on these principles, it simply found these were factors to consider in projecting the demand of the Lilly Drugs. ECF No. 65-1 at 26–27. It is not unreasonable to consider missuses or price differences in attempting to calculate a projected national demand.

Finally, Plaintiffs assert that the FDA improperly evaluated how much compounding was occurring. ECF No. 65 at 22. Plaintiffs claim that the FDA erred in considering only the "first six months of 2024" while considering [redacted] for Lilly's data. But the data from the first six months of 2024, was "the most recent complete reporting period" that was available to them. ECF No. 65-1 at 24–25. Plaintiffs also assert that the FDA overcalculated how much Plaintiffs were producing. ECF No. 65 at 22. Even if true, this does not show error as the FDA conducted its

analysis based on inflated compounding numbers, which would only have helped Plaintiffs' position on the shortage. Lastly, Plaintiffs argue that the FDA should have investigated more based on the evidence provided that thirty-seven pharmacies produced roughly 500,000 doses per month. ECF No. 65 at 22. The FDA considered this evidence and found that "[e]ven assuming that all of these doses have been supplied to the market and, upon the curtailing of compounding, would translate to demand for Lilly's products, this would represent a very small amount relative to Lilly's production and inventory." ECF No. 65-1 at 24. Furthermore, the FDA had no obligation "to conduct or commission [its] own empirical or statistical studies." *Prometheus Radio Project*, 592 U.S. at 427. Accordingly, the Court finds that the FDA's treatment of the evidence submitted by Plaintiffs, and others, was reasonable based on the evidence it had before it. *Id.* Thus, Plaintiffs are not likely to succeed on this claim.

B. Irreparable Injury

Parties frequently confuse the magnitude of a harm with the irreparability of a harm. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 18–20 (2008); *Rest. Law Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023) (citing *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) ("In determining whether costs are irreparable, the key inquiry is 'not so much the magnitude but the irreparability.'")). Yet even enormous harms can be compensable by money damages, thus failing to justify injunctive relief. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("The key word in this consideration is irreparable. Mere injuries, however substantial . . . are not enough. The possibility that adequate compensatory or other relief will be available at a later date . . . weighs heavily against a claim of irreparable harm.") (internal quotations omitted). That's off the table here, as Plaintiffs sue the federal government and cannot recover monetary compensation. *See Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1136 (5th Cir. 2021). And "complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (internal citation omitted); *see generally Rest. Law Ctr.*, 66 F.4th at 433. Here, without a

preliminary injunction, Plaintiffs will suffer unrecoverable financial losses, which constitutes irreparable harm.[14] *White Lion Invs., LLC*, 16 F.4th at 1136.

C. Public and Private Interests

Finally, Plaintiffs must show that, if the injunction is denied, the threatened injury outweighs any harm that will result if the injunction is granted, and that the granting of an injunction will not disserve the public interest. *See Mock v. Garland*, 75 F.4th 563, 577 (2023). These factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). On one hand, if the Department is enjoined, it "suffers the irreparable harm of denying the public interest in enforcement of its laws." *Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017). On the other, "it is always in the public interest" to stop enforcement of unconstitutional or invalid laws. *See Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 n.9 (5th Cir. 2014) (internal citations omitted). The Parties' arguments for both interests are the same.

Plaintiffs argue that if the Court denies an injunction, patients will be deprived of their medications. ECF No. 65 at 24. In contrast, the FDA Defendants claim that if the Court grants an injunction, patients will continue to be subject to dangerous compounded versions. ECF Nos. 83 at 24; 90 at 22–25. Congress considered both of these interests in crafting the relevant regulatory scheme. As discussed above, compounding is generally prohibited due to the reduced oversight and the potential harms associated with the practice. However, Congress chose to allow for compounding when a drug is on the FDA's shortage list so that patients can receive their medications. If Congress thought it prudent to account for both of the asserted public interests at issue here, it is not for this Court to make a policy determination on which is

[14]Lilly argues that Plaintiffs are compounding in violation of the relevant statutes. However, the FDA does not contest this element. The Court agrees with Plaintiffs that this argument has no place in this case and must be decided, if at all, in a different lawsuit. Thus, for the purposes of this Motion, the Court does not consider that argument.

greater.[15] Thus, the Court finds that the public and private interests at issue in this case are a wash and do not weig in favor of or against the granting of an injunction.

CONCLUSION

For the reasons set out above, Plaintiffs' Motion for Preliminary Injunction and Stay is **DENIED.**

Given the agreed confidentiality agreement that was entered into by the Parties, and enforced by the Court, the undersigned finds it appropriate to file this unredacted opinion under seal. Shortly after the opinion is filed, the Parties will be provided, via email, an unsigned PDF version of the order. It is **ORDERED** that, **on or before 4:00 p.m., March 7, 2025**, the Parties shall submit, via response to the email, an agreed upon version of the order containing any appropriate redactions. After receiving and reviewing the Parties' version, the Court will issue the redacted order.

SO ORDERED on this **5th day of March 2025.**

Mark T. Pittman

MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE

[15]The Court agrees with John Adams's sentiment that the judiciary should avoid exercising the powers of the legislative and executive branches, so that this Nation may remain "a government of laws and not men." Mass. Const. art. 30; *John Adams, Architect of American Government*, https://www.mass.gov/guides/john-adams-architect-of-american-government.

SUMMARY AND CONSIDERATION:

A Reviewing Board Member (RBM) opined Dr. Bania violated AS 08.64.326(a)(7) and (9) as well as 12 AAC 40.967(14). The RBM reviewed the case and the application for reinstatement, noting Dr. Bania is not competent to resume practice in Alaska and recommended his license not be reinstated. The RBM opined Dr. Bania did not take accountability for his actions, show remorse, complete medical education or therapy related to the violations. The RBM also opined Dr. Bania provided no evidence he has changed. The RBM opined Dr. Bania is a threat to public safety and should not be reinstated.

This Reinstatement Denial is being presented to the Board for consideration.

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Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

April 1, 2025

Natalie Norberg
Executive Administrator
Alaska State Medical Board
333 Willoughby Ave., 9th FL
Juneau, Alaska 99801

Re: Mounjaro® and Zepbound® and Continued Patient Safety Concerns

Dear Ms. Norberg,

I write on behalf of Eli Lilly and Company ("Lilly") to alert the Alaska State Medical Board (the "Board") regarding a recent development related to tirzepatide, the active ingredient in Lilly's Mounjaro® and Zepbound® medicines. As you may be aware, tirzepatide was removed from the Food and Drug Administration's ("FDA") drug shortage list last year. A Texas federal court denied an attempt to block FDA's decision, holding that "Lilly regains its statutory exclusivity over tirzepatide products" and all other sellers "must cease production of their versions of the drugs." See Attachment. Then, on March 10, 2025, FDA announced that it would immediately begin enforcing the essentially-a-copy prohibition in section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA").[1]

Nevertheless, it appears that some telehealth providers and associated physicians have continued to mass prescribe and mass produce unapproved, untested compounded tirzepatide, putting patients across Alaska at risk. We are writing to alert you to these patient safety concerns and request your help in protecting the public from the dangers of large-scale marketing and sale of copies Lilly's FDA-approved medicines.

Lilly's FDA-Approved Medicines

Lilly's Mounjaro® and Zepbound® medicines are FDA approved to treat serious medical conditions. Mounjaro® is indicated in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Zepbound® is indicated, in addition to diet and exercise, for adults with obesity or those who are overweight and also have at least one weight-related additional condition, such as hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease, to lose weight.

The active pharmaceutical ingredient ("API") in both Mounjaro® and Zepbound® is called tirzepatide. Lilly is the only lawful supplier of FDA-approved tirzepatide and does not provide tirzepatide API to compounding pharmacies, other manufacturers, or anyone else. Because these

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1 FDA, "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize," (March 10, 2025), https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

medicines are sterile injectables, Lilly manufactures Mounjaro® and Zepbound® under strict controls. Lilly only sells Mounjaro® and Zepbound® through authorized channels, such as licensed pharmacies authorized by the state to dispense FDA-approved medicines prescribed by a healthcare provider. And we own the intellectual property rights related to Mounjaro® and Zepbound®.

Mounjaro® and Zepbound® should only be used when prescribed by a licensed healthcare professional. Lilly does not promote or encourage use of Mounjaro®, Zepbound®, or any other Lilly medicine outside of the medicine's FDA-approved indication.

Unlawful Sale and Prescription of Tirzepatide Knockoffs Risks Harming Patients

Numerous entities are currently marketing and selling illegal copycat versions of Lilly's tirzepatide. These illegal sellers are purporting to offer "compounded" drugs. Drug compounding is a practice where a pharmacist combines, mixes, or alters ingredients to create a drug tailored to the unique needs of an individual patient. Compounding is permitted only in very limited circumstances, such as when an FDA-approved drug is not commercially available or where a particular patient's "medical needs cannot be met by commercially available drug products."[2]

Entities previously claimed they were permitted to compound tirzepatide because FDA deemed Lilly's FDA-approved medicines in "shortage" for a period of time. But Mounjaro® and Zepbound® have now been out of shortage for months. In October 2024, FDA announced that the shortage of tirzepatide injection had been resolved. On December 19, 2024, FDA re-confirmed that decision, concluding that Lilly's supply of its medicines Mounjaro® and Zepbound® were sufficient to meet demand. And, as noted, a Texas federal court recently denied an attempt to block FDA's decision, upholding Lilly's "statutory exclusivity over tirzepatide products" and making clear that compounders must "cease production of their versions of the drugs." See Attachment. And FDA subsequently announced that immediately begin enforcing the essentially-a-copy prohibitions in the FDCA.[3]

FDA has repeatedly cautioned that these compounded products are "risky for patients."[4] That's because compounded drugs do not have to meet the same stringent safety regulations that FDA-approved medications do. Compounded tirzepatide is not studied in clinical trials, and is never FDA-approved, which means that FDA does not review the product to evaluate it for the safety, efficacy, or quality American patients expect and deserve. Compounding pharmacies do not have to register or list their products with FDA, are not required to meet FDA's "Good Manufacturing Practices," and do not have to report adverse events. While some falsely equate compounded products with

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2 21 U.S.C. § 353a(b)(1)(D).

3 https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

4 https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

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Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

generic medicines, generics are FDA-approved and must be manufactured according to the same rigorous standards as branded medicines like Mounjaro® and Zepbound®—compounded drugs are neither.

As reported in JAMA Health Forum, most websites selling compounded GLP-1 drugs exclude important safety information and many mislead consumers about the safety and efficacy of their products.[5] The Obesity Action Coalition explained, "using a compounded medication is like playing a guessing game with your health. You don't know what you're getting, and if something goes wrong, it's hard to know why."[6] The American Diabetes Association recommended that patients avoid compounded products "due to uncertainty about their content, safety, quality, and effectiveness."[7]

Federal regulators, 37 State Attorneys General, and State Drug Task Forces have all warned the public about the dangers of these unsafe and unapproved products, including compounders using "non-sterile ingredients" and taking "no steps to sterilize them."[8] FDA recently warned a tirzepatide mass compounder for violating federal law by producing drugs in unsanitary conditions and using active ingredients from an unregistered entity.[9] And Lilly continues to discover compounded tirzepatide with critical safety, sterility, and efficacy problems, including products infected with dangerous bacteria and endotoxins.[10]

Continued Prescriptions of Unlawfully Compounded Drugs

We are concerned that even with tirzepatide out of shortage and fully available to meet patients' needs, some physicians are continuing to prescribe compounded tirzepatide that is illegally compounded and risky for patients. We are similarly concerned that decisions to compound, market, sell, and prescribe these compounded drugs are driven by financial considerations in a way that may not be in the best interests of patient health.

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5 https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225.

6 https://www.obesityaction.org/why-compounded-glp-1-medications-arent-the-answer/.

7 https://nclnet.org/the-national-consumers-league-urges-the-public-to-heed-warnings-about-unregulated-versions-of-glp-1-weight-loss-drugs/; https://diabetes.org/sites/default/files/2024-12/24.11.8%20compounding%20statement%20press%20release_FINAL.pdf.

8 https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/; https://www.nbcnews.com/health/health-news/tennessee-woman-accused-selling-fake-weight-loss-drugs-counterfeit-con-rcna184154; https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

9 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prorx-llc-696742-12202024.

10 *Complaint for False Advertising and Deceptive Trade Practices, Eli Lilly v. Thrive Health*, Case No. 25-cv-00104, Dkt. No. 1 (D. Colo. January 13, 2025).

Lilly

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

When an FDA-approved product is not in shortage, federal law permits compounding a drug only when it differs from the FDA-approved medicine in a way that makes a "significant difference" for a specific patient. A classic example is when a patient is allergic to an inactive ingredient in an FDA-approved medicine, such as gluten; a compounded product without the inactive ingredient—e.g., a gluten-free version—is permitted because it produces a "significant difference" for that specific patient.

Tirzepatide does not contain any common allergen. Yet under the pretext of offering "personalized care," certain telehealth providers and drug compounders are mass-producing and mass-marketing tirzepatide with manipulated ingredients, doses, or route of administration, and providers are prescribing them without regard to patient need. These manipulated products have never been clinically tested or proven to be safe and effective, and a product that is mass produced and prescribed in the same manipulated formulation to many patients clearly is not designed to meet any specific patient's individual needs. None of these schemes is allowed, and all of them put patients at risk.

- *Additives.* Some physicians are prescribing compounded tirzepatide with added ingredients like B-3, B-6, B-12, or glycine. Compounders cannot simply add an ingredient to avoid legal restrictions against knockoff FDA-approved medicines that are not in shortage. There is no clinical evidence that adding these other ingredients to tirzepatide works better than tirzepatide alone or that there is a clinical need for any particular patient.

- *Altered Doses.* The FDA-approved labels for Mounjaro® and Zepbound® recommend 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, and 15mg doses with a four-week titration schedule (for slowly increasing dosage). Some physicians are prescribing new, different doses under the pretext of providing "personalized" care. There is no clinical evidence that would support adjusting the FDA-approved dosing regimen—and certainly not routinely prescribing an unapproved dosing regime for all patients.

- *Oral Versions.* Some physicians are prescribing what compounders claim are pill, under-the-tongue, or other oral versions of tirzepatide. There are no clinical trials or other human studies involving any oral tirzepatide product, meaning these physicians are experimenting on unsuspecting patients. Anyone claiming that oral tirzepatide products are safe or effective is doing so without clinical support.

We are also concerned about the troubling relationship between certain prescribing physicians, telehealth companies, and compounding pharmacies, which appear to work hand in glove to direct patients exclusively to untested, unapproved, illegally mass-produced compounded drugs. The routine—sometimes exclusive—prescribing of compounded tirzepatide, including tirzepatide with altered formulas, manipulated doses, or untested and unapproved routes of administration, when Lilly's FDA-approved products are available suggests that some physicians are not prioritizing patient health when prescribing tirzepatide products. Not only does this practice risk patient health, it may also put a physician malpractice insurance in jeopardy. As one senior risk consultant for a medical

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

malpractice insurer recently observed: "Some compounders . . . may believe the FDA enforcement manpower is so weak that the FDA won't be enforcing the prohibition that closely. . . . Physicians need to be aware of that. From a risk standpoint, I don't think they'd want to be associated with a compounder that's in violation of the law."[11]

Preventing Prescriptions of Unlawfully Compounded Tirzepatide

In light of the above, Lilly requests the Board's continued help to protect Alaska patients from the risks of unlawfully compounded prescription drugs. Specifically, Lilly requests that the Board:

- Inform Alaska physicians of FDA's December 19, 2024 Declaratory Order and the Texas federal court's ruling, attached to this letter, upholding FDA's removal of Lilly's medicines from the drug shortage list and confirming that compounding of tirzepatide must stop; and FDA's confirmation that it will immediately "take action against compounders for violations of the FD&C Act" related to tirzepatide as of March 19[12];

- Issue guidance to Alaska physicians concerning compounded tirzepatide, making clear that prescribing tirzepatide with added substances (like vitamin B-6 or B-12), in untested and unapproved oral formulations, or with altered doses intended to create the appearance of "personalization" is unlawful; and

- Work with your state board of pharmacy and board of medicine, together with any relevant state health and consumer protection regulators, and the FDA, in any investigation or enforcement action related to improper compounding of tirzepatide or improper prescriptions.

We appreciate your attention to these issues.

Sincerely,

Jillian V. Fuhs

Jillian V. Fuhs, JD, PharmD
Associate Vice President, Global Regulatory Affairs - Americas
Eli Lilly and Company

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11 https://www.medscape.com/viewarticle/end-compounded-glp-1s-what-physicians-need-know-2025a100063o?form=fpf.

12 https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL.,

Plaintiffs,

v. **No. 4:24-cv-0953-P**

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants.

OPINION & ORDER

Before the Court is Plaintiffs Outsourcing Facilities Association's and North American Custom Laboratories LLC Partners' (collectively "Plaintiffs") Motion for Preliminary Injunction and Stay (ECF No. 64). Having considered the briefing and applicable legal authorities, the Court will **DENY** Plaintiffs' Motion.

BACKGROUND

A. Regulatory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA") generally prohibits the introduction of a "new drug" into interstate commerce without the United States Food and Drug Administration's (the "FDA") approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer generally must submit a new drug application ("NDA"). *Id.* § 355(b)(1). The FDA adjudicates such applications and approves them only if it finds, based on the evidence before it, that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the new drug generally must comply with "current good manufacturing practice[s]" ("cGMP"), which "assure[s] that such drug meets the requirements of this chapter as to safety and has the identity

and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B); *see* 21 C.F.R. Pts. 210, 211.

In order to protect patients and ensure efficacy, the FDA's approval process is demanding. Each drug seeking the FDA's approval must be evaluated through three increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials. The sponsor must detail every ingredient and component in its application to the FDA. 21 U.S.C. § 355(b)(1)(A)(i)–(viii). The FDA conducts inspections to ensure compliance with cGMP, *id.* § 351(a)(2)(B), reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings and contraindications, *id.* § 352(f)(1)–(2), and monitors advertising and promotion to ensure it is not misleading, *id.* §§ 321(n), 352(a)(1), 352(n). The FDA also requires manufacturers to track and trace each finished product, *id.* § 360eee-1, to promptly report all adverse events, *id.* § 355(k), and to conduct further post-approval studies, *id.* § 355(o). Because of the FDA's rigorous requirements, "[o]n average, it takes 10-15 years and costs $2.6 billion to develop one new medicine."[1]

Despite the difficulties in getting new drugs approved, companies regularly invest in the research and development of new drugs due to the incentives created by Congress. Relevant here, new chemical entity exclusivity is earned whenever the FDA approves a new medicine for the first time. 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii). This statutory exclusivity means that for five years the FDA is prohibited from approving another manufacturer's application for any drug using the same active moiety. *Id.*

In addition to subjecting all new drugs to the NDA process, the FDCA regulates when drug compounding is permitted. Drug compounding is "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Thompson v. W. States*

[1]PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://tinyurl.com/5eecdtm9.

Med. Ctr., 535 U.S. 357, 360–61 (2002) (internal citation omitted). For example, the FDCA allows licensed pharmacists and physicians to compound a version of an FDA-approved product to address patient-specific needs, such as creating a liquid version of a medication for a patient who has trouble swallowing solids. *See* 21 U.S.C. § 353a.

Compounding pharmacies and physicians whose drugs meet the conditions of 21 U.S.C. § 353a (hereinafter "503A compounders") are not required, *inter alia*, to follow cGMP. On the other hand, outsourcing facilities (hereinafter "503B compounders") are subject to cGMP, registration, and product reporting requirements. *Id.* § 353b. Regardless of who produces them, compounded drugs are not subject to the safety requirements that apply to FDA-approved drugs because they do not undergo the FDA's premarket review for safety, effectiveness, and quality. Due to this reduced oversight, Congress has generally prohibited compounders from producing products that "are essentially copies of a commercially approved drug." *Id.* §§ 353a(b)(1)(D); 353b(a)(2)(A)(ii). Nonetheless, this prohibition is temporarily lifted when a drug is placed on the "shortage list."

The FDCA defines "shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c. Further, the FDCA requires the FDA to "maintain an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." *Id.* § 356e(a). For every drug the FDA adds to its shortage list under this provision, it is required to identify "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the shortage as determined by the [FDA]." *Id.* § 356e(b)(1)–(4). When a drug is placed on the FDA's shortage list, Congress permits 503A compounders to compound copies of the drug and 503B compounders to compound from that drug's active ingredient—which is otherwise prohibited—including by compounding drugs that are "essentially a copy" of an approved drug. *See Id.* §§ 353b(a)(2)(A)(ii), (a)(5), (d)(2)(A). Because, as discussed above, compounders are subject to less oversight

than drug manufactures, the FDCA permits this type of compounding only while a shortage persists.

B. Factual and Procedural Background

The drugs relevant to this case are Mounjaro® and Zepbound® (collectively the "Lilly Drugs"). The FDA approved the Lilly Drugs pursuant to Intervener Eli Lilly and Company's ("Lilly") marketing applications in 2022 and 2023, respectively. The Lilly Drugs contain a complex molecule called tirzepatide, which targets hormone receptors (called GIP and GLP-1). The FDA approved Mounjaro® for adults with type 2 diabetes mellitus seeking to improve their glycemic control. And the FDA approved Zepbound® for adults with obesity, weight-related medical problems, and moderate to severe obstructive sleep apnea. Given the groundbreaking nature of these drugs, Lilly experienced unprecedented demand, which it was unable to meet. As a result, the FDA placed the Lilly Drugs on its drug shortage list.

The Lilly Drugs remain protected by statutory exclusivity, meaning that the FDA is prohibited by law from accepting an NDA or abbreviated NDA for any tirzepatide product from any company other than Lilly until June 2027. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2), (b)(3). However, as discussed above, this exclusivity is suspended while the drugs remain on the FDA's shortage list. Thus, until the drugs are removed from the shortage list, compounders can legally produce similar products to help satisfy the demand not filled by Lilly.

In an effort to regain its exclusive right to produce and sell tirzepatide products—by having the Lilly Drugs removed from the FDA's shortage list—Lilly spent roughly $23 billion to build, expand, acquire, or obtain internal and external manufacturing facilities in the United States and Europe. Additionally, in August 2024, Lilly obtained supplemental FDA approvals authorizing the sale of the Lilly Drugs in single-use vials—on top of addition to the already approved auto-injector devices—allowing Lilly to more readily supply doses of the drugs. As a result of Lilly's efforts, the FDA updated the shortage list to reflect that "[a]ll doses of Mounjaro® and Zepbound® [were] available." Two

months after that announcement, on October 2, 2024, the FDA announced that the tirzepatide shortage was over and that the Lilly Drugs would be removed from the shortage list.

Five days later, on October 7, 2024, Plaintiffs filed this lawsuit. On October 11, 2024, the FDA filed an unopposed motion to remand and stay the case so that the FDA could "reevaluate the decision at issue in this case." The Court granted the motion, and the FDA reconsidered its decision. On December 19, 2024, the FDA issued a "Delisting Action" reaffirming its decision to remove the Lilly Drugs from the shortage list. The Delisting Action was memorialized in two documents. The first, titled the "Decision," presented the evidence considered by the FDA and its reasoning. The second, titled the "Order," summarized the FDA's rationale and provided that the FDA would exercise its enforcement discretion to delay the enforcement of its decision.

Thereafter, on January 1, 2025, Lilly filed its Motion to Intervene, which the Court granted on January 6, 2025. On January 2, 2025, Plaintiffs and the FDA filed a Joint Motion to Reopen the Case and Enter Scheduling Order. After holding a hearing on January 14, 2024, the Court reopened the case and set a briefing schedule for the present Motion. The Parties, and *Amici Curiae*, have filed their respective briefs and the Motion is ripe for determination.

LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy" and will be granted only if the movants carry their burden on four requirements. *Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). The movants must show: "(1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) the threatened injury to the movant outweighs the threatened harm to the party sought to be enjoined; and (4) granting the injunctive relief will not disserve the public interest." *City of Dall. v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017) (cleaned up). "The decision to grant or deny a preliminary injunction is discretionary with the district court." *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ANALYSIS

The Court begins with Plaintiffs' likelihood of success on the merits for their claims against Defendants. For the reasons stated *infra*, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of their claims, which is the most important (and usually decisive) factor. *See Tesfamichael v. Gonzales*, 411 F.3d 169, 176 (5th Cir. 2005); *Baird v. Bonta*, 81 F.4th 1036, 1041 (9th Cir. 2023). While the Court's analysis could end there, in an abundance of caution, the Court will briefly address the other preliminary injunction elements.

A. Likelihood of Success on the Merits

Plaintiffs' Amended Complaint raises six claims for why the FDA's Delisting Action should be set aside. *See generally* ECF No. 68. Plaintiffs, in their Motion for Preliminary Injunction, do not address their fifth cause of action—unlawful interpretation of the statute under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). *Id.* at 22. Thus, because Plaintiffs did not raise it as a basis for injunctive relief, the Court's analysis focuses on the other five claims, which are addressed in Plaintiffs' Motion.

Those claims are: (1) rulemaking without conducting notice and comment; (2) failure to consider the statutory factors; (3) facially contradictory findings that undermine the basis of the agency action; (4) failure to consider countervailing evidence; and (5) failure to publish a rule in the federal registry. ECF No. 68 at 17–24. Because claims one and five are both predicated on the Delisting Action being a rule, the Court considers them together. Similarly, Plaintiffs' remaining three claims are considered together as they all involve whether the Delisting Action was arbitrary and capricious.

1. Notice-and-Comment and Failure to Publish Claims

For the Court to determine Plaintiffs' likelihood of success on the merits on their notice-and-comment and failure to publish claims, the Court must first determine how to categorize the Delisting Action. The Parties do not dispute that the Delisting Action is a final agency action subject to judicial review under the Administrative Procedures Act

("APA"). However, the Parties do dispute how to classify the FDA's Delisting Action. Plaintiffs assert that the Delisting Action is a substantive rule. ECF No. 64 at 8. On the other hand, Lilly and the FDA (collectively the "FDA Defendants") claim that the Delisting Action is an informal adjudication. ECF Nos. 83 at 16; 90 at 17–18. If the Delisting Action is a substantive rule, as Plaintiffs urge, then then the FDA was required to comply with the APA's stringent notice-and-comment requirements and that process is reviewed under the arbitrary and capricious standard. But if the Delisting Action is an informal adjudication, as the FDA Defendants urge, then the Court simply reviews the decision under the arbitrary and capricious standard.

As best the Court can tell, the question of how to classify the FDA's removal—or addition—of a drug from its shortage list has never been raised or answered. In fact, the regulatory scheme is seemingly silent as to what procedure the FDA must use to make its shortage determinations. Plaintiffs argue that the Delisting Action is a substantive rule under the APA because it "changed the law by establishing a new prohibition." ECF No. 64 at 8. Specifically, Plaintiffs assert that the Delisting Action "creates law by prohibiting all compounding of tirzepatide by Section 503B outsourcing facilities and compounding drugs that are essentially copies of branded tirzepatide products by Section 503A pharmacies" because "there is no difference between" the FDA explicitly declaring "that 'compounding of tirzepatide is prohibited' and removing it from the shortage list." *Id.*

In contrast, the FDA Defendants argue that the Delisting Action is not a substantive rule and was properly issued through adjudication for two reasons. *First*, the FDA simply resolved a factual dispute according to an established statute rather than promulgating a policy-like standard or new interpretation of a statute. *See* ECF No. 83 at 16. And *second*, the FDA has discretion to choose whether to proceed through adjudication or rulemaking because the statutory framework does not explicitly provide what procedure the FDA must use. *See* ECF No. 83 at 16–17.

In reviewing whether an agency action was a rulemaking or an adjudication, courts consider two things. "First, we consider the agency's

characterization of its own action. Second, we must examine the ultimate product of the agency action." *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). The Court will first address whether the FDA had the discretion to proceed through adjudication before turning to whether the Delisting Action is in effect an adjudication or substantive rule.

a. The FDA's discretion

When a statutory scheme is silent as to what procedure an agency must use to act, an agency has discretion to proceed through either rulemaking or adjudication. *McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981) ("[T]he Supreme Court held that the decision to make new law through rulemaking or adjudication 'is one that lies primarily in the informed discretion of the administrative agency.'") (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)). An agency's decision to proceed through rulemaking or adjudication is reviewed under an abuse of discretion standard, and the agency's judgment "is entitled to great weight." *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *see also Neustar, Inc. v. Fed. Commc'ns Comm'n*, 857 F.3d 886, 894 (D.C. Cir. 2017) (internal citations omitted) ("[A]s a general matter, '[i]n interpreting and administering its statutory obligations under [an] Act, [an agency] has very broad discretion to decide whether to proceed by adjudication or rulemaking."). Here, the FDA Defendants argue that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication because: (1) Congress requires the shortage list to be "up-to-date" and rulemaking is incompatible with that mandate; (2) engaging in a meaningful notice-and-comment process was not possible given the confidential materials involved; and (3) Congress permits the FDA to withhold confidential information, including the very existence of a shortage. ECF No. 83 at 17–18.[2] Having reviewed the Parties' arguments and the applicable law, the Court finds that the FDA did not

[2]Because the Court finds that the FDA did not abuse its discretion to proceed through adjudication because of the requirement that the list be up-to-date and the issues presented by the confidential data, the Court declines to address the third argument—that the FDA is allowed to withhold information.

abuse its discretion by choosing to proceed through adjudication because notice-and-comment rulemaking is incompatible with Congress's mandate to keep an up-to-date list.[3]

Congress has tasked the FDA with "maintain[ing] an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." 21 U.S.C. § 356e(a). Merriam-Webster defines "up-to-date" as "extending up to the present time: including the latest information." *Up-to-date*, Merriam-Webster's Collegiate Dictionary (11th ed. 2003). If the FDA had chosen to proceed through rulemaking, as Plaintiffs urge, it would have been required by the APA to provide adequate "opportunity to participate in the rule making through submission of written data, views, or arguments. . . ." 5 U.S.C. § 553(c). Generally, for an agency to give adequate opportunity for notice and comment, the APA "requires . . . a minimum thirty-day comment period." *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 779 (5th Cir. 2023). An agency is then required to review the comments, respond to "significant" comments, and make any appropriate changes before officially promulgating a rule. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Thus, even if the FDA expeditiously participated in notice-and-comment rulemaking, the process would take well over a month. Given the constant fluctuation in national supply and demand numbers for a given drug, a rule based on data that is more than a

[3]Additionally, and in the alternative, the Court finds that the FDA did not abuse its discretion due to the issues presented in achieving meaningful notice and comment while maintaining Lilly's confidentiality. Plaintiffs argue that the Delisting Action is invalid because, *inter alia*, the FDA did not post it in the federal registry for notice and comment before issuing it. However, a simple review of the redacted version of Plaintiffs' Brief in Support of its Motion evidences the difficulty—if not the impossibility—of giving sufficient notice of the data that the FDA relied upon in drafting the proposed "rule," and allowing for meaningful comment on it. *See* ECF No. 66 at 14–19. The redacted data in the above reference section of Plaintiffs' Brief was not even made available to them through the issuance of the Delisting Action. Rather, Plaintiffs were not allowed to see the data until, as a part of this lawsuit, the Court signed and entered an agreed confidentiality agreement. Requiring the FDA to do the same with everyone who wishes to participate in the notice-and-comment process is unattainable and unenforceable.

month old cannot be said to be based on "the latest information" available.

Moreover, the APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez*, 575 U.S. at 101 (internal citation omitted); *Texas v. Biden*, 646 F. Supp. 3d 753, 771 (N.D. Tex. 2022); *Ctr. for Biological Diversity v. Regan*, 691 F. Supp. 3d 1, 8 (D.D.C. 2023). Consequently, if the FDA is required to participate in notice-and-comment rulemaking to remove a drug from its shortage list, then it is required to do the same to add a drug to the shortage list. Requiring the FDA to participate in a lengthy rule-making process to add and remove drugs from the shortage list—based on stale information—cannot be said to be congruent with Congress's mandate for the FDA to maintain an "up-to-date list of drugs . . . in shortage in the United States." 21 U.S.C. § 356e(a)

To emphasize this point, the Court proposes the following scenario. Company A creates a breakthrough drug and is unable to supply enough of the drug to meet an unprecedented national demand. Company A reports its inability to meet demand, as required, and a couple months later the FDA, after going through notice-and-comment rulemaking, places the drug on the shortage list. Company A, understanding the value of its drug, invests tens-of-billions of dollars to ramp up production in order to meet demand. Company A's investment pays off, and it is able to supply enough of the drug to meet the national demand. The FDA, based on the data provided by Company A, engages in notice-and-comment rulemaking, and a couple of months later removes the drug from the shortage list. The day after the rule is final, the demand numbers for the preceding month come in, and due to an unexpected spike, Company A's supply capabilities no longer meet the national demand. Not only did the FDA remove a drug that is in a shortage based on stale information, but it must now once again participate in a lengthy rulemaking process to allow compounders to fill the unmet demand. In contrast, through informal adjudication the FDA can act in a matter of days not months. And while efficiency may not always be the benchmark for agency action, Congress's explicit

command to keep the shortage list up-to-date makes efficiency important here. This example demonstrates why the Court finds that the FDA did not abuse its discretion in choosing to proceed through an informal adjudication rather than notice-and-comment rulemaking.

Based on the foregoing, the Court agrees with the FDA Defendants that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication. However, the label the FDA has attached to the Delisting Action is not dispositive of whether the action should be classified as such. *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017) ("An agency may not escape the requirements of § 553 by labeling its rule an 'adjudication'"). If the FDA properly exercised its discretion to proceed though adjudication, but the Delisting Action is a substantive rule in effect, then the APA requires that it be subject to notice-and-comment rulemaking. Therefore, the Court now turns to whether the Delisting Action is an adjudication or substantive rule in its effect.

b. Substantive rule or informal adjudication in effect

As a preliminary matter, it appears to the Court that this issue is a "lose-lose scenario" for Plaintiffs. As discussed above, the APA requires the FDA to use the same procedure to add a drug to the shortage list that it uses to remove a drug from the list. Thus, if the FDA's removal of the Lilly Drugs from the shortage list required notice and comment, then so did the FDA's addition of the Lilly Drugs to the list. It is undisputed that Plaintiffs are only able to compound their versions of the Lilly Drugs because of the FDA's placement of the Lilly Drugs on the shortage list. Consequently, if Plaintiffs are correct and the FDA's removal of the Lilly Drugs from the shortage list is invalid because it violated the APA's notice-and-comment requirements, then the FDA's listing of the Lilly Drugs without notice and comment is similarly invalid and Plaintiffs should not have been allowed to compound their versions of the drugs. But, if Plaintiffs are wrong, and the Delisting Action is an adjudication, then both the addition and removal of the Lilly Drugs were proper, and Plaintiffs can no longer compound their versions

of the drugs.[4] Nevertheless, the Court turns to the Parties' arguments regarding whether in effect the Delisting Action is a substantive rule or informal adjudication.

Plaintiffs assert that the Delisting Action is a substantive rule because it created law and is "no different in its force and effect than if Congress had enacted a statute prohibiting" the compounding of tirzepatide. ECF No. 65 at 7–11. Additionally, Plaintiffs argue that the Delisting Action cannot be an adjudication because it does not resolve a factual dispute between two parties, but, rather, is generally applicable to an entire industry. *Id.* The Court will begin with the latter before addressing the former.

i. Broad impact argument

Plaintiffs first argue that the Delisting Action cannot be an adjudication because of its broad impact. While "[a]djudications typically 'resolve disputes among specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals,'" "[i]t is true that an agency need not be presented with a specific dispute between two parties in order to" proceed through adjudication "because § 554 does not limit an agency's use of declaratory rulings to terminating controversies between parties." *City of Arlington, Tex.*, 668 F.3d at 242–43. This is the case because "[j]ust as a class action can encompass the claims of a large group of plaintiffs without thereby becoming a legislative proceeding, an adjudication can affect a large group of individuals without becoming a rulemaking." *Goodman v. F.C.C.*, 182 F.3d 987, 994 (D.C. Cir. 1999) (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 292 (1974) (explaining that an agency may "promulgate a new standard that would govern future conduct" of non-parties in an adjudication)); *see also Neustar, Inc.*, 857 F.3d at 894 ("The fact that an order rendered in an adjudication 'may affect agency policy and have general prospective application,' does not make it rulemaking

[4]Plaintiffs argue that the FDA adding a drug to the shortage list is less legally consequential than removing a drug from the list. The Court finds the opposite to be true. An agency action that suspends statutory exclusivity and allows for a statutorily prohibited action to be temporarily performed is a greater "change" in law than restoring the statutory norms.

subject to APA section 553 notice and comment."); *Nat'l Biodiesel Bd. v. Env't Prot. Agency*, 843 F.3d 1010, 1018 (D.C. Cir. 2016) (internal citation omitted) ("[T]he fact that an agency action applies to a 'large number of [parties]' 'carr[ies] [little] weight' in [the Court's] analysis.").

As pointed out by the FDA Defendants, the FDA routinely conducts adjudications that affect large numbers of third parties: the new drug approval process. *See* 21 U.S.C. §§ 355(d)–(g). The FDA's approval of an NDA triggers numerous effects on potential competitors, such as: (1) prohibiting the FDA from approving a competitor's NDA for any drug containing the same active moiety; and (2) triggering statutory restrictions on compounding drugs that are essentially copies of the approved drug. *Id.* §§ 353b(a)(5), (d)(2)(A); *id.* § 355(c)(3)(E)(ii).[5] The Supreme Court has endorsed the FDA's use of informal adjudications to approve NDAs and remove unsafe drugs from the market, despite those adjudications triggering broad sweeping effects on "several persons or manufacturers." *See, e.g., Weinberger v. Hynson, Westcott & Dunning Inc.*, 412 U.S. 609, 624–26 (1973). Consequently, the Court is unpersuaded by Plaintiffs' broad impact argument.

ii. Creates new law argument

Turning now to Plaintiffs' argument that the Delisting Action is a substantive rule in effect because it creates law, Plaintiffs rely on a series of cases in which an agency listing action was considered a rule.

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[5]In their Reply, Plaintiffs attempt to distinguish the FDA's approval of an NDA from an FDA's shortage determination by arguing that an NDA application involves a specific party while a shortage determination does not. *See* ECF No. 98 at 3–4. The Court is unpersuaded by this argument. To approve an NDA, the FDA reviews data submitted by a company and determines whether it satisfies a set of requirements. If the FDA approves an NDA, it triggers statutory exclusivity for the submitting company as well as a statutory prohibition against compounding the drug. Similarly, to make a shortage determination, addition or removal, the FDA reviews data submitted by a company to determine whether supply is greater than demand over a period of time. If, for example, the FDA finds that a shortage no longer exists, it reinstates the same statutory exclusivity and prohibitions that the FDA's approval of that drug's NDA put into place. And those statutory provisions apply to the same company and compounders that were affected by the NDA adjudication. Thus, Plaintiffs argument that one affects specific parties and the other does not, is unpersuasive.

ECF No. 65 at 8–10. Of the cases cited by Plaintiffs, they rely most heavily on *Safari Club*. 878 F.3d 316. Because that case is demonstrative and dispositive of Plaintiffs' other cited authorities, the Court will focus its analysis on *Safari Club*.

The "basic distinction between" an adjudication and rulemaking is that adjudications are "proceedings designed to adjudicate disputed facts in particular cases," whereas rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *See United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 244–45 (1973); *see also* 5 U.S.C. §§ 551(4) (defining "rule"), 551(6) ("order"), 551(7) ("adjudication"). The "line between" adjudication and rulemaking "is frequently a thin one. . . ." *Gen. Am. Transp. Corp. v. Interstate Com. Comm'n*, 883 F.2d 1029, 1030 n.2 (D.C. Cir. 1989). While it can be difficult to decipher where courts draw the thin line between adjudication and rulemaking, courts generally find that an agency action is an adjudication when it involves "concrete and narrow questions of law the resolutions of which would have an immediate and determinable impact on specific factual scenarios." *City of Arlington, Tex.*, 668 F.3d at 243. Rulemaking, on the other hand, is identifiable when the application of the action "will only become clear after adjudication of the dispute in a court of competent jurisdiction." *Id.*

This distinction can be seen in *Safari Club*. In *Safari Club*, the United States Fish and Wildlife Service (hereinafter the "Service") issued findings providing that it lacked sufficient information to make a positive finding that the sport-hunting of elephants would enhance the survival of the species. 878 F.3d at 323. The Service's findings also "temporarily banned imports of sport-hunted trophies of elephants." *Id.* The plaintiffs filed a lawsuit challenging the findings and argued, *inter alia*, that the findings were substantive rules despite the Service's insistence that they were adjudications. *Id.* at 331–34. The United States Court of Appeals for the District of Columbia agreed and held that the Service's findings could not be adjudications because, unlike the denial of "an application for an import permit," they had "no immediate legal consequences for any specific parties." *Id.* at 334–35. Rather, the D.C. Circuit held that the findings were substantive rules because they

"established a standard binding on the agency . . . to be applied to future requests" and were "only meant to bind hunters in future permitting adjudications and enforcement actions." *Id.* at 334.

Applying the principle that "adjudications immediately bind parties" while rules have "only future effect" to this case, the Court finds that the Delisting Action is an adjudication for two reasons. *First*, the Delisting Action undoubtably has immediate legal consequences for specific parties. The immediate consequences of the Lilly Drugs being removed from the shortage list are, *inter alia*, that Lilly regains its statutory exclusivity over tirzepatide products, and that 503A and 503B Compounders, like Plaintiffs, must cease production of their versions of the drugs. Plaintiffs seemingly concede the immediate effect the Delisting Action has on them as they argue that the removal of the Lilly Drugs from the shortage list will force their tirzepatide products "off the market," causing them irreparable harm. ECF No. 65 at 2, 23. In contrast, the Service's findings in *Safari Club*, did not cancel any prior but unfulfilled importation approvals, they only served to govern the Service's consideration of future applications. *See Safari Club*, 878 F.3d at 333 ("[T]he Service's ban on imports was only meant to bind hunters in future permitting adjudications and enforcement actions . . . ."). Thus, unlike *Safari Club*, where the findings had no immediate impact on a specific party, the Delisting Action triggered statutory provisions, immediately restoring Lilly's exclusivity and requiring compounders to stop compounding tirzepatide.

And *second*, the Delisting Action does not promulgate a new policy-type rule or standard that will govern the FDA's future actions. Instead, it made a specific factual determination based on the statutory definition of shortage. The Delisting Action did not change or interpret the statutory definition of shortage. It simply fulfilled the FDA's mandate to determine whether tirzepatide products are in shortage. Put another way, unlike *Safari Club*, where the Service's findings "implement[ed] and interpret[ed] [a rule's] enhancement requirement" to make a policy like judgment about what level of protection elephants needed to be afforded to enhance their chance of survival; the FDA's Delisting Action simply looked at the evidence presented and made a

factual determination on whether one number was bigger than another. 878 F.3d at 334 (internal quotations omitted). While it is true that the FDA's numerical determination had the immediate effect of prohibiting Plaintiffs from continuing to compound tirzepatide products, that prohibition did not come by way of a new agency interpretation, but rather by operation of an existing statute.

This distinction is further evidenced by the difference in the prospective effect of the respective agency actions. In *Safari Club*, the Service's findings determined that a ban on the future importation of elephant parts was appropriate until further notice to protect the species. This new standard served as a guide for the Service's consideration of future importation applications. In contrast, rather than creating a standard by which the FDA will consider future compounding applications,[6] the Delisting Action immediately reinstated, as discussed above, statutory protections and prohibitions. In fact, the Delisting Action provides no guidance for any future shortage determination the FDA must make, as every shortage determination—even potentially one involving tirzepatide—must be made on a case-by-case basis. Such case-by-case factual determinations have been found by courts to be adjudications. *See, e.g., Vanda Pharms., Inc. v. FDA*, 436 F. Supp. 3d 256, 270 n.4 (D.D.C. 2020) (rejecting the argument that the FDA's analysis of scientific literature in an adjudication applied to future cases such that it was a legislative rule, and noting that, unlike in *Safari Club*, the agency's analysis was "in the context of 'adjudicating a particular set of disputed facts'").

The FDA's Delisting Action made a factual determination about whether from [redacted] to [redacted], and projecting forward through [redacted], the supply of the Lilly Drugs was equal to or greater than the demand. It did not make a policy-like determination. Therefore, the Court finds that the Delisting Action was an informal adjudication—not a rule. And as a result, the FDA was not required to submit the Delisting Action to notice and comment or publish it in the

[6]In fact, the statutory exclusivity that Lilly immediately regained upon the issuance of the Delisting Action explicitly prohibits the FDA from even considering an application. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

Federal Registry. Accordingly, Plaintiffs are unlikely to succeed on their notice-and-comment and failure to publish claims.

2. Arbitrary and Capricious Claims

The Court now turns to whether Plaintiffs demonstrate a likelihood of success on the merits because the FDA's actions were arbitrary and capricious. Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 120 F.4th 494, 504 (5th Cir. 2024) (citing *Medina Cnty. Env't Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). "If the agency articulates a rational relationship between the facts found and the choice made it does not act arbitrarily or capriciously." *Joseph v. Dir. of Texas Serv. Ctr., U.S. Citizenship & Immigr. Servs.*, No. 24-40249, 2025 WL 458001, at *3 (5th Cir. Feb. 11, 2025) (internal quotation and citation omitted). The "focal point" of that review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And "[j]udicial review under that standard is deferential, a[s] a court may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While courts "may not supply a reasoned basis for the agency's action that the agency itself has not given," courts are to "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Tex. Med. Ass'n,* 120 F.4th at 504 (citing *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (quotations omitted)).

Here, Plaintiffs assert that the Delisting Action is arbitrary and capricious because: (1) it does not sufficiently identify or analyze the key parameters of the shortage determination; (2) it is facially incoherent and inconsistent; and (3) it improperly ignored countervailing evidence. *See* ECF No. 68 at 19–22; *see also* ECF No. 65 at 13–23. The Court will address each in turn.

a. Identification of key parameters[7]

Plaintiffs first argue that the Delisting Action is arbitrary and capricious because it fails to identify what time period the FDA looked at to make its shortage determination. ECF No. 68 at 19–20; ECF No. 65 at 14–19. Plaintiffs assert that the Delisting Action's failure to state a specific time frame is fatal because it is inconsistent with the statutory language and it "blinded [the] FDA to Lilly's inconsistent temporal presentations that concealed shortages." ECF No. 65 at 14. The Court need not spill much ink on this argument as it plainly fails.

Even assuming without deciding that the FDA was required to explicitly provide what period of time on which it based its shortage determination, the FDA satisfied that burden. On multiple occasions, the Delisting Action clarifies that it considered the previously produced supply and demand numbers for [redacted] to [redacted], as well as the recently released [redacted] numbers and the projected numbers through [redacted]. *See* ECF No. 65-1 at 1, 7, 8, 9, 10, 14, 15. This time period was seemingly evident to Plaintiffs as, in the same section of their brief, they take issue with the specific period of time used and argue that the Delisting Action is arbitrary because it failed to consider evidence from outside that time period. ECF No. 65 at 15–16 (asserting that the FDA erred because it did not consider past deficits or surplusages in its analysis as it started [redacted]" and looked at the numbers through [redacted]). Thus, in one breath, Plaintiffs assert that the FDA failed to identify a specific time frame and in another that the FDA's time frame was erroneous. While the Delisting Action occasionally references narrower time frames, the decision as a whole focuses on a set of data and projected data from a specific time frame—[redacted] to [redacted].

Thus, the Court finds that the FDA sufficiently identified what time period it considered in making the shortage determination. Further, the Court finds that because it is tasked to determine whether a shortage

[7]The Court does its best to separate out Plaintiffs' first two arbitrary and capricious claims as they intermingle them in their brief. *See* ECF No. 65 at 14–19.

exists over a specific period of time, the FDA did not err in failing to consider evidence from outside that time frame. Therefore, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of this claim.

b. Facially incoherent and inconsistent

Before turning its attention to Plaintiffs arguments for why the Delisting Action is facially incoherent and inconsistent, the Court finds it prudent to begin by briefly summarizing the FDA's decision.

i. Summary of the Delisting Action

The Delisting Action concluded that the tirzepatide shortage was over because the data demonstrated "that Lilly's supply is currently meeting or exceeding demand for these drug products, and that Lilly has developed reserves that it now holds in its finished product inventory, plus significant units of semi-finished product." ECF No. 65-1 at 1. Additionally, the FDA noted that Lilly received approval to produce doses in vials, and that it has scheduled substantial additional production over the coming months. *Id.* [redacted]

In making its determination, the FDA reviewed:

> [D]etailed information and data regarding its production and inventory of these drug products at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of these drug products; cumulative quantities supplied to and demanded by its customers in the year 2024; projected demand and supply in future months; and wholesaler inventory data, among other information.

Id.[8]

The data reviewed by the FDA is best summarized by two tables contained within the Delisting Action, as shown below:

[8]"[A]mong other information" includes numerous information submitted by Plaintiffs and others to demonstrate the existence of a shortage. Because that is the basis for Plaintiffs' third arbitrary and capricious claim, the Court does not discuss that information in this section.

Table 4. Lilly-reported cumulative demand and cumulative supply of tirzepatide single-dose pens for [redacted] (thousands of doses)[31]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Table 6. Lilly-reported projected cumulative demand and cumulative supply of tirzepatide single-dose pens [redacted] (thousands of doses)[58]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Id. at 10, 15.

These tables summarize Lilly's reported and projected supply and demand numbers beginning in [redacted] and concluding in [redacted]. The tables are constructed in a cumulative fashion with each month building on the previous month(s). This means that each month's column shows the total supply and demand numbers from [redacted] to the specified month. As a consequence, the numbers for [redacted] appear astronomically larger than those for [redacted].

The FDA determined that the shortage had concluded based on the fact that: (1) from [redacted] to [redacted], Lilly's total supply

([redacted]) outpaced total demand ([redacted]); (2) at least through [redacted], the shortage would not return based on the projections that Lilly's total supply ([redacted]) would continue to outpace total demand [redacted]; and (3) the information provided by wholesalers "further indicate[d] that nationwide supply for [Lilly's] products is exceeding demand." ECF No. 65-1 at 10–15. Furthermore, the FDA noted that its determination was bolstered by: (1) the months-long production of data by Lilly to the FDA; (2) Lilly's supply of over [redacted] units of semi-finished syringe products (products that have already completed sterile manufacturing and are awaiting labeling and packaging); (3) the recent approval of Lilly's vial versions of the drugs, which allows Lilly to supply more product than currently projected; and (4) Lilly's investment into additional production facilities that will soon be in operation. *Id.* After reviewing the other evidence provided by Plaintiffs, and others, the FDA determined that the nationwide shortage had ended and reaffirmed its decision to remove the Lilly Drugs from the shortage list. *Id.* at 16–23.

ii. Plaintiffs' arguments

Plaintiffs seemingly insist that the Delisting Action needed to be perfect. It did not. Rather, it needed only to "articulate[] a rational relationship between the facts found and the choice made." *Joseph*, 2025 WL 458001, at *3. Thus, the Court need not confuse the trees for the leaves. The question before the FDA was, for "a period of time" did "the demand or projected demand for the [Lilly] drug[s] within the United States exceed the supply of the [Lilly] drug[s]." 21 U.S.C. § 356c(h)(2). The FDA answered that question in the negative and therefore found that the shortage had ended. Consequently, the question before the Court is whether the FDA's decision, that supply of the Lilly drugs outpaced demand for a period of time, was reasonable in light of the evidence before it. For the reasons set out *infra*, the Court answers that question in the affirmative.

The crux of Plaintiffs' argument that the Delisting Action is incoherent and inconsistent is that "Lilly's use of cumulative figures misled or at least confused [the] FDA." ECF No. 65 at 15. Plaintiffs claim that this confusion obfuscated the fact that the shortage still persists

and created an unreasonable reliance on Lilly's statements. *Id.* at 15–19. Specifically, Plaintiffs argue that the Delisting Action is facially incoherent and inconsistent because: (1) the FDA looked at the total supply and demand data for the relevant period rather than at "monthly snapshots;" (2) the FDA [redacted], but then did not [redacted]; (3) the "FDA made no finding of demand under any consistently defined time period" as "[o]nly cumulative tables report demand, and each month has a different baseline;" and (4) the Delisting Action "turns on" Lilly's unsupported statement that it can supply over [redacted] a month. *Id.*

Plaintiffs' first argument, that the Delisting Action should not have considered cumulative data, fails. It is axiomatic that to consider something for a period of time requires considering it for the entire period of time. Yet, Plaintiffs argue that the FDA's decision is without reason because there were data points from shorter periods of time, within the overall time frame, that could lead to a different result. The real and "detailed data" considered by the FDA shows that for the period of [redacted] to [redacted], Lilly supplied some [redacted] more than were demanded ([redacted] supplied - [redacted] demanded). The FDA, relying on projected data,[9] found that for the period of [redacted] to [redacted], Lilly would be capable of supplying at least [redacted] more than would be demanded [redacted] supplied - [redacted] demanded).

Plaintiffs insist that the FDA should have considered the data on a month-to-month basis, rather than through cumulative numbers, and point out that there was more demand than supply produced for individual months. However, this argument ignores the fact that even if

[9]There is no evidence to show that the FDA's reliance on the projections was unreasonable as they provided that Lilly's [redacted] " ECF No. 65-1 at 14. Further, [redacted]

the charts were based on each individual month's numbers, the FDA would have had to add them together to get the total numbers for the relevant period of time. Thus, the result would have been the same as surplus carries over[10] and every month ([redacted]) ended with a net total surplus. *See* ECF No. 65-1 at 10, 15. Consequently, Plaintiffs are unlikely to succeed on the basis that the FDA fatally erred by considering cumulative numbers.

Plaintiffs next argue that the Delisting Action is arbitrary because the FDA [redacted]. In addition, Plaintiffs argue that the FDA erred by [redacted]. Plaintiffs claim that the FDA had no reason to [redacted], because doing so ignores the fact that surpluses/shortages carry over. While true, it ignores the fact that a period of time requires a starting and ending point. Thus, it was not unreasonable for the FDA to [redacted], as it was the beginning of the relevant time period.[11] Additionally, for the same reason Plaintiffs' cumulative numbers argument fails so does their assertion that the FDA should have [redacted]. In evaluating data for a period of time, one looks at the whole not just part. Therefore, Plaintiffs are unlikely to succeed on the basis that the FDA arbitrarily started [redacted], and [redacted].

Plaintiffs third argument, that the FDA "made no finding of demand under any consistently defined time period" fails for the same reasons. The FDA considered total demand for the relevant time period based on actual and projected data. The argument that the cumulative demand numbers were based on different lengths of time ignores the fact that the supply numbers were based on the same lengths of time. Additionally, just as above, even if they were broken down by month, the FDA would have still been required to total the months up to

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[10]Each dose can be stored for up to 24 months. ECF No. 90 at 12.

[11]Plaintiffs do not, and cannot, argue that the FDA was required to look at numbers all the way back to the approval of the Lilly drugs. As Plaintiffs do argue, the FDA was required to choose a time period for its analysis. The FDA did and it looked at the actual and projected numbers for that time frame. The statute does not require more of the FDA and neither does this Court.

evaluate if the total demand outpaced total supply for the time period being considered. Thus, Plaintiffs are unlikely to prevail on their demand calculation argument.

Finally, Plaintiffs assert that the Delisting Action is arbitrary because it "turns on" Lilly's unsupported representation that it can now supply over [redacted] a month. This argument also fails. Even assuming without deciding that Lilly's [redacted] a month estimate is unsupportable, Plaintiffs cannot show that the FDA's determination has no reasonable relationship to the facts presented for two reasons. *First*, Plaintiffs statement is a mischaracterization, as the FDA considered significantly more information than Lilly's explicit [redacted] estimate. *See* ECF No. 35-1 at 1. And *second*, even if the monthly estimate is unsupportable by the data, that does not negate the fact that the actual numbers show that total supply outpaced demand for the relevant period. *Id.* at 10, 15. Thus, even if the FDA was never presented with Lilly's estimate, the actual supply and demand numbers provide the FDA with a reasonable basis for determining that the Lilly Drugs are no longer in shortage. Accordingly, because the FDA was not required to be perfect, Plaintiffs are unlikely to succeed on their claim that the Delisting Action is incoherent and inconsistent.

c. Countervailing evidence

Finally, Plaintiffs assert that the Delisting Action "arbitrarily waved away all evidence of shortage." ECF No. 65 at 19–23. Specifically, Plaintiffs claim that the FDA reviewed all of the evidence provided by them, and others, with "hyper-skepticism."[12] *Id.* Plaintiffs, and others, provided four categories of evidence to the FDA: (1) screenshots of pharmacy wholesalers websites; (2) patient reports; (3) news reports; and (4) compounding numbers. *Id.* Plaintiffs argue that all of this evidence shows that the FDA unreasonably relied on Lilly's assertions and should not have been waved away. *Id.* The Court will address each

[12]As a preliminary matter, the Court notes that the FDA also scrutinized and rejected some of Lilly's evidence based on the same standards it applied to the countervailing evidence. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53. If nothing else, this shows that the FDA did not blindly rely on Lilly's assertions and evidence.

set of evidence to determine if the FDA's finding that it did not outweigh or undermine the evidence provided by Lilly was reasonable in light of the facts before it.

First, Plaintiffs point to the screenshots of wholesalers' webpages showing that on certain days some tirzepatide products were unavailable. *Id.* at 19–20. The FDA reviewed the screenshots and found that the evidence did not "undermine[] or outweigh[] the information provided by Lilly . . . with respect to availability of product to wholesalers and retailers" because: (1) Lilly provided data from the wholesalers showing that Lilly is meeting or exceeding wholesaler demand for the Lilly Drugs; (2) of supply chain dynamics; (3) most of the screenshots were undated; (4) Lilly [redacted] and (5) some localized and temporary supply issues do not demonstrate a national shortage. ECF No. 65-1 at 19–21.

Plaintiffs take issue with all of the FDA's explanations, but most notably argue that "[d]elay in shipping of the drug" is a statutory indicator of a shortage. ECF No. 65 at 20 (citing 21 U.S.C. § 356e(b)(3)(F)). While a significant delay in shipping could affect supply on a national level, it was reasonable for the FDA to conclude that a "[redacted]" delay for a specific dose of tirzepatide on a specific retailer's website does not rise to the level of a national shortage. Similarly, the Court finds that the FDA's review and explanation of the data related to screenshots of wholesalers' websites was not unreasonable in light of the additional data provided and supply chain dynamics.

Second, Plaintiffs claim that the FDA unreasonably found that Lilly's evidence was not outweighed by the "tens of thousands" of "reports of patients" not being able to obtain tirzepatide. ECF No. 65 at 20. Plaintiffs, and others, submitted website "survey data" where people responded in the affirmative to a question asking if they have had "an inability to access name brand GLP-1s." *Id.* at 20; ECF No 65-1 at 17. The FDA reviewed the submissions and found that they did not undermine Lilly's evidence that the shortage was over because: (1) there is no way to verify how many individuals actually filled out the reports,

when they filled out the reports, or when their inability to obtain the drugs occurred; (2) the prompt does not define "inability to access" so some may be reporting that a pharmacy was out of stock and others that their doctor did not prescribe them the medication; (3) of business decisions made by pharmacies as well as their limited storage capacities; and (4) some localized and temporary supply issues do not demonstrate a national shortage. ECF No 65-1 at 16–19. Given the issues with the evidence as articulated by the FDA, the Court finds that the FDA did not unreasonably determine that Lilly's evidence is not outweighed by the patient survey reports.[13]

Third, Plaintiffs assert that the FDA "ignored" news coverage of the shortage situation. ECF No. 65 at 21. With regard to this evidence, the FDA stated:

> FDA reviewed various articles and blog posts submitted by various groups, as well as other news coverage. While these pieces discussed various aspects of the shortage situation, FDA did not find them to contain probative evidence relevant to the analysis FDA must conduct to determine whether a shortage has resolved. While some of these sources contained personal accounts of inability to get a particular product at a particular time, like the evidence discussed in sections II.B.1.i and ii above, those individual accounts do not undermine or outweigh the more specific, reliable, comprehensive, and current information that has been provided by Lilly demonstrating its ability to supply enough product to meet demand.

ECF No. 65-1 at 21.

The Court finds that it was not unreasonable for the FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly, than news reports and blog posts from sources who may have had ulterior motives and lacked the same detailed data presented to the FDA. Consequently, the Court finds that the FDA did not arbitrarily wave away the news coverage of the shortage situation.

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[13]As previously noted, the FDA found some of Lilly's evidence to be unpersuasive [redacted]. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53.

Fourth, and finally, Plaintiffs argue that the "FDA erred" by "disregarding the '[] sales volume of compounded tirzepatide' as evidence of demand." ECF No. 65 at 21–23. Specifically, Plaintiffs claim that FDA "erroneously deemed compounded products irrelevant," "disregard[ed] demand for compounded products because they beat Lilly's on price," failed to take into account the correct volume of compounding, and incorrectly assumed that some patients were using compounded tirzepatide for off-label uses. *Id.*

Plaintiffs' first point, that the FDA deemed compounded products irrelevant, fails. The FDA stated that the number of compounded products has "minimal relevance" on the current demand of the Lilly Drugs, but that it is relevant to projected demand—after the compounded drugs are removed from the market. ECF No. 65-1 at 22–23. On that basis, the FDA considered whether Lilly would be able to fill the demand hole that would be left after the compounded drugs were removed. *Id.* at 23–28. After a lengthy discussion, the FDA found that based on the projections Lilly would be able to meet the projected demand. *Id.*

Plaintiffs' second and fourth arguments similarly fail. In essence, Plaintiffs take issue with the FDA's statements that demand for compounded drugs does not translate one-for-one to demand for the Lilly Drugs because of price considerations and patients' current off-label use. ECF No. 65 at 21–23. Lilly did not zero out the projections of demand based on these principles, it simply found these were factors to consider in projecting the demand of the Lilly Drugs. ECF No. 65-1 at 26–27. It is not unreasonable to consider missuses or price differences in attempting to calculate a projected national demand.

Finally, Plaintiffs assert that the FDA improperly evaluated how much compounding was occurring. ECF No. 65 at 22. Plaintiffs claim that the FDA erred in considering only the "first six months of 2024" while considering [redacted] for Lilly's data. But the data from the first six months of 2024, was "the most recent complete reporting period" that was available to them. ECF No. 65-1 at 24–25. Plaintiffs also assert that the FDA overcalculated how much Plaintiffs were producing. ECF No. 65 at 22. Even if true, this does not show error as the FDA conducted its

analysis based on inflated compounding numbers, which would only have helped Plaintiffs' position on the shortage. Lastly, Plaintiffs argue that the FDA should have investigated more based on the evidence provided that thirty-seven pharmacies produced roughly 500,000 doses per month. ECF No. 65 at 22. The FDA considered this evidence and found that "[e]ven assuming that all of these doses have been supplied to the market and, upon the curtailing of compounding, would translate to demand for Lilly's products, this would represent a very small amount relative to Lilly's production and inventory." ECF No. 65-1 at 24. Furthermore, the FDA had no obligation "to conduct or commission [its] own empirical or statistical studies." *Prometheus Radio Project*, 592 U.S. at 427. Accordingly, the Court finds that the FDA's treatment of the evidence submitted by Plaintiffs, and others, was reasonable based on the evidence it had before it. *Id.* Thus, Plaintiffs are not likely to succeed on this claim.

B. Irreparable Injury

Parties frequently confuse the magnitude of a harm with the irreparability of a harm. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 18–20 (2008); *Rest. Law Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023) (citing *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) ("In determining whether costs are irreparable, the key inquiry is 'not so much the magnitude but the irreparability.'")). Yet even enormous harms can be compensable by money damages, thus failing to justify injunctive relief. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("The key word in this consideration is irreparable. Mere injuries, however substantial . . . are not enough. The possibility that adequate compensatory or other relief will be available at a later date . . . weighs heavily against a claim of irreparable harm.") (internal quotations omitted). That's off the table here, as Plaintiffs sue the federal government and cannot recover monetary compensation. *See Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1136 (5th Cir. 2021). And "complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (internal citation omitted); *see generally Rest. Law Ctr.*, 66 F.4th at 433. Here, without a

preliminary injunction, Plaintiffs will suffer unrecoverable financial losses, which constitutes irreparable harm.[14] *White Lion Invs., LLC*, 16 F.4th at 1136.

C. Public and Private Interests

Finally, Plaintiffs must show that, if the injunction is denied, the threatened injury outweighs any harm that will result if the injunction is granted, and that the granting of an injunction will not disserve the public interest. *See Mock v. Garland*, 75 F.4th 563, 577 (2023). These factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). On one hand, if the Department is enjoined, it "suffers the irreparable harm of denying the public interest in enforcement of its laws." *Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017). On the other, "it is always in the public interest" to stop enforcement of unconstitutional or invalid laws. *See Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 n.9 (5th Cir. 2014) (internal citations omitted). The Parties' arguments for both interests are the same.

Plaintiffs argue that if the Court denies an injunction, patients will be deprived of their medications. ECF No. 65 at 24. In contrast, the FDA Defendants claim that if the Court grants an injunction, patients will continue to be subject to dangerous compounded versions. ECF Nos. 83 at 24; 90 at 22–25. Congress considered both of these interests in crafting the relevant regulatory scheme. As discussed above, compounding is generally prohibited due to the reduced oversight and the potential harms associated with the practice. However, Congress chose to allow for compounding when a drug is on the FDA's shortage list so that patients can receive their medications. If Congress thought it prudent to account for both of the asserted public interests at issue here, it is not for this Court to make a policy determination on which is

[14]Lilly argues that Plaintiffs are compounding in violation of the relevant statutes. However, the FDA does not contest this element. The Court agrees with Plaintiffs that this argument has no place in this case and must be decided, if at all, in a different lawsuit. Thus, for the purposes of this Motion, the Court does not consider that argument.

greater.[15] Thus, the Court finds that the public and private interests at issue in this case are a wash and do not weig in favor of or against the granting of an injunction.

CONCLUSION

For the reasons set out above, Plaintiffs' Motion for Preliminary Injunction and Stay is **DENIED.**

Given the agreed confidentiality agreement that was entered into by the Parties, and enforced by the Court, the undersigned finds it appropriate to file this unredacted opinion under seal. Shortly after the opinion is filed, the Parties will be provided, via email, an unsigned PDF version of the order. It is **ORDERED** that, **on or before 4:00 p.m., March 7, 2025**, the Parties shall submit, via response to the email, an agreed upon version of the order containing any appropriate redactions. After receiving and reviewing the Parties' version, the Court will issue the redacted order.

SO ORDERED on this **5th day of March 2025.**

Mark T. Pittman

MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE

[15]The Court agrees with John Adams's sentiment that the judiciary should avoid exercising the powers of the legislative and executive branches, so that this Nation may remain "a government of laws and not men." Mass. Const. art. 30; *John Adams, Architect of American Government*, https://www.mass.gov/guides/john-adams-architect-of-american-government.

SUMMARY AND CONSIDERATION:

A Reviewing Board Member (RBM) opined Dr. Bania violated AS 08.64.326(a)(7) and (9) as well as 12 AAC 40.967(14). The RBM reviewed the case and the application for reinstatement, noting Dr. Bania is not competent to resume practice in Alaska and recommended his license not be reinstated. The RBM opined Dr. Bania did not take accountability for his actions, show remorse, complete medical education or therapy related to the violations. The RBM also opined Dr. Bania provided no evidence he has changed. The RBM opined Dr. Bania is a threat to public safety and should not be reinstated.

This Reinstatement Denial is being presented to the Board for consideration.

From:	Paula Colescott
To:	Norberg, Natalie M (CED)
Subject:	Fwd: How MDMA"s Pharmacology and Pharmacokinetics Drive Desired Effects and Harms - Michael White - 2014 - The Journal of Clinical Pharmacology - Wiley Online Library
Date:	Thursday, May 1, 2025 11:16:39 AM
Attachments:	coehen-et-al-2012-a-randomized-controlled-pilot-study-of-mdma-(-3-4-methylenedioxymethamphetamine)-assisted (1).pdf Position-Use-of-Psychedelic-Empathogenic-Agents.pdf legislationhallucinogens.pdf ICER reportonMDMAinPTSD.pdf

---------- Forwarded message ---------
From: **Paula Colescott** <pcolescott1@gmail.com>
Date: Thu, May 1, 2025 at 10:58 AM
Subject: Bibliography--Psychedelics

Hi Natalie,
Additional Bibliography that may not have been sent to you; there will be more bibliography when the final draft is approved by the Task Force, for the Medical Board Review.

How MDMA's pharmacology and pharmacokinetics drive desired effects and harms. C Michael White
PMID: 24431106 DOI: 10.1002/jcph.266

MDMA (Ecstasy/Molly) | National Institute on Drug Abuse (NIDA)

Psilocybin (Magic Mushrooms) | National Institute on Drug Abuse (NIDA)

Search | American Medical Association
https://accp1.onlinelibrary.wiley.com/doi/10.1002/jcph.266

Controlled Substances Advisory Committee - Alaska Department of Law

From:	Pam Ventgen
To:	Norberg, Natalie M (CED); Alexander von Hafften, Jr; maryannf@gci.net; Sarah Troxel; henry llewellyn; mherndon@pobox.alaska.net
Subject:	FW: Listening to the Psychedelic task force meeting.
Date:	Wednesday, April 2, 2025 3:32:55 PM

Paula has been serving on the psychedelic task force.

Pam Ventgen
Executive Director
Alaska State Medical Association
907-244-7266 (direct)

From: Paula Colescott <pcolescott1@gmail.com>
Sent: Wednesday, April 2, 2025 2:47 PM
To: Pam Ventgen <pventgen@asmadocs.org>; maryannf@gci.net; Lex Vonhafften <avh@gci.net>
Subject: Fwd: Listening to the Psychedelic task force meeting.

Pam, could you forward this to the Medical Boards, to Lex, and all PHC facilitators?

These are recordings of the meetings.

I'd like ASMA to review materials I can provide, and make a statement regarding the use of psychedelics.

This is going to likely follow the trajectory of cannabis,—- first legalization for medical aspects and then legalization for everyone, with retail Business is cashing in on the profits. This is already happening in Colorado.

Paula

---------- Forwarded message ---------
From: **Anna Brawley** <anna@tinybirchak.com>
Date: Wed, Apr 2, 2025 at 10:11 AM
Subject: Re: Listening to the discussion
To: Paula Colescott <pcolescott1@gmail.com>

Hello,

Yes, all of these meetings are streamed live from the Capitol (using one of the committee rooms) and is recorded for later viewing. THey are kind of buried on the Leg. website (www.akleg.gov) but if you search by the day of the meeting, and scroll down toward the end (they are in chrono order, these are in the evenings), you can find them as a type of "miscellaneous meeting."
Here is the one from 3/19 - the one for tonight will also be posted somewhere under todays' date.
https://www.akleg.gov/basis/Meeting/Detail?Meeting=SPSY%202025-03-19%2017:15:00

A

On Tue, Apr 1, 2025 at 7:13 PM Paula Colescott <pcolescott1@gmail.com> wrote:

> Anna, you mentioned that other individuals could listen in on the Discussion of the Task Force. Did I understand that correctly?
> If so could you send me the link?
>
> thanks!
> Paula Colescott MD

From:	Pam Ventgen
To:	Norberg, Natalie M (CED); Alexander von Hafften, Jr; maryannf@gci.net; Sarah Troxel; henry llewellyn; mherndon@pobox.alaska.net
Subject:	FW: Introductory remarks about psychedelics, how they work, and toxicities reported.
Date:	Wednesday, April 2, 2025 3:33:58 PM
Attachments:	image.png image001.png

Paula's report.

Pam Ventgen
Executive Director
Alaska State Medical Association
907-244-7266 (direct)

From: Paula Colescott <pcolescott1@gmail.com>
Sent: Tuesday, April 1, 2025 7:12 PM
To: Anna Brawley <anna@tinybirchak.com>; Pam Ventgen <pventgen@asmadocs.org>; maryannf@gci.net
Subject: Introductory remarks about psychedelics, how they work, and toxicities reported.

Dear Anna,

Here is an introductory statement about psychedelics in general, how they work in the body, and noted side effects, stated in plain language. I thought that who ever covers medicalization can enter the studies most important that would suggest that the psychedelics can be used in a select population.

I. About Psychedelic Therapies Under FDA Review

A. GENERAL CONTEXT:

DEFINITIONS AND MECHANISMS OF ACTION OF PSYCHEDELICS PROPOSED FOR MEDICAL USE TO INCLUDE: LSD, PSILOCYBIN, MDMA

Psychedelics (meaning "mind-manifesting,a term coined by Humphrey Osmond), are a varied group of plant-derived synthetic compounds that have in common the ability to produce sensory, perceptual, and cognitive changes without impairing attention or level of consciousness.

They do so by influencing communication networks in the brain that depend on a host of chemicals released by the billions of neurons in the brain. These chemicals are called neurotransmitters; these neurotransmitters affect the

neighboring neuron by attaching to a particular receptor on that neuron eliciting its response. This communication between neurons is called neurotransmission.

MESCALINE, PSILOCYBIN, LSD, all belong to a class called *phenyethylamines* which are considered the classic hallucinogens.

These compounds influence Serotonergic neurotransmission by binding to the neurons which have the 5HT2 receptor on their surface membrane**.**

The most prominent subjective effects of the classic Hallucinogens are influenced by set and setting, that is, the expectations and personality of the person who uses hallucinogens, coupled with the environmental and social conditions of use. Mood can vary from euphoria and feelings of spiritual insight to depression, anxiety, and terror. Perception usually is intensified and distorted, and alterations in the sense of time, space and body boundaries. While illusions (visual and auditory distortions of perception) are common, true hallucinations (perceptions that do not have any basis in reality) are not. Synesthesia, a blending of the senses wherein colors are heard, and sounds are seen is a common perceptual distortion. Cognitive function may range from clarity to confusion and disorientation, although reality testing usually remains intact. include alterations in perception, cognition, affect, sense of meaning, and/or sense of self. **Psilocybin has been researched for the treatment of Depression**

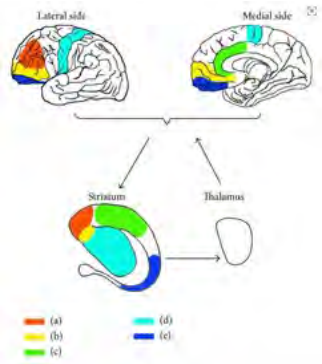
There is a small group of compounds similar in structure, but whose pharmacology differs from the classic hallucinogens. They have been named ENTACTOGENS with the prototype being MDMA, Entactogen is derived from the roots “en” (Greek, within), “tactus” (Latin, touch), and “gen” (Greek, produce) connoting substances that “produce a touching within.” Entactogens have a mechanism of action and subjective effects distinct from the classic hallucinogens. While these substances affect emotion and promote social interaction, they do not produce the major alterations in sensory perceptions that are typical of the classic hallucinogens (5)

MDMA is being proposed for the treatment of PTSD

MECHANISM OF ACTION OF PSYCHEDELICS PROPOSED AS MEDICAL INTERVENTIONS

Psychedelics affect more than the Serotonergic system, and evidence from animal and human studies suggests that hallucinogens disrupt information processing in multiple neural pathways, referred to as the

CorticoStriatoThalamocortical (CSTC) feedback loops; These loops continually receive and integrate neuronal activity distributed across wide cortical regions, and function as gates in regulating the level of awareness and attention that generate the conscious experience. The following image illustrates the areas of the brain affected:



(114,118).

Blood oxygen level–dependent (BOLD) imaging via fMRI and magnetoencephalography (MEG) have been used to study human brain activity following administration of psilocybin or LSD.

Carhart-Harris et al. (127) published the first study of resting state functional connectivity (RSFC) in 15 healthy humans after they had received an **intravenous administration of 2 mg of psilocybin**. The study revealed decreased cerebral blood flow and BOLD signal that affected regions in the CorticoStriatoThalamoCortical (CSTC) feedback loops; (thalamus and anterior and posterior cingulate cortex (PCC).

This is thought to explain how arousal is preserved, but the distinction between inner thought and external focus becomes blurred.

Most recently, Carhart-Harris et al. (130) used BOLD, and MEG to image brain activity in 20 healthy human subjects administered **90 µg of IV LSD.** Dysregulation, characterized by a decrease in neural connections in regions in the parahippocampus correlated with "ego dissolution and altered meaning. Consistent with their previous research with psilocybin, a significant relationship was found between decreased PCC alpha (and delta) power and ego-dissolution. **Taken together with results from their earlier studies, it appears that psychedelics destabilize and disintegrate normally well-established brain networks and reduce the degree of segregation between them.**

Associated Risks And Toxicities of Psychedelics

ADDICTIVE POTENTIAL

Psychedelics to varying degrees lack two important characteristics that contribute to the addiction liability:

1., They are not consistently pleasurable, and in some cases are aversive. (Exception: MDMA)

2. The rapid development of tolerance to the desired effects limits whatever reading effects they might have.

3. They cause limited dopaminergic stimulation

Approximately 5% of people with h/o hallucinogen use will develop dependence

Past ear and lifetime HUD prevalence: 0.05% and 0.60%. Most prevalent among 18-20 yos (0.33% and 0.26%)

Of patients with HUD, past year/lifetime prevalence of severities are:

- Mild: 79.9% and 66.8%
- Moderate: 13.1% and 18.5%
- Severe 7.0% and 14.6%

Bogenschultz & Ross, 2017; NSDUH, 2019; Shalit et al, 2019

DRUG DRUG INTERACTIONS:

(Exerp from ASAM Principles of Addiction Medicine, Sixth Edition, Pg. 245

"There are few known interactions between the classic hallucinogens and psychiatric medications. Based on limited retrospective self-reports, tricyclic antidepressants, lithium, and bupropion may increase sensitivity to LSD, while SSRIs and MAO inhibitors decrease its effects (257). Because ayahuasca contains MAO inhibitors, serotonin syndrome is a concern if it is combined with serotonin reuptake inhibitors (258), although few such cases have been reported.

Several significant drug–drug interactions involving MDMA have been reported, mostly involving antidepressant medications. Serious complications from combinations of MDMA with antiretroviral agents have been reported (259). Citalopram attenuates the psychological and cardiovascular effects of MDMA, presumably through interaction with the serotonin transporter (260,261). Because MDMA is metabolized primarily by CYP2D6, medications that inhibit this enzyme can slow metabolism and increase levels of MDMA. Pretreatment with paroxetine (a potent CYP2D6 inhibitor) increases MDMA levels, but still decreases its cardiovascular and subjective effects (262). Likewise, duloxetine attenuates the physiological and subjective effects of MDMA and decreases circulating norepinephrine levels, in spite of increasing MDMA levels (263). Bupropion attenuates cardiovascular effects of MDMA but increases MDMA levels and duration of subjective effects, while MDMA increases plasma levels of bupropion (264).

Substances such as alcohol, cannabis, and stimulants are commonly used together with MDMA (265). Co-ingestion of stimulants (including caffeine) can worsen side effects and neurotoxicity of MDMA (265,266). Coadministration of alcohol prolongs the euphoric effects of MDMA and modestly increases MDMA levels (267). Alcohol decreases MDMA-induced fluid retention and possibly attenuates temperature increase, but does not moderate its cardiovascular effects rate or blood pressure (268).:

TOLERANCE

As with other drugs of abuse tolerance occurs. This is seen with the daily administration of LSD leading essentially to complete loss of sensitivity to the effects of the drug by day 4 (74,75). Likewise, daily administration to humans of the hallucinogenic amphetamine 2,5-dimethoxy-4-methylamphetamine (DOM) also led, by day 3, to significant tolerance to the drug effect (76). In man, cross-tolerance occurs between mescaline and LSD (77) and between psilocybin and LSD (78). Tolerance and cross-tolerance to hallucinogens also develop in animal models (79–86). Cross-tolerance between the various chemotypes of hallucinogens supports the notion that the classic serotonergic hallucinogens have a similar if not identical mechanism of action.

ADVERSE EVENTS

- **The Bad Trip & Impaired Judgment** Hallucinogen ingestion can result in an acute toxic delirium that is characterized by delusions, hallucinations, agitation, confusion, paranoia, and inadvertent suicide attempts (attempts to fly

or perform other impossible activities) In an unsupervised situation can have dangerous and occasionally fatal consequences.

❖ **Psychiatric complications** including psychotic episodes have been reported in the context of illicit use (29) but are extremely rare when LSD is administered in the context of clinical research (155). Hallucinogens can trigger or exacerbate psychotic disorders.

❖ **Traumatic experiences ranging from mild anxiety to being terrified,** can have long-lasting effects, including mood and anxiety symptoms and, more rarely, flashback phenomena (29,156–159). Setting is vital to prevention.

❖ The DSM-5 recognizes **Hallucinogen Persisting Perception Disorder** as a diagnostic entity characterized by reexperiencing of perceptual symptoms of hallucinogen intoxication,(Geometric hallucinations, false perceptions of movement in the peripheral visual field, flashes of color, intensified colors, trails of images of moving objects, positive afterimages, halos around objects, macropsia and micropsia.) which persists long after use, causing significant distress & impairment.

❖ **MDMA:** Low to moderate oral doses of MDMA (50-150 mg) typically produce an intense "rush" especially if taken on an empty stomach, that may last 30-45 minutes Desired effects include increased wakefulness and energy, euphoria, increased sexual desire and satisfaction, heightened sensory perception, sociability, and increased empathy and sense of closeness to others (157,160,161). The rush is followed by several hours of less intense experience ("plateau"), during which repetitive dancing is common. This continual exertion has been associated with hyperthermia, dehydration, and seizures. Persons using MDMA often start to "come down" 3-6 hours after ingestion (154).

❖ **The acute physical effects of MDMA** at low to moderate doses resemble those of a stimulant: increased muscle tension, jaw clenching, tooth grinding (bruxism), restlessness, insomnia, ataxia, headache, nausea, decreased appetite, dry mouth, dilated pupils, and increased heart rate and blood pressure (157,160,161).

❖ **Doses >200 mg are associated with life-threatening toxicities** t characterized by hyperthermia with core body ttemperatures > 102. F, due to the increased physical activity and thermogenic effect caused by the drug. This can result in significant dehydration and electrolyte imbalance. If not medically managed, muscle breakdown with attending kidney damage can ensue.

❖ Although hallucinogen withdrawal is not recognized in the DSM-IV or DSM-5**, some people who use MDMA experience a pronounced "crash" after using MDMA,** which in 1% of such people meets DSM-IV research criteria for withdrawal "(ASAM Principles of Addiction Medicine, Sixth Edition. Pg: 240)

Well, this may be more than anyone would ever want to know. There is current publications coming from Colorado, a state that has legalized Psychedelics, on serious side effects being reported. I'll send this to you separately

Best Wishes,

Paula Colescott MD

Boarded in Internal Medicine/ Preventive Medicine: Addiction Medicine

From:	Norberg, Natalie M (CED)
To:	davebarnes@mtaonline.net; mheilala@gmail.com; Lydia Mielke; Dr Paulson; sampsmith1@gmail.com; akbt64@gmail.com; Wilson, David (DOT sponsored)
Subject:	FOR BOARDS - Psychedelic Medicine Task Force - Draft Recommendations for Public Comment
Date:	Tuesday, April 22, 2025 4:14:37 PM
Attachments:	image001.png Psych Med Task Force - Draft Recommendations - 4.21.25.pdf Psych Med Task Force - Public Comment Flyer - Apr 2025.pdf
Importance:	High

Dear Board members,

Please review the attached documents related to submitting public comments on the recommendations from the Psychedelic Medicine Task Force. The final deadline for written public comments is **Monday, May 5**, or next **Monday, April 28** to have your comments included in the materials for the task force's meeting on April 29.

You are welcome as members of the public to submit your own comments. If you believe the Medical Board should weigh in as a body**, please email me directly to let me know**.

In accordance with the Public Meetings Act, please do NOT "reply all" your response.

Thank you!

Natalie Norberg
Executive Administrator
Alaska State Medical Board

From: Saviers, Glenn A (CED) <glenn.saviers@alaska.gov>
Sent: Tuesday, April 22, 2025 12:15 PM
To: Norberg, Natalie M (CED) <natalie.norberg@alaska.gov>; Wolf, Patty J (CED) <patty.wolf@alaska.gov>; Bowles, Michael P (CED) <michael.bowles@alaska.gov>; Northcutt, Amberly A (CED) <amberly.northcutt@alaska.gov>; Honea, Miriam R (CED) <miriam.honea@alaska.gov>; Adams, Marlo M (CED) <marlo.adams@alaska.gov>; Castles, Alyssa P (CED) <alyssa.castles@alaska.gov>
Cc: Robb, Sylvan S (CED) <sylvan.robb@alaska.gov>; Dumas, Melissa L (CED) <melissa.dumas@alaska.gov>; Campbell, Karmen L (CED) <karmen.campbell@alaska.gov>; Pace, Jeanne M (CED) <jeanne.pace@alaska.gov>; Derr, Lacey E (CED) <lacey.derr@alaska.gov>
Subject: FOR BOARDS - Psychedelic Medicine Task Force - Draft Recommendations for Public Comment
Importance: High

Good afternoon board liaisons,

Please forward this email and the included attachments to the members of your respective boards **today**. If the board is not meeting in time to provide a board comment, members can submit comments as individual practitioners and/or are welcome to share with industry associations, other professionals, and/or members of the public that they think they be interested. This email should be shared with members of the State Medical Board, Board of Nursing, Board of Pharmacy, Board of Marital & Family Therapy, Board of Professional Counselors, Board of Psychologist & Psychological Associate Examiners, and Board of Certified Social Workers.

As some of you may know, the Legislature passed a bill last year that created the Psychedelic Medicine Task Force. Its purpose is to prepare for potential medicalization of psychedelic medicines by the FDA, to make policy recommendations to the Legislature concerning insurance and licensure, and to ensure Alaska is prepared if psychedelic medicines become available for prescription. I serve as the Commissioner Sande's delegate on the task force. Please be aware the Task Force has not voted on any of these recommendations, so our department has not decided or expressed whether we plan to vote in favor or opposition of the individual draft recommendation being included in the final report. Decisions on how to vote on each individual draft recommendation will be made after public comments are received and reviewed.

There are two items attached to this email: (1) the Task Force's draft recommendations; and (2) a flyer about public comment on the draft recommendations. **The Task Force is seeking comments and feedback on the draft recommendations. Comments are accepted in writing until 5pm on Monday, May 5th and will be accepted verbally during the Task Force Meeting on Tuesday, April 29th, as noted below.** The Task Force will consider all comments received by the May 5th deadline.

- The comment period is open through 5pm Monday, May 5, 2025.
  - Written comments should be sent to: rep.justin.ruffridge@akleg.gov
  - Written comments received by 5pm Monday, April 28 will be included in the agenda packet for the April 29 meeting.
  - Comments received later will be compiled and shared with members by e-mail.
- To provide verbal comments, attend the Task Force meeting on Tuesday, April 29th (5:30-7:00pm).
  - Testimony is limited to 3 minutes (you can send a written version by e-mail).
- Alaska Psychedelic Medicine Task Force Meeting on Tuesday, April 29th from 5:30-7:00pm:
  - To attend in-person: Alaska Capitol Building, Butrovich Committee Rm 205, Juneau.
  - To attend via teleconference – Legislative teleconference numbers:
    - If you're in Juneau: (907) 586-9085
    - If you're in Anchorage (907) 563-9085
    - If you're in a city besides Juneau or Anchorage: (884) 586-9085
  - *NOTE: Do not go to a Legislative Information Office (LIO), they are closed after-hours.*

Thank you!

Glenn Saviers
Deputy Director
Division of Corporations, Business, and Professional Licensing
https://www.commerce.alaska.gov/web/cbpl

The Alaska Psychedelic Medicine Task Force

is seeking public comment and feedback on its draft recommendations, to be published May 2025. Please share written comments and/or participate in our public comment opportunity at the upcoming meeting!

Task Force Meeting

- Tuesday, April 29th
- 5:30 - 7:00 PM
- Capitol Building, Butrovich Committee Room 205
- Livestream: akl.tv

Testify by phone

Juneau: 907-586-9085
Anchorage: 907-563-9085
All other locations: 844-586-9085

Written comments

Send written comments to Rep.Justin.Ruffridge@akleg.gov
Comments must be received by 5PM April 28th to be included in the April 29th meeting packet.

Please note

- Guests will have 3 minutes to testify.
- Public comment period closes May 5th at 5 PM
- Please do not use your local LIO, as they may be closed

View draft recommendations at https://tinyurl.com/AlaskaPMTF

Alaska Task Force for the Regulation of Psychedelic Medicines

Task Force Report | **PUBLIC COMMENT DRAFT**

April 21, 2025

Instructions for Public Comment

- Public comment will be accepted by the Task Force from **Monday, April 21, 2025** through **Monday, May 5, 2025**.
- E-mail written comments to: Rep.Justin.Ruffridge@akleg.gov. Comments received by 5pm on Monday, April 28 will be included in the Task Force's meeting packet. Comments received later will be shared with the Task Force by e-mail.
- Public testimony will be taken in the next Task Force meeting on Tuesday, April 29, 2025, 5:30-7:00 p.m. at the Alaska Capitol, Butrovich Committee Room 205, Juneau, Alaska, and via the Legislative teleconference system. Testifiers have 3 minutes, and are encouraged to send written comments. See www.akleg.gov for meeting information.
- The Task Force will review and consider all comments received in writing or through verbal testimony, to inform revisions to the recommendations and to prepare the final report to the Legislature in May 2025.

CONTENTS

About the Alaska Psychedelic Medicine Task Force

The Psychedelic Medicine Task Force was created through HB 228 (passed 2024) to deliberate and make recommendations regarding potential implementation of therapeutic use of FDA-approved psychedelic medicine to treat certain mental health conditions. The Task Force is time-limited, and charged with producing a recommendations report to the Legislature in 2025.

Origin of the Task Force: Alaska House Bill 228 (2024)

In 2024, the Alaska Legislature passed House Bill 228, sponsored by Rep. Jennie Armstrong, with companion bill SB 166, sponsored by Sen. Dunbar, to establish a task force to identify implementation needs and potential barriers for future authorization by the FDA of prescription drugs containing psychedelic substances. Use of these medications to treat conditions including anxiety, depression, and PTSD has grown in recent years, with initial promise as a treatment modality, and an emerging evidence base with best practices for psychedelic-assisted therapy.

The FDA is currently reviewing data from multiple clinical trials including use of psilocybin and MDMA, and likely to take action in coming years approving one or more of the therapies under consideration. A few states, including Oregon, Colorado, and New Mexico, have already taken steps to create a regulatory framework for medicinal use, and others (such as Minnesota) have created similar task forces to consider what steps would be needed at the state level, following FDA approval of one or more therapies being evaluated, and prepare recommendations for policymakers and regulators.

Scope and Purpose

HB 228 directs that the Psychedelic Medicine Task Force, with defined membership of designated seats from a variety of perspectives and fields, meet at least four times to consider four topic areas identified in the bill. HB 228 directs that by the end of regular Legislative session (May 2025), the Task Force must produce a report of recommendations to deliver to the Legislature and Governor, to inform future policy decisions. Below is an excerpt of the bill, describing the purpose and scope of the Task Force:

> Purpose: To prepare for potential medicalization of psychedelic medicines by U.S. FDA; to make policy recommendations to the Alaska Legislature concerning insurance and licensure, given the unique nature of the administration of psychedelic medicines; and to ensure the state is prepared if psychedelic medicines become available for prescription.
>
> (1) assess potential use of psychedelic medicine in addressing Alaska's mental health crisis;
>
> (2) consider barriers to implementation and equitable access;
>
> (3) consider and recommend licensing and insurance requirements for practitioners in the state if psychedelic medicines are federally reclassified and approved by the FDA; and
>
> (4) consider legal and regulatory changes that could be necessary in the state after federal medical approval of psychedelic medicines.

Task Force Membership

The following people serve on the Task Force. HB 228 directed appointment of two co-chairs, each from the Senate and House; designated seats for state agencies and other organizations named in the bill; and an option for the Task Force to select an at-large member.

Name	Role	Affiliation
Sen. Forrest Dunbar	Co-chair	Alaska Senate, HB 228 co-sponsor, Attorney
Rep. Justin Ruffridge	Co-chair	Alaska House, Pharmacist
Dr. Robert Lawrence	Designated Seat	Designee, Chief Medical Officer, Dept. Health
Angela Laflamme	Designated Seat	Designee, Dept. Military & Veterans Affairs
Glenn Saviers	Designated Seat	Designee, Dept. Commerce, Community & Economic Development
Justin Heminger	Designated Seat	NAMI Alaska, Board Member
Ann Ringstad	*Alternate*	NAMI Alaska, Executive Director
Dr. Kristen Maves	Designated Seat	Alaska Native Health Board Designee #1, Southcentral Foundation, Pharmacist
Dustin Allen	Designated Seat	Designee, Knik Tribe, Clinical Supervisor
Lauree Morton	Designated Seat	Alaska Network on Domestic Violence and Sexual Assault, Deputy Director
Dr. Paula Colescott	Designated Seat	Alaska State Medical Association
Dr. Lisa Lindquist	Designated Seat	Southcentral Fdn.; AK Psychiatric Assn.
Dr. Michael DeMolina	Designated Seat	Wisdom Traditions Counseling
Dr. Sara Kozup-Evon	Designated Seat	Advanced Practice Registered Nurse Alliance
Dr. Brittany Karns	Designated Seat	Alaska Pharmacy Association
Jennie Armstrong	At-Large Seat	Former Alaska Representative, HB 228 sponsor

The Task Force is supported by legislative staff of the co-chairs, and a contracted facilitator to support the process:

- Arielle Wiggin and Sethan Tigarian, Office of Sen. Dunbar
- James (Bud) Sexton, Office of Rep. Ruffridge
- Tristan Walsh, Office of Rep. Armstrong (through December 2024)
- Anna Brawley, Tiny Birch Consulting (contractor)

Task Force Process

The Task Force was fully constituted in December 2024, with preparatory and logistics work to prepare for official meetings in 2025. The Task Force has scheduled a total of six meetings, with five held as of this draft report's publication, and the last scheduled to hear public comment:

- Meeting 1: Tuesday, February 4, 2025
- Meeting 2: Tuesday, February 26, 2025
- Meeting 3: Wednesday, March 19, 2025

- Meeting 4: Wednesday, April 2, 2025
- Meeting 5: Wednesday, April 16, 2025
- Meeting 6: Tuesday, April 29, 2025 (scheduled, to hear public comment)

Meetings are held in person in Juneau at the Alaska Capitol, Butrovich Committee Room, as well as online, with most members participating by Microsoft Teams; meeting proceedings were livestreamed and are available as recordings at http://www.akleg.gov.

The Task Force adopted Guidelines and Meeting Procedures (*will be attached as appendix in final report*) for conducting meetings, and the process for adoption of recommendations and final approval of the report.

Public Comment Process

Given the time-limited nature and defined scope of the Task Force, the group was required to move swiftly and stay focused on achieving the intent of HB 228. The group also determined that having opportunity for public comment and gathering feedback on a draft product is important. To meet this objective within the timeframe, the group prepared a working draft of the recommendations, and portions of the report still in progress, to publish for public comment over a 14-day period, including an opportunity for testimony at a Task Force meeting. The timeline is as follows:

- Monday, April 21: Draft recommendations and report published, with a notice flyer to share with the general public and interested stakeholders. Written comments to be collected by legislative staff and distributed to the Task Force.
- Monday, April 28: All written comments received by end of day will be packaged and shared with the Task Force with its April 29 agenda packet. (Comments received after this date will also be provided to the Task Force by e-mail, but will be received too late to be included in the packet).
- Tuesday, April 29: Task Force Meeting #6, with public comment period. Public comment will be taken in person in Juneau, via the telephonic legislative testimony system, as well as in writing by e-mail.
- Monday, May 5: Closing date for written public comment.
- May 2025 (date TBD): Task Force considers all public comments, revises recommendations, and takes final vote to approve the report.

About Psychedelic Medicine Therapies

Overview of Psychedelic Medicines

Psychedelics (meaning “mind-manifesting,a term coined by Humphrey Osmond), are a varied group of plant-derived synthetic compounds that have in common the ability to produce sensory, perceptual, and cognitive changes without impairing attention or level of consciousness.

They do so by influencing communication networks in the brain that depend on a host of chemicals released by the billions of neurons in the brain. These chemicals are called neurotransmitters; these neurotransmitters affect the neighboring neuron by attaching to a particular receptor on that neuron eliciting its response. This communication between neurons is called neurotransmission.

Mescaline, psilocybin, and LSD belong to a class called *phenyethylamines* which are considered the classic hallucinogens. These compounds influence Serotonergic neurotransmission by binding to the neurons which have the 5HT2 receptor on their surface membrane.

The most prominent subjective effects of the classic Hallucinogens are influenced by set and setting, that is, the expectations and personality of the person who uses hallucinogens, coupled with the environmental and social conditions of use. Mood can vary from euphoria and feelings of spiritual insight to depression, anxiety, and terror. Perception usually is intensified and distorted, and alterations in the sense of time, space and body boundaries. While illusions (visual and auditory distortions of perception) are common, true hallucinations (perceptions that do not have any basis in reality) are not. Synesthesia, a blending of the senses wherein colors are heard, and sounds are seen is a common perceptual distortion. Cognitive function may range from clarity to confusion and disorientation, although reality testing usually remains intact. include alterations in perception, cognition, affect, sense of meaning, and/or sense of self. Psilocybin has been researched for the treatment of Depression.

There is a small group of compounds similar in structure, but whose pharmacology differs from the classic hallucinogens. They have been named ENTACTOGENS with the prototype being MDMA, Entactogen is derived from the roots “en” (Greek, within), “tactus” (Latin, touch), and “gen” (Greek, produce) connoting substances that “produce a touching within.” Entactogens have a mechanism of action and subjective effects distinct from the classic hallucinogens. While these substances affect emotion and promote social interaction, they do not produce the major alterations in sensory perceptions that are typical of the classic hallucinogens (5). MDMA is being proposed for the treatment of PTSD.

Status of Applications for US Food & Drug Administration (FDA) Approval

The goal of phase I studies with the Food and Drug Administration (FDA) is to establish initial safety in humans, which occurs after preclinical laboratory and animal testing have been completed. The drug is given to a small number of healthy volunteers. Side effects and dose ranges are determined. As of April 2025, there are 23 psychedelic compounds undergoing phase I trials registered with the FDA.

In phase II the drug is tested in a small number of volunteers who have the condition the drug is intended to treat. Safety data across a range of doses is collected. Conclusions to efficacy cannot be drawn due to small sample sizes, but the information gathered guides the protocols for phase III studies. There are 31 psychedelic drugs in phase II trials registered with the FDA.

Phase III trials determine a drug's safety and efficacy in a large group of patients with the identified condition or disease. Due to the large number of patients required to complete the study, these typically occur at multiple study sites both within the US and internationally. Typically two phase III studies are needed to provide sufficient evidence of efficacy.

There are six compounds in phase III studies registered with the FDA as of April 2025:

Compass Pathways	Comp360 (Psilocybin)	Treatment Resistant Depression
Usona Institute	Psilocybin	Major Depressive Disorder
Cybin	CYB003 (Deuterated Psilocybin Analog)	Major Depressive Disorder
MindMed	MM120 (LSD D-Tartrate ODT)	Generalized Anxiety Disorder
Awakn	Ketamine	Alcohol Use Disorder
Lykos Therapeutics	MDMA	Post-Traumatic Stress Disorder

Once a drug has completed phase III studies, a drug company will submit a New Drug Application to the FDA. The FDA reviews information from preclinical studies through phase III studies, weighing the risk versus benefit of a given drug for the condition indicated. If approved, a pharmaceutical will be eligible for sale and marketing in the U.S. A typical review time for the FDA to decide on a NDA is 10 months.

At times the FDA may grant an investigational drug Breakthrough Therapy Designation (BTD), the goal of which is to expedite development and review of treatments for serious or life threatening conditions for which there is an unmet medical need. For drugs that receive BTD designation, the FDA is more involved in the phase III study design, potentially shortening the time to review. Between 2017 and 2025, five psychedelic compounds have received BTD. These include MindMed's MM120 LSD analog for generalized anxiety disorder, Cybin Inc's CYB003 (Psilocybin) for major depressive disorder, Compass Pathway's COMP360 (Psilocybin) for treatment resistant depression, Usona Institute's psilocybin for major depressive disorder, and Lykos therapeutics MDMA for post-traumatic stress disorder.

Given the number of psychedelic compounds in phase III trials with the FDA that have breakthrough therapy designation, it is not unreasonable to imagine an FDA approved psychedelic medicine being available in our community by 2027.

Current and Emerging Best Practices[1] for Use of Psychedelic Medicine-Assisted Therapies

In accordance with HB 228, and informed by the Task Force's review of national protocols, ethics frameworks, and practitioner training models, the following best practices are recommended to guide the safe, effective, and culturally responsive use of psychedelic-assisted therapies in Alaska once federally approved.

Therapeutic Care Model

The preferred model for administering psychedelic medicines in a therapeutic setting follows a structured, tri-phasic process:

1. Preparation sessions focus on screening, consent, safety planning, and rapport-building.
2. Medicine sessions involve supervised administration of the psychedelic compound in a controlled, supportive setting.
3. Integration sessions assist the participant in meaning-making, emotional processing, and translating insights into behavior change.

This model has been consistently supported in practitioner manuals, ethics codes, and training curricula and is expected to reflect protocols outlined by the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) upon scheduling.

Professional Roles and Competency Standards

Best practice treatment delivery for psychedelic-assisted medication requires a multidisciplinary team consisting of licensed prescribers, trained facilitators, integration therapists, and program supervisors. Practitioners should demonstrate proficiency in:

- Trauma-informed, Trauma-Sensitive care
- Navigating states of consciousness
- Cultural and psycho-spiritual responsiveness
- Risk identification and emergency response
- Professional ethics and reflective practice.

Standards established by the State of Colorado are a useful model for consideration for non-licensed facilitators, who still require training and certification to perform this function. Colorado's regulatory structure provides a comprehensive and scalable model for non-licensed individuals, including those without formal degrees in counseling or mental health. Specifically, Colorado requires a minimum of 150 hours of didactic instruction covering ethics, trauma-informed care, safety protocols, and cultural competence; 40 hours of supervised practicum; and 50 hours of consultation. These requirements ensure that facilitators are adequately prepared to support individuals through psychedelic experiences with professionalism and clinical sensitivity.

[1] Current at the time of publication; the evidence base is expected by the Task Force, and clinical community at large, to change over time as additional research and evaluation is conducted.

Ethical and Safety Guidelines

All psychedelic care providers should adhere to a codified set of ethical standards, including:

- Voluntary, informed consent
- Maintenance of ethical and professional boundaries in Pre-, Post-, and during non-ordinary states
- Strict confidentiality and documentation practices
- Harm-reduction strategies for emotional and physical safety.

The Multidisciplinary Association for Psychedelic Studies (MAPS) Code of Ethics[2] and guidance from the American Psychedelic Practitioners Association (APPA), offer foundational frameworks.

Adaptations for Alaska's Geography and Populations

Given Alaska's unique geographic and health access challenges, existing best practices must be adapted to rural and remote communities. These may include:

- Telehealth platforms for preparation and integration
- Hybrid in-home models with safety protocols adapted from anticipated nationally approved standards
- Clinic partnerships for medicine administration
- Respectful collaboration with tribal health entities and Indigenous providers.

DRAFTING NOTE: The final report will include additional information about best practices as currently established at the time of this publication.

[2] Link to MAPS Code of Ethics, adopted 2021 and revised 2022: https://maps.org/wp-content/uploads/2022/06/MAPS_Psychedelic_Assisted_Psychotherapy_Code_of_Ethics_V4_22_June_2022_Final.pdf

Recommendations

The Task Force is directed to consider the four following topics, with recommendations about how to address these topics:

1. *Potential Therapeutic Use*
2. *Implementation and Access*
3. *Licensing and Insurance Requirements*
4. *Potential Legal and Regulatory Changes*

The Task Force has prepared the following draft findings and recommendations for feedback. Recommendations are not categorized into the four topics, but have been formed as the group considers each topic and how they are interrelated questions.

Draft Findings for Public Comment

1. **Finding**: The Task Force has reviewed the available literature on psychedelic medicine therapies, as well as their status in FDA review, and determined that the available evidence suggests there are potential therapeutic uses.

2. **Finding**: The current evidence base and best practices indicate that effective use of psychedelic medicines for treatment of certain mental health conditions, such as treatment-resistant PTSD, means medicines are used in a treatment setting as part of an overall psychotherapeutic approach, and not simply self-administered. Furthermore, this requires a team approach, with potentially multiple provider types playing roles in the treatment process, from medical evaluation and psychological assessment, to prescribing medications, to ongoing monitoring during patient sessions.

3. **Finding**: Alongside FDA approval, the DEA would be expected to re-schedule certain psychedelic substances with medical uses. If the DEA re-scheduled psychedelic medicines as a Schedule II, III, and IV controlled substances, the medications would be subject to the requirements (and exemptions) of the Alaska Prescription Drug Monitoring Program (PDMP).[3]

4. **Finding**: The current clinical evidence and experience with other behavioral health therapies indicates that a team approach to care is important, including a team of providers who may be playing distinct roles in the treatment, with differing types of licensing and credentials. For example, a medical doctor may be authorized to prescribe the medications, while a registered nurse may administer the medication, and a health aide may be responsible for monitoring the patient during a medication session.

5. **Finding**: Consent is especially important with psychedelic therapy, and requires meaningful work to inform and educate the patient about the process, establish clear boundaries and informed consent before treatment begins, with decisions about how

[3] See Alaska Board of Pharmacy statutes and regulations, pp. 56-58. Link: https://www.commerce.alaska.gov/web/Portals/5/pub/PharmacyStatutes.pdf

treatment will be provided, what type(s) of facilitator or other providers the patient will work with, determining consent for interaction before, during, and after treatment sessions (for example, what types of touch the patient consents to, or does not consent to), and generally establishing the patient has provided informed consent.

6. **Finding**: The Task Force discussed at length, but did not make a definitive recommendation, about whether a non-licensed facilitator model (such as one modeled on the regulatory structure in place in the state of Oregon) would be appropriate for use in Alaska. The group considered role(s) for non-licensed providers, and made recommendations for certification, but did not take a position on whether or not to consider an equivalent model to that of Oregon.

Draft Recommendations for Public Comment

1. **Recommendation**: If and when psychedelic medicine therapies are FDA approved, the state should take action to allow for their use in Alaska, rather than prohibiting use.

2. **Recommendation**: Identify clinical working group(s) whose function is to regularly review updated studies and the evidence base to make recommendations, and rely on these entities to provide ongoing guidance on use of these therapies.

3. **Recommendation**: To the extent possible, reserve use of state statute for broad enabling language and key components of a regulatory structure, and leave most regulatory decisions to the relevant boards and agencies. Regulations still require robust public process in order to be adopted, but can be updated or modified more predictably and easily than statute changes, which require an act of the Legislature. It is likely that appropriate parameters for use of these therapies will change over time, as the evidence base matures and FDA approval may be granted for multiple therapies.

4. **Recommendation**: If and when psychedelic medicine therapies are FDA approved, the Alaska State Medical Board should update the Guidelines for Prescribing Controlled Substances to include appropriate use of psychedelic medication for approved indications.

5. **Recommendation**: If and when psychedelic medicine therapies are FDA approved, the Alaska Board of Nursing should develop and adopt an advisory opinion on the use of FDA approved psychedelic medications in non-acute settings.

6. **Recommendation:** If and when psychedelic medicine therapies are FDA approved, and if pending legislation to expand Pharmacist prescriptive authority (SB 147 introduced in 2025, or a future bill) is passed, the Alaska Board of Pharmacy should develop and adopt an advisory opinion on the use of FDA approved psychedelic medications in non-acute settings by pharmacists working under collaborative agreements.

7. **Recommendation**: Regulate uses of these products according to evidence-based treatment protocols. Depending on the therapies and substances approved for clinical

use, there may be multiple approved ways to administer these medications, such as micro-dosing (taking small amounts) or conducting a session via telehealth.

8. **Recommendation**: The State should consult with the existing Controlled Substances Advisory Committee, established in AS 11.71.100, who should:
    - Recommend regulations to the Board of Pharmacy regarding the prevention of excessive prescribing and the diversion of newly approved drugs.
    - Evaluate the effectiveness of treatment resources for persons with existing substance use disorders stemming from use of the psychedelic class of drugs.
    - Evaluate the enforcement policies and practices regarding crimes involving controlled substances.
    - Review budget requests and recommend appropriations regarding the building out of regulations around handling of FDA approved psychotropic medications.
9. **Recommendation**: Align licensing and credentialing requirements for providers with treatment models in evidence-based therapies, with attention to what each provider is authorized to do.
10. **Recommendation**: Upon FDA approval and DEA scheduling, the State should fully mirror federal scheduling and Risk Evaluation and Mitigation Strategies (REMS) without adding duplicative or conflicting state rules, and whether DEA licensure is required for prescribers. This approach respects federal science and streamlines access for patients and providers.
11. **Recommendation:** To ensure safety and prevent diversion, the Task Force recommends integrating psychedelic medicines into the Alaska Prescription Drug Monitoring Program (PDMP) upon federal scheduling. This would allow for real-time monitoring of prescribing and dispensing, with no major new cost to the State.
12. **Recommendation**: Develop a pathway for a non-licensed psychedelic facilitator role, with a State-issued certification requirement that includes any necessary required training for monitoring patients during treatment. Benefits of this pathway include increased access to psychedelic care that is a cultural fit to the preferences and needs of the patient as well potentially increasing access to psychedelic care by decreasing costs. Potential models for this role include the Community Health Aide Program (CHAP), as well as the Traditional Healers track of the Alaska Commission for Behavioral Health Certification process.Topics may include training in heart rate and oxygen level monitoring, emergency and first aid response if the patient experiences an emergency during treatment. State certification of non-licensed providers also provides regulatory and enforcement oversight by the State, which increases patient protection.
13. **Recommendation**: The State should determine what training(s) and continuing education are necessary to maintain a license, endorsement on a license, certification, and/or demonstrating competency in their scope of practice, such as prescribing authority. The State should also consider how providers can access appropriate trainings and certification based on FDA guidance and other clinical sources. If there is current federal

guidance or requirements for training, the State should follow these; if this does not exist at the time of FDA approval, it may require the State to establish training requirements or guidelines in the interim to address this need.

14. **Recommendation:** In developing Alaska's training and certification framework for psychedelic-assisted therapy facilitators, the Task Force recommends modeling the standards established by the State of Colorado. Adopting a similar model in Alaska will support public safety, uphold ethical standards, and ensure statewide consistency while maintaining accessibility for rural and Indigenous communities.

15. **Recommendation**: Allow prescription and/or administration authority for any provider with existing authorizations for controlled substances, if the treatment is within their scope of practice and consistent with their training.
Includes: Physicians, physician assistants (PAs) with dispensing authority, advanced practice registered nurses (APRNs) with dispensing authority.
Pending/Potential: Pharmacists with dispensing authority (Alaska SB 147).
Excludes: Dentists, veterinarians, and optometrists.

16. **Recommendation**: Treatment and access to prescriptions should not occur through use of standing orders of medication, but regardless of setting and provider, the patient should first undergo both medical and clinical evaluations to determine the treatment is appropriate.

17. **Recommendation**: The State must consider Alaska's unique geographic and health access challenges, particularly for rural and remote communities. Creating regulatory systems for provider licensing and credentialing, defining methods of accessing and delivering treatment, and considerations for culturally appropriate practices, should take into account the challenges and limited capacity of rural health systems. This includes methods for patient access, such as whether preparation and integration sessions (non-medication sessions) could be conducted through telehealth; it also includes considerations for what provider types and pathways for certification exist, such as the proposed equivalent to the Traditional Healer track (*see Recommendation 12*).

18. **Recommendation**: A code of ethics should be created, or adopted by reference, for all providers engaged in psychedelic-assisted therapy, and integrate this code of ethics into any required licenses, certifications, or other roles who work with patients. This is important not only for upholding high standards of care, but also provides codified expectations on providers, given the nature of the therapy and potential for patient harms if violations of boundaries, consent, or other ethical issues occur.

19. **Recommendation**: The State should establish requirements for informing patients of their rights, as well as a venue and process for addressing grievances. For example, requiring postings or notices about patients' rights and what to expect; requiring a consent form signed by the provider and patient before treatment begins; publishing where and how to report grievances; and (likely through a certification or endorsement system for providers), establishing which entity(ies) have authority to take action in the case of grievances.

20. **Recommendation**: Health care payors (insurers) should uniformly and equally apply reimbursement rates for the same type of health care service or supply and for health care providers who are practicing within their scope of their license and who are authorized to bill for health care services or supplies under the current CPT codes adopted by the AMA or other industry standard method of coding.

21. **Recommendation**: Regarding determining the amounts to be billed: Medicaid Pharmacy and Therapeutics committee will need to consider the availability of this drug and determine the structure for prior authorization as well as what can be billed for.

22. **Recommendation**: Medicaid Pharmacy and Therapeutics committee shall consider the pricing of the medications that fall within the category of Psychedelic medication to be part of the Medicaid pharmacy benefits, rather than part of a “buy and bill” model which hinders access.

23. **Recommendation**: Advocacy is needed to ensure active efforts by the American Medical Association, (AMA) and Centers for Medicare & Medicaid Services, (CMS) on developing billing codes that will promote sufficient reimbursement for psychedelic therapy delivery are vital to ensuring patient access post-FDA approval.

DRAFT EXAMPLE: *Alaska Psychedelic Practitioner Credentialing Matrix*

This table is an illustrative example of defined provider roles that could be recognized for delivering psychedelic-assisted therapies, as well as required experience, training, competencies, and applicable certification(s). This example is provided for consideration, and is not a specific recommendation of the Task Force.

Role	Experience Required	Practicum Hours	Training Hours	Required Competencies	Reference Requirements	Certification or Endorsement
Psychedelic Facilitator (Entry-Level)	None (Entry-level support role under supervision)	# hours direct observation Internship # hours Consultation	# contact hours in ethics, somatics, safety, documentation, cultural awareness	Basic understanding of psychedelic care, Ethics, boundaries, Trauma- Informed Care, Cultural Considerations, Support techniques	# personal or professional references	Completion of approved training program and supervisor sign-off
Certified Psychedelic-Assisted Therapy Practitioner (Licensed)	# years (# hours) clinical experience	# hours supervised Trauma-Informed / Trauma Sensitive practicum	# contact hours including pharmacology, trauma care, ethics, integration therapy	Trauma- informed care, altered states navigation, cultural humility	# references, # from a licensed supervisor	State-recognized certification or license in mental health field
Traditional Healing Practitioner (THP)	Community-recognized experience in traditional healing practices	Community-verified training or mentorship under recognized traditional practitioners	Flexible; documentation of oral/traditional transmission or cultural training accepted	Ability to guide healing practices using cultural and spiritual knowledge	# community-based references (tribal, spiritual, elder-based)	Endorsed by tribal council, spiritual authority, or cultural review board

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Medical Board	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22	FY 23	Biennium	FY 24	FY 25 1st -3rd QTR
Revenue											
Revenue from License Fees	$ 347,304	$ 2,380,618	$ 2,727,922	$ 578,308	$ 2,597,830	$ 3,176,138	$ 945,106	$ 2,876,309	$ 3,821,415	$ 852,030	$ 2,457,966
General Fund Received					$ -	-	$ 272,744	$ 173,090	445,834	$ 40,368	$ -
Allowable Third Party Reimbursements	3,517	184	3,701	$ -	$ -	-	$ -	$ -	-	$ 1,071	$ -
TOTAL REVENUE	$ 350,821	$ 2,380,802	$ 2,731,623	$ 578,308	$ 2,597,830	$ 3,176,138	$ 1,217,850	$ 3,049,399	$ 4,267,249	$ 893,469	$ 2,457,966
Expenditures											
Non Investigation Expenditures											
1000 - Personal Services	488,823	473,122	961,945	420,810	521,976	942,786	446,216	454,584	900,800	507,288	456,804
2000 - Travel	17,577	15,801	33,378	13,357	-	13,357	8,875	1,471	10,346	3,442	-
3000 - Services	44,741	31,730	76,471	23,009	46,044	69,053	69,997	97,210	167,207	93,406	17,531
4000 - Commodities	2,016	1,525	3,541	1,252	1,290	2,542	3,278	3,045	6,323	2,972	2,078
5000 - Capital Outlay	-		-	-	-	-	-	-	-	-	-
Total Non-Investigation Expenditures	553,157	522,178	1,075,335	458,428	569,310	1,027,738	528,366	556,310	1,084,676	607,108	476,412
Investigation Expenditures											
1000-Personal Services	210,010	226,965	436,975	264,001	272,106	536,107	289,348	336,511	625,859	411,332	258,234
2000 - Travel		2,104	2,104	2,032	-	2,032	2,655	-	2,655	-	-
3023 - Expert Witness	1,700	7,577	9,277	16,050	22,775	38,825	31,350	14,000	45,350	39,107	3,300
3088 - Inter-Agency Legal	60,885	34,329	95,214	56,267	33,435	89,702	42,629	208,613	251,242	484,830	276,927
3094 - Inter-Agency Hearing/Mediation	9,299	28,803	38,102	18,640	911	19,551	11,870	61,195	73,065	164,138	105,078
3000 - Services other		3,348	3,348	1,919	625	2,544	1,257	2,126	3,383	1,112	787
4000 - Commodities		-	-	-	-	-	-	-	-	126	-
Total Investigation Expenditures	281,894	303,126	585,020	358,909	329,852	688,761	379,109	622,445	1,001,554	1,100,645	644,326
Total Direct Expenditures	835,051	825,304	1,660,355	817,337	899,162	1,716,499	907,475	1,178,755	2,086,230	1,707,753	1,120,738
Indirect Expenditures											
Internal Administrative Costs	225,669	263,046	488,715	285,614	316,771	602,385	250,301	286,502	536,803	250,148	187,611
Departmental Costs	150,736	168,176	318,912	123,361	143,500	266,861	122,427	120,114	242,541	143,482	107,612
Statewide Costs	78,101	72,595	150,696	90,219	108,989	199,208	92,456	86,033	178,489	88,909	66,682
Total Indirect Expenditures	454,506	503,817	958,323	499,194	569,260	1,068,454	465,184	492,649	957,833	482,539	361,905
			-			-					
TOTAL EXPENDITURES	**$ 1,289,557**	**$ 1,329,121**	**$ 2,618,678**	**$ 1,316,531**	**$ 1,468,422**	**$ 2,784,953**	**$ 1,372,659**	**$ 1,671,404**	**$ 3,044,063**	**$ 2,190,292**	**$ 1,482,643**
Cumulative Surplus (Deficit)											
Beginning Cumulative Surplus (Deficit)	$ 137,265	$ (801,471)		$ 250,210	$ (488,013)		$ 641,395	$ 486,586		$ 1,864,582	$ 567,759
Annual Increase/(Decrease)	(938,736)	1,051,681		(738,223)	1,129,408		(154,809)	1,377,996		(1,296,823)	975,322
Ending Cumulative Surplus (Deficit)	$ (801,471)	250,210		$ (488,013)	$ 641,395		$ 486,586	$ 1,864,582		$ 567,759	$ 1,543,081
Statistical Information											
Number of Licenses for Indirect calculation	7,138	8,421		9,801	12,808		8,259	9,221		7,676	

Additional information:

- *General fund dollars were received in FY21-FY24 to offset increases in personal services and help prevent programs from going into deficit or increase fees.*
- *Most recent fee change: Fee reduction FY25*
- *Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.*

Appropriation Name (Ex)	(Multiple Items)
Sub Unit	(All)
PL Task Code	MED1

Sum of Budgetary Expenditures	Object Type Name (Ex)			
Object Name (Ex)	1000 - Personal Services	3000 - Services	4000 - Commodities	Grand Total
1011 - Regular Compensation	367,624.61			367,624.61
1014 - Overtime	873.80			873.80
1021 - Allowances to Employees	288.00			288.00
1023 - Leave Taken	67,947.30			67,947.30
1028 - Alaska Supplemental Benefit	26,782.66			26,782.66
1029 - Public Employee's Retirement System Defined Benefits	27,025.61			27,025.61
1030 - Public Employee's Retirement System Defined Contribution	17,675.07			17,675.07
1034 - Public Employee's Retirement System Defined Cont Health Reim	11,276.74			11,276.74
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	2,783.70			2,783.70
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	58,020.65			58,020.65
1039 - Unemployment Insurance	270.11			270.11
1040 - Group Health Insurance	108,460.49			108,460.49
1041 - Basic Life and Travel	9.22			9.22
1042 - Worker's Compensation Insurance	2,433.27			2,433.27
1047 - Leave Cash In Employer Charge	10,060.58			10,060.58
1048 - Terminal Leave Employer Charge	6,636.87			6,636.87
1053 - Medicare Tax	6,130.19			6,130.19
1069 - SU Business Leave Bank Contributions	186.00			186.00
1077 - ASEA Legal Trust	346.38			346.38
1079 - ASEA Injury Leave Usage	40.39			40.39
1080 - SU Legal Trst	165.96			165.96
3002 - Memberships		3,881.00		3,881.00
3023 - Expert Witness		3,300.00		3,300.00
3026 - Transcription/Record		93.77		93.77
3035 - Long Distance		89.52		89.52
3036 - Local/Equipment Charges		9.84		9.84
3045 - Postage		696.23		696.23
3057 - Structure, Infrastructure and Land - Rentals/Leases		134.64		134.64
3085 - Inter-Agency Mail		71.94		71.94
3088 - Inter-Agency Legal		288,876.23		288,876.23
3094 - Inter-Agency Hearing/Mediation		106,470.00		106,470.00
4005 - Subscriptions			2,077.50	2,077.50
Grand Total	**715,037.60**	**403,623.17**	**2,077.50**	**1,120,738.27**

ALASKA PDMP

PRESCRIPTION DRUG MONITORING PROGRAM

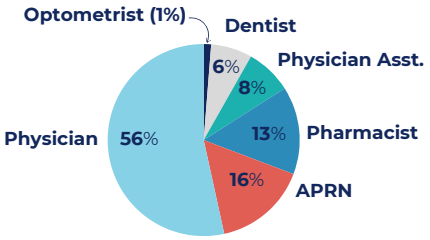
Q1 2025

78,071 PATIENTS

Alaskan patients receiving at least one controlled substance prescirption.

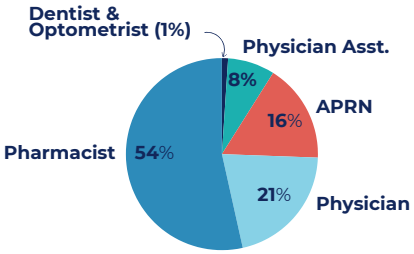
8,723 REGISTERED USERS

% registered by license type, excluding IHS, military, VA, and delegates.



300,303 SEARCHES

% of searches by user type, excluding IHS, military, VA, and delegates.



85% EHR ACCESS

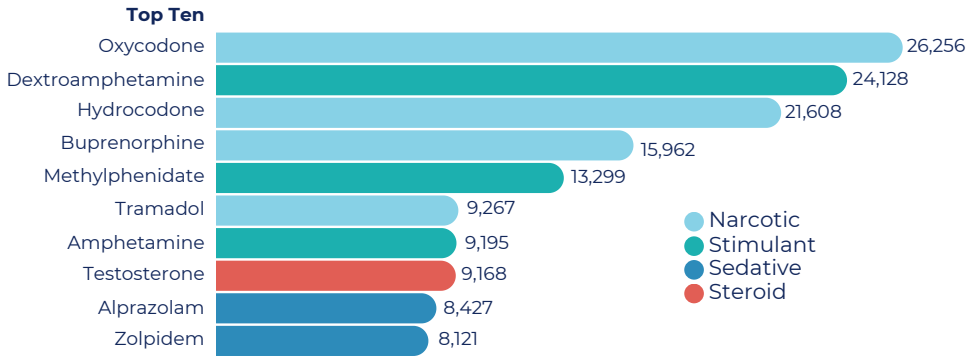
% of providers using electronic health record system (EHR) integration to search patient information within their clinical workflow.

246 DISPENSERS

Pharmacies or dispensing providers with at least one controlled substance dispensation to Alaska patients.

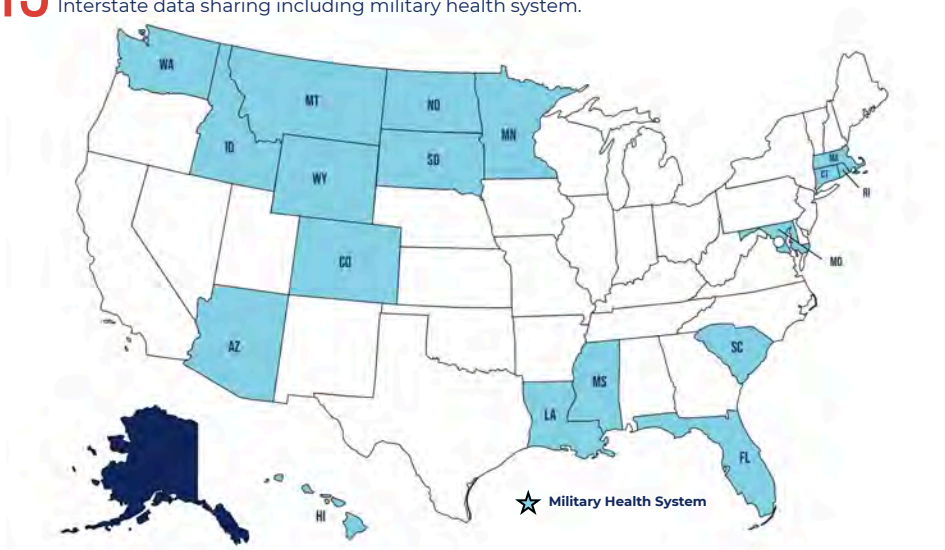
Data is presented for informational purposes only. Data represents prescription and dispensation activity reported to Alaska Prescription Drug Monitoring Program (PDMP) from January 1, 2025 to March 31, 2025. For more in formation, visit pdmp.alaska.gov.

188,221 CONTROLLED SUBSTANCE DISPENSATIONS

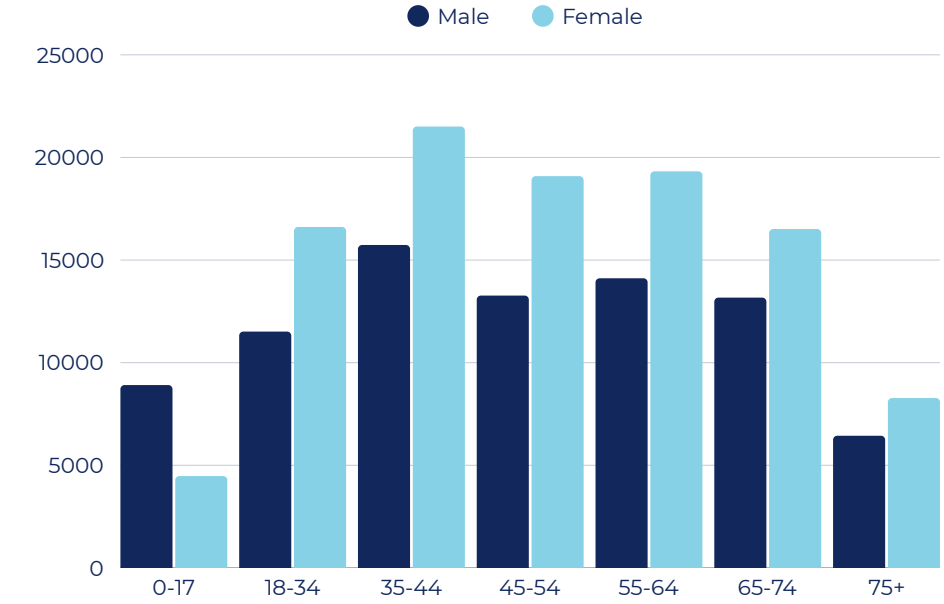


19 PARTNER STATES

Interstate data sharing including military health system.



PRESCRIPTION COUNT BY PATIENT AGE & GENDER



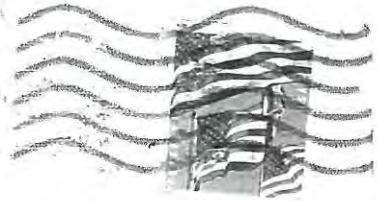
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing

Dear Alaska State Medical Board,

I am writing You regarding Your statements regarding a position of opposition to gender affirming Care. As a Hospital Social worker I wanted to sternly remind You of the medical oath of "Do no harm" - And appeal to Your Humanity as it appears to be Lacking. Finally I would also Like to appeal to Your Curiosity - is it possible that the same age ~~d~~ Youth who Decide they Desire Breast reduction or Hair removal? I noticed those statements didn't take Situations Like these in Consideration → ~~Roasted~~ Bluntly Because Your Statements were exceedingly Narrow minded & Bigotted as well as influenced by what I Can only assume is Your religion which has No Part in Your Duties as Doctors or a State Medical Board. Stay in Your Lane. get to know Some transgendered Patients And be Better Thank You, Kathryn Hickman MSW

Katie Hickman
2802 Klamath Dr.
unit B
Anchorage, AK 99517

ALASKAN FRONTIER
995-997
9 MAY 2025 PM 1 L



Alaska Medical Board
550 W 7th Ave
Ste. 1500
Anchorage, AK 99581-3567

Received
Anchorage
MAY 10 2025
CBPL

Received
Anchorage
MAY 10 AM
CBPL

99501-355775

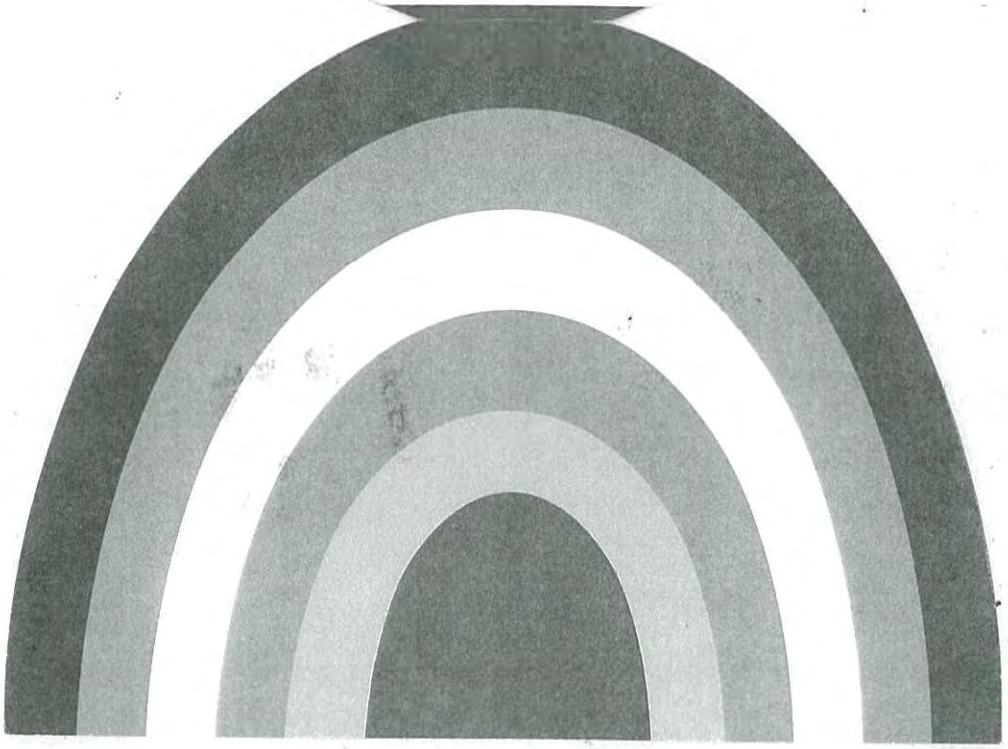
Hello AK Medical Board,

You recently issued a statement opposing gender-affirming care for AK trans youth. As an Alaskan resident, I find this deeply concerning and very dangerous. There are mountains of research, let alone the testimony of thousands of trans adults nationwide, showing the high risk for suicidality and self-harm in trans youth when they are denied gender-affirming care. Trans people need you to listen to them — when they tell you gender-affirming care keeps kids alive, it's true! The medical board must rescind this statement immediately

AK youth already face enough challenges. Let's not make life harder. Let them live. Help them thrive. Let kids ~~grow~~ be kids.

Trans lives matter.

Sincerely,
Kayla J Ewert
Anchorage, AK



From: Marilyn Wick <bquickr3@gmail.com>
Sent: Thursday, April 17, 2025 8:58 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Sexual transitioning of minors

Having missed the zoom comments, i would like to express my opinions regarding this highly controversial area of 'medical treatment'.

Having 5 adult children, one of whom is lesbian, I am aware of different perceptions/understandings or lack thereof. I have delved much into homosexuality, and also into/about sexually transitioning into the opposite sex; pros & cons.

Transitioning out of nowhere started popping up in high society; their circles of friends, acquaintances. It seems a fad, a status symbol to have A CHILD who has been transitioned. In school settings, it has been encouraged more by progressive teachers, counselors under a cloak of secrecy, as being, THE ANSWER ALL to confused or questioning kids/teens as to who they are and why.

As a kid, I was teased a lot & called Pork Chops by my siblings. I wasn't fat, but unlike my taller, thinner siblings was shorter, slightly chubby. I was a tomboy, happy in the woods & being my Dad's helper. Around age 12, I became very insecure, suicidal. Entering Jr High from a country school; all new people, no real friends, I became less confident in who I was; was I even pretty compared to other girls, was I fun to be around? Thankfully I had 2 horses as my friends. I made it through the rough years.

Why can't people just let kids be kids, go through their awkwardness with a little extra love, reassurance & stories shared of awkward times between parents & kids, instead of deciding the kid JUST needs to have their entire being ALTERED, their biological chemistry & physical attributes all castrated? Think they were confused before, alter who they are into someone sexually different, guaranteed, mental issues will surely crop up. The kids may get kudos from online acquaintances, adults or popular school mates, but transitioning, a minor, disfiguring, sterilizing minors without them knowing & understanding the lifelong ramifications involved is a horrible choice to make for any MINOR who has NO UNDERSTANDING of what will be happening FOR THEIR ENTIRE LFE! That is something an adult has encouraged a minor to undertake, an unjustified travesty. When the child fully matures into a adult with a completely developed brain, at that point if they choose to transition,& are aware of everything associated with transitioning; go for it. Their body, their choice, their life.

Dr. Beal, totally in favor of medically transitioning minors, claims she has seen? Read? THOUSANDS of scientific studies in support of successful transitions; I find that doubtful. I have seen mental instability in numerous cases as reported in the news, have read and watched documentaries declaring grooming played a convincing part, stating that for the grooming, the transitioning wouldn't have occurred as they had serious doubts about the entire procedure.

Dr Beal professes to have aided a 15-year-old male transition; wonder how well he'll be doing in another 10-15 years? Not enough documented long-term follow-ups to date have occurred to be scientifically reviewed & proved as a positive procedure.

Another thing, regarding Dr. Beal, founder of Queer Doctors; although she is a licensed practicing physician, she herself admits she has not been trained in pediatric transitioning.

I fully get why, as founder of Queer Doctors, a money making, mutualization of minors who have NO UNDERSTANDING or SAY about it, she would be pushing for the State Medical board to give approval, a green GO AHEAD, completely safe, with no serious negativities associated with the procedures performed, and to recommend that the AK legislature AND Governor's office give a thumbs up.

A side note;

My youngest daughter is lesbian, married to another women. She is the GORGEOUS police deputy/ husband, provider. As a kid never would take a shower & ALWAYS wore baggy boy clothes, sagging pants. She views transitioning as an unhealthy choice, stating, "its hard enough living life as a gay person as acceptance by others is not necessarily offered. However, I am aware of societal boundaries and in respecting others, I am, we are careful to not be TOO GAY around families & other social activities".

BAN sexual transitioning of ANY MINOR.

Thank you,

Marilyn Wick

From: Waynette Coleman <swcburkhardt@gmail.com>
Sent: Thursday, April 10, 2025 1:51 PM

To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Transgender treatment.

Dear Medical board of AK

Thank you for being on the side of true science and the welfare of our young people. I personally applaud your stance on the no chemical, no body mutilation etc…of our youth. Thank you for being for the person. First do no harm.

The act of transitioning a youth before they fully appreciate their minds and bodies is certainly criminal. Furthermore, as a tax payer my dollars should not be spent on extreme elective surgeries and drugs. Nor as a follower of Christ am I supporting any of this.

Again, I thank you.

Waynette Coleman retired RN

Ninilchik, AK

-----Original Message-----
From: finley@ak.net <finley@ak.net>
Sent: Monday, March 31, 2025 1:02 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Recent letter you sent to the legislature

Dear Sirs and Madam,

From the press, I understand you, as a Board, have sent a letter to the legislature recommending making care for transgender minors illegal. I am an adult cardiologist so I am not involved directly in this issue. However, I am aware pediatricians and others are not of the same conviction as the Board regarding this issue. Nationally, the Board's apparent opinion is not generally accepted among the medical community at large. Witness the recent article in the March 13/20, 2025 New England Journal of Medicine.

Admittedly, I have not seen the actual letter you sent, as you apparently were not seeking comment before sending the letter. However, it appears the decision to send this letter is based on personal and political beliefs and is not based on generally accepted medical opinion. The recommendation to prohibit competent, conscientious physicians from pursuing the practice of medicine according to their training and beliefs is an unfortunate and unnecessary self limitation on the practice of medicine.

John C Finley MD, FACC, FASE

Practicing Physician in the State of Alaska for 50 years.

From: Rachel Samuelson <samuelson.rachel@gmail.com>
Sent: Sunday, March 30, 2025 10:41 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: In Regards to the Alaska State Medical Board's statement on gender affirming are in minors

Hello Members of the Alaska State Medical Board,

I'm Dr. Rachel Samuelson, family medicine physician and lifelong Alaskan. I was quite surprised and dismayed to see your statement, out of the blue, about gender affirming care for minors. I have a couple of concerns with this:

1. While I don't personally provide gender affirming care for minors, I know and understand how important this work is. There have been over 21 peer-reviewed studies on transgender youth, and all the following medical associations support access to transgender medical care as medically necessary and life-saving: The American Medical Association, American Psychiatric Association, American Academy of Pediatrics, and the American Academy of Child and Adolescent Psychiatry. We know that without appropriate and individualized evidence-based medical care (along with psychological care) for minors with gender dysphoria, people have increased rates of depression and anxiety, increased suicidal ideation and suicide attempts, and decreased self-esteem and life functioning. We know that not all minors with gender dysphoria need or want hormonal treatment. But those that do need it, and receive this care after very careful consideration, have such improved lives. It is cruel to consider denying them this essential healthcare.

2. I'm concerned that this was a politically motivated statement. There are many pressing issues in the area of medicine in Alaska (maternal mortality, HIV epidemic, concern for avian flu and measles, to just name a few), and I was surprised that the board chose to comment on this one, in these already politically charged days.

3. I'm sure you are aware of Alaskan's constitutionally encoded right to privacy regarding their medical care. If we start to legislate on one issue, what is to stop the legislature from

trying to regulate a whole host of other issues in the future? I do not think this will sit well with our independent- thinking state.

I do want to say, despite my concerns above: I really do appreciate all the work you all do on the board to keep the public's trust in physicians, PAs and podiatrists. Without you, it would be a medical wild west out here. Thank you for doing the tough work that very few want to do. You do very important work and I am grateful for it.

Sincerely,

Rachel Samuelson, MD

-----Original Message-----
From: Sherri Jackson <sj_wyoak@yahoo.com>
Sent: Thursday, March 27, 2025 9:10 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Thank you

Thank you for taking a stand against this insane medical mutilation of our kids.

Sent from my iPhone

From: Dustin Morris <dustin@northernrelations.com>
Sent: Wednesday, March 26, 2025 9:19 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Urgent Concerns Regarding the Board's Stance on Gender-Affirming Care

State Medical Board

550 W 7th AVE, STE 1500
Anchorage, AK 99501-3567

Dear Members of the State Medical Board,

I am writing to express deep concern and disappointment regarding your opposition to the provision of gender-affirming care for transgender and gender-diverse youth. Your stance directly contradicts the medical consensus upheld by the American Academy of Pediatrics (AAP), the American Medical Association (AMA), the American Psychiatric Association, and virtually every other major medical and mental health organization in the United States.

These professional bodies support gender-affirming care because it is evidence-based, medically necessary, and often life-saving. According to the AAP, “youth who identify as transgender and gender diverse should have access to comprehensive, gender-affirming, and developmentally appropriate health care.” The AMA similarly recognizes that denial of such care puts young people at significant risk for poor mental health outcomes, including depression, anxiety, and suicide.

So I ask:
How does your opposition help kids and their families?
How does it reduce our state's alarming suicide rates?
How does it provide any meaningful response to the youth mental health crisis that both our state and nation are facing?

If your board’s role is to protect and promote public health, this current stance is a grave failure.

In 2022, The Trevor Project found that transgender and nonbinary youth who received gender-affirming hormone therapy reported significantly lower rates of depression and suicidal ideation compared to those who wanted such care but did not receive it. Denying this care, or placing unnecessary political barriers between providers and patients, is not neutrality—it is harm.

Furthermore, data from the U.S. Centers for Disease Control and Prevention (CDC) show that LGBTQ+ youth, particularly transgender youth, face dramatically higher rates of suicide than their cisgender peers. In a state already struggling with mental health resources and high youth suicide rates, the decision to undermine medically recommended care is not just irresponsible—it’s dangerous.

This issue is not about politics or ideology—it is about science, medicine, and the lives of real young people and their families. If you truly care about health outcomes in our state, then you must listen to the medical professionals who have spent their careers studying, treating, and advocating for youth well-being.

I urge you to reverse course, align with the standard of care endorsed by leading medical associations, and fulfill your duty to support the health and dignity of all young people—including transgender youth.

Your legacy will be defined not just by the decisions you make but by the lives you either save or put at risk.

Sincerely,
Dustin Morris

Anchorage, AK

--

Dustin Morris (he/him/his)

2SLGBTQIA+ Ally

Mobile: 907-529-0610

Email: dustin@northernrelations.com

Facebook | Instagram | LinkedIn | #dustindoodles

From: megan clancy <clancymegan@hotmail.com>
Sent: Wednesday, March 26, 2025 6:49 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Trans care for minors

so you had no problem allowing quacks to push unproven and potentially dangerous "treatments" for Covid, no issues with these strangers "don't worry kid answering the door, I'm a doctor" dropping off candy and threatening letters at our private homes, but you're stopping care for the most vulnerable and bullied group (transitioning transgender children and teens) because of……a president who's staff leaks war plans on chat apps?

Cmon guys. You are DOCTORS!!!! be better than that!

Megan Clancy, MD Infectious disease

-----Original Message-----
From: Joy Jessup <akjoyrider@gmail.com>
Sent: Tuesday, March 25, 2025 5:40 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Thank you

Thank you all for standing up for our youth protecting them from transgender surgery etc.

Please keep up the good fight!

God’s blessings on each of you.

Sincerely

J. Jessup

-----Original Message-----
From: Vickie Becker <thebeckers@gci.net>
Sent: Sunday, March 23, 2025 2:26 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Thank you

I'm so happy that the medial board has and is making a stand for children. I realize that this stand has been part of your work for a long time and now that President Trump has opened the way for getting this terrible mess turned around, you's are speaking out . Thank you for doing so. It is so tragic of what has happened, but now we can change that.Blessings to you all. Don and Vickie

From: Anna Jansen <bananajansen@yahoo.com>
Sent: Sunday, March 23, 2025 8:19 AM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Thank you

Dear members if the Medical Board of Alaska,

Thank you for having the courage to make a public statement to the state legislature opposing hormonal and surgical treatments for gender dysphoria on minors.

It is refreshing and encouraging, especially at a time when public trust in our medical institutions has been shattered by the Covid response, to see our medical professionals use reason and courage to stand up for patients based on evidence and the hypocritical oath.

Thank you sincerely for your thoughtful statement.

Anna Deal

"*The Alaska State Medical Board opposes hormonal and surgical treatments for gender dysphoria in minors due to insufficient evidence of long-term benefits and risks of irreversible harm. We view these interventions as lacking legitimacy as standard medical practice for those under the age of 18 years old. We support legislative limits on such treatments and promote psychological support and counseling as safer alternatives. This reflects our duty to protect patients and uphold evidence-based care*."

From: Byron Perkins <byperkins00@yahoo.com>
Sent: Saturday, March 22, 2025 10:40 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Well Done

As a member of the ASMB, and a licensed physician in the State of Alaska since 1986, I am pleased with the unequivocal action taken by ASMB regarding surgical and medical/homornal interventions in minors under 18 years of age suffering from gender dysphoria. Thank you for your courage and support in the face of resistance during these times of misinformation and transideation.

-----Original Message-----
From: Dana Degraw <danadegraw@gmail.com>
Sent: Saturday, March 22, 2025 9:59 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Our Children

I would like to thank you for standing up for our children here in Alaska and children around the world. These horrible medical treatments have absolutely no place in children's lives. Thank you and please please let us the community know what we can do to help.

Dana De Graw

From: Eva LoForte <loforteeva@gmail.com>
Sent: Saturday, March 22, 2025 9:31 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Safe, healthy children of Alaska

Thank you for your common sense stand regarding child mutilation, sex changes, puberty blockers and other early hormones. We want our

children protected and nurtured as all children of God need to be.

Eva LoForte

From: akyank96 <akyank96@yahoo.com>
Sent: Saturday, March 22, 2025 8:02 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Saving gender dysphoric youth

All,

Thank you for your timely condemnation of providing gender dysphoric youths with hormone blockers and deforming mutilation surgeries.

It is the rightful position by any sane metric.

Thank you!

From: Renee Saunders <sitka7@gmail.com>
Sent: Saturday, March 22, 2025 7:57 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Protection of children

Than you SO MUCH for your statement opposing all forms of medical intervention concerning gender dysphoria for minor children! I am hoping the state of Alaska will follow suit.

Renee Saunders

Houston, AK

-----Original Message-----
From: felicity young <fpt_2000@hotmail.com>
Sent: Saturday, March 22, 2025 5:11 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Thank you

Thank you for having the courage to stand with children against harmful mutilation they are too young to fully grasp.

Felicity Young

Alaskan resident

From: Tiffany Morehouse <tiffann2772@yahoo.com>
Sent: Saturday, March 22, 2025 4:31 PM
To: Board, Medical (CED sponsored) <medicalboard@alaska.gov>
Subject: Genger dysphoria

I would like to thank you for your decision to discourage the use of puberty blockers and operations to change the sex of children.

God bless you and keep you and make His face shine upon you and give you peace.

Tiffany Bean

Juneau, Ak

March 24, 2025

Matanuska-Susitna Delegation

34th Alaska State Legislature

Point of Contact:
Cassandra Day
Cassandra.Day@akleg.gov
(907) 465 1487

For Immediate Release

Mat-Su Delegation Supports State Medical Board Decision to Treat Children with Gender Dysphoria with Counseling, Psychological Care

JUNEAU – The legislature's **Matanuska-Susitna Delegation** stands with the Alaska State Medical Board in opposition to hormonal and surgical treatments for gender dysphoria in minors due to insufficient evidence of the long-term effects.

The delegation agrees with a statement issued from the board supporting safer alternatives, such as psychological support and counseling.

Representative Jubilee Underwood (R – Wasilla) said, "As mentors, coaches, teachers, and parents, we have a duty to safeguard children's mental and physical well-being. The former school board president continued, "True care means providing compassionate psychological support – not irreversible interventions that compromise their future."

According to **Senator Rob Yundt (R – Wasilla)**, "I applaud the board for standing against the hormonal and surgical procedures on children." The local mentor and coach continued, "These so-called 'treatments' should never been allowed in the first place. Furthermore, any doctor that performed these procedures contributed to harming an innocent child."

"It is long past due the medical profession weighs in on the issue and utilize the science to protect our children, said **Representative Kevin McCabe (R – Big Lake).** "It is heartbreaking to think about how many children had to suffer at the hands of medical professionals before this was stopped."

According to **Senator Shelley Hughes (R --Palmer)**, "We need to stop treating Alaska's children as lab rats." The prior health care executive continued, "Disfiguring procedures are irreversible, and render youth with damaging, lifelong impacts. A young person experiencing gender confusion needs counseling, not a knife or chemicals."

We appreciate the board's dedication to protecting patients and upholding evidence-based care, and our delegation looks forward to working with the Alaska State Medical Board to support policy protecting our children from harmful and fringe medical ideologies.

Instead of encouraging children to harm their bodies, we should be working together to heal their minds.

###

Matanuska – Susitna Delegation

From: Kelly Alfred
To: Kelly Alfred
Subject: FSMB Board Member Training Webinars
Date: Thursday, May 8, 2025 12:14:39 PM
Attachments: image001.png

Dear State Medical Board Chairs/Presidents and Executive Directors,

We are excited to announce the return of FSMB's Board Member Training program, an initiative designed to support and educate new members of state medical boards on their critical roles and responsibilities. This comprehensive training, offered virtually over three interactive webinars, will cover a wide array of topics, including foundational aspects of professional regulation, legal overviews, policymaking, accountability, licensing, and disciplinary processes, as well as ethics and professionalism, among others.

The three (3) training webinars will be held on the following dates and times:

Tuesday, June 10, 2025 @ 2:00-4:00 PM (ET) – Click here to register
Monday, July 21, 2025 @ 12:00-2:00 PM (ET) – Click here to register
Wednesday, August 20, 2025 @ 1:30-3:30 PM (ET) – Click here to register

The training has been designed with the expressed needs of state medical boards in mind. While the training is targeted at new board members who have recently joined state medical boards and are seeking to understand the landscape of medical regulation and their part in it, the webinars are open to all board members and leadership staff. Faculty for the webinars is comprised of experienced professionals and experts in the field of medical regulation and board governance, ensuring that participants receive the highest quality education directly from individuals who have staffed and served on state medical boards.

We encourage all member boards to inform their new appointees about this valuable opportunity. In the meantime, should you have any questions, please don't hesitate to reach out.

Sincerely,

Kelly C. Alfred, M.S.
Director, Education Services

Federation of State Medical Boards
400 Fuller Wiser Road | Suite 300 | Euless, TX 76039
o. 817-868-5160 | kalfred@fsmb.org | www.fsmb.org

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Natural Resources

DIVISION OF AGRICULTURE
Alaska Plant Material Center
5310 S. Bodenburg Spur
Palmer, AK 99645-7646
Main: 907.745-4469

Industrial Hemp and Intoxicating Hemp Products FAQ for Professional Licensees

What is legal industrial hemp?

To be legal, an industrial hemp product that is intended for human or animal consumption, must be endorsed by the Division of Agriculture. The Division does not endorse any product that contains delta-9-THC or a non-naturally occurring cannabinoid, including a cannabinoid made from an ingredient extracted from industrial hemp and modified beyond its original form. Legal products may only be offered to consumers by retailers that are registered with the Division to participate in the Alaska industrial hemp program.

Products that are not endorsed by the Division include delta-9 THC, delta-8 THC-O, delta-10 THC-O, delta-6 THC-O, THCA, THCV, THCP, HHC, HHCP, or other synthetic or lab-created cannabinoids derived from hemp. These products may not be used or offered to consumers under the industrial hemp program. Products derived from the seeds of the hemp plant may be offered to consumers without an endorsement. These products contain no cannabinoids like CBD or THC and the seeds themselves do not naturally contain tetrahydrocannabinol (THC), the main psychoactive ingredient in cannabis.

Why do health care providers and other professional licensees need to know this information?

Commonly, industrial hemp products like CBD oil are used in professional practices regulated under AS 08, including massage therapy, veterinary medicine, chiropractic, naturopathy, esthetics, human medicine, and nursing. Under 11 AAC 40.900(13), consumption means any method of ingestion of or application to the body. In addition to using these products onsite, they may even currently be sold by licensed professionals. For these transactions to be legal, these products must be endorsed and businesses offering them to consumers must be registered by the Division of Agriculture.

What are the risks of not following these laws?

First, unless these products have been tested and endorsed by the Division of Agriculture, users cannot be certain whether the labeling reflects the actual product inside. Products containing these substances may be labeled using terms like "broad spectrum" or "full spectrum" that do not clearly inform the user or retailer of their contents. Counterfeit, mislabeled, or misleading product information is rampant, and Alaskans have detected intoxicating levels of cannabis in otherwise innocuously labeled products. This poses a significant public health risk to minors, pets, consumers who do not wish to get high, and consumers who do not wish to test positive on drug screens.

Second, using or selling these products illegally poses a significant risk for civil and criminal action, including possible discipline by state licensing boards and boards in other jurisdictions where practitioners may be licensed.

Where can I find more information?

The Division of Agriculture maintains a web site to share information about Alaska's industrial hemp requirements. The Alcohol and Marijuana Control Office, which partners with the Division of Agriculture in enforcement of industrial hemp laws, is also the regulator of recreational cannabis. Please visit these web sites and carefully follow instructions if you wish to use or sell hemp-derived products in your business.

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

OFFICE OF THE COMMISSIONER
Juneau Office

P.O. Box 110800
Juneau, Alaska 99811-0800
Main: 907.465.2500
Fax: 907.465.5442

MEMORANDUM

TO: State Medical Board

DATE: Thursday, May 01, 2025

FROM: Sara Chambers
Boards and Regulations Advisor

RE: Delegation to unlicensed personnel

We recently asked the Department of Law's advice on what constitutes "professional judgment" as it may be exercised by licensees under AS 08.64 (MED) and 08.68 (NUR), in the context of a licensee's role as a medical director of trained but generally unlicensed providers of medical-adjacent services as may be provided in a "medical spa" within the context of the DCCED Medical Spa Services Work Group. Specifically, we asked about three scenarios:

1. *Can an unlicensed person perform certain limited and controlled medical procedures if they have received training and education to the satisfaction of the medical director? Examples include performing deep facials, laser resurfacing, cryotherapy, and placing and starting IVs (but not evaluating patients, diagnosing disease, prescribing or ordering prescriptions, or other processes requiring complex medical judgment). Persons can obtain extensive training and certification on these and similar procedures, not unlike performance of phlebotomy or ultrasound procedures, which are ostensibly medical procedures that are currently unregulated by the state but allowed under these delegation provisions.*

2. *How does a medical director rely on statute and regulation to identify these boundaries? Or, is this up to their personal professional discernment?*

3. *What restrictions are placed on the medical director in these situations? For example, is there a requirement to be able to safely perform the delegated procedure him/herself or a requirement to be physically onsite?*

The attorney reviewed the applicable statutes and regulations as well as reported decisions from both the medical and nursing boards. Not surprisingly, since the care model described is fairly new, the attorney didn't find any precise roadmaps to guide medical directors as the Medical Spa Services Work Group has defined that role, but some solid guidance may be gleaned from the cited authoritative sources. They are discussed briefly and pasted substantially below.

I. IN GENERAL

To summarize, if a licensee with the ability to delegate determines (1) the procedure can be delegated and (2) the licensee and the person to whom they are delegating meet the qualifications--both of which as determined within reason by the licensee under statute or regulation--then the delegation is permissible.

It would be nearly impossible to list every potentially delegable procedure in regulation, so exercise of a provider's professional judgment within the boundaries of law is crucial to the continued practice of health care—especially when practices are changing rapidly due to innovation.

Delegation of the practice of medicine or nursing to unlicensed personnel is commonplace. Examples include respiratory therapists, phlebotomists, and ultrasound/x-ray/CAT/MRI technicians. These practitioners are not licensed or regulated by the State of Alaska but operate under delegation by a medical director. The medical director ensures the personnel meet the training and education standards that he or she have established or authorized for the practice. Medical spas, IV hydration clinics, and other novel settings have introduced new business models but do not demand substantial diversion from the expectations of oversight, safety, sanitation, and competence that exist current delegation guidelines.

More specifically, regarding the questions above, the answer to Question #1 appears to be yes, with the devil in the details of the medical director's role. The preliminary step is to identify what procedures are *permissible* to be delegated to unlicensed persons. These are fairly well spelled out in medicine at 12 AAC 40.920(e) and (f). They are discussed briefly and pasted substantially below.

The circumstances under which delegable procedures may be delegated, how the unlicensed practice must be supervised, and how a medical director makes those assessments (Questions #2 and #3) are substantially addressed for medicine at 12 AAC 40.920(b) – (d).

The harder question, and one that applies in every consideration of delegation, is what constitutes appropriate professional judgment as it pertains to the medical director's interpretation of these cited regulations. The AMA Code of Ethics adopted by reference by the medical board at 12 AAC 40.955 provides useful guidance as to what appropriate professional judgment looks like in a medical director who is licensed under AS 08.64. The Code of Ethics characterizes medical judgment as being guided by specific principles, especially relating to transparency of communication and respect for patient autonomy.

II. GUIDANCE FOR MEDICAL DIRECTORS WHO ARE LICENSED IN MEDICINE

AS 08.64.106 Delegation of routine medical duties

The board shall adopt regulations; the regulations must

(1) require that an agent who is not licensed under this chapter may perform duties delegated under this section only if the agent meets applicable standards established by the board,

(2) require that a physician, podiatrist, osteopath, or PA may not delegate duties related to pain management and opioid use and addiction, and

(3)(define "routine medical duties").

12 AAC 40.920 Standards for delegation of routine duties

(a) A physician, podiatrist, osteopath, or physician assistant licensed under AS 08.64 may delegate the performance of routine medical duties to an agent of the physician, podiatrist, osteopath, or physician assistant, if the following conditions are met:

(1) the duty to be delegated must be within the scope of practice of the delegating physician, podiatrist, osteopath, or physician assistant;

(2) a licensed physician, podiatrist, osteopath, or physician assistant must assess the patient's medical condition and needs to determine if a duty for that patient may be safely delegated;

(3) the patient's medical condition must be stable and predictable;

(4) the person to whom the duty is to be delegated has received the training needed to safely perform the delegated duty, and this training has been documented;

(5) the delegating physician, podiatrist, osteopath, or physician assistant determines that the person to whom a duty is to be delegated is competent to perform the delegated duty correctly and safely and accepts the delegation of the duty and the accountability for carrying out the duty correctly;

(6) performance of the delegated duty would not require the person to whom it is delegated to exercise professional medical judgment or have knowledge of complex medical skills;

(7) the delegating physician, podiatrist, osteopath, or physician assistant provides to the person, with a copy maintained on record, written instructions that include

(A) a clear description of the procedure to follow to perform each task in the delegated duty;

(B) the predicted outcomes of the delegated task;

(C) procedures for observing, reporting, and responding to side effects, complications, or unexpected outcomes in the patient; and

(D) the procedure to document the performance of the duty in the patient's record.

(b) A physician, podiatrist, osteopath, or physician assistant who has delegated a routine duty to another person shall provide appropriate direction and supervision of the person, including the evaluation of patient outcomes. Another physician, podiatrist, osteopath, or physician assistant may assume delegating responsibilities from the delegating physician, podiatrist, osteopath, or physician assistant if the substitute physician, podiatrist, osteopath, or physician assistant has assessed the patient, the skills of the person to whom the delegation was made, and the plan of care. Either the original or substitute delegating physician, podiatrist, osteopath, or physician assistant shall remain readily available for consultation by the person to whom the duty is delegated, either in person or by telecommunication.

(c) The delegation of a routine duty to another person under this section is specific to that person and for that patient, and does not authorize any other person to perform the delegated duty.

(d) The physician, podiatrist, osteopath, or physician assistant who delegated the routine duty to another person remains responsible for the quality of the medical care provided to the patient.

(e) Routine medical duties that may be delegated to another person under the standards set out in this section means duties that

(1) occur frequently in the daily care of a patient or group of patients;

(2) do not require the person to whom the duty is delegated to exercise professional medical knowledge or judgment;

(3) do not require the exercise of complex medical skills;

(4) have a standard procedure and predictable results; and

(5) present minimal potential risk to the patient.

(f) Duties that require the exercise of professional medical knowledge or judgment or complex medical skills may not be delegated. Duties that may not be delegated include

(1) the assessment of the patient's medical condition, and referral and follow-up;

(2) formulation of the plan of medical care and evaluation of the patient's response to the care provided;

(3) counseling of the patient and the patient's family or significant others regarding the patient's health;

(4) transmitting verbal prescription orders, without written documentation, from the patient's health care provider;

(5) duties related to pain management and opioid use and addiction;

(6) the initiation, administration, and monitoring of intravenous therapy, including blood or blood products;

(7) the initiation administration, and monitoring of procedural sedation;

(8) assessing sterile wound or decubitus ulcer care;

(9) managing and monitoring home dialysis therapy;

(10) oral tracheal suction;

(11) medication management for unstable medical conditions requiring ongoing assessment and adjustment of dosage or timing of administration;

(12) placement and administration of nasogastric tubes and fluids;

(13) initial assessment and management of newly-placed gastrostomy tubes and the patient's nutrition; and

(14) the administration of injectable medications, unless

(A) it is a single intramuscular, intradermal, or subcutaneous injection, not otherwise prohibited under 12 AAC 40.967(33); and

(B) all other provisions of this section are met; and

(C) the delegating physician, podiatrist, osteopath, or physician assistant is immediately available on site.

(g) The provisions of this section apply only to the delegation of routine medical duties by a physician, podiatrist, osteopath, or physician assistant licensed under AS 08.64; they do not apply when duties have not been delegated, including when a person is acting

(1) within the scope of the person's own license;

(2) under other legal authority; or

(3) under the supervision of another health care provider licensed under AS 08, who has authority to delegate routine duties.

AMA Code of Medical Ethics, adopted by reference at 12 AAC 40.955

The Code of Ethics addresses primarily physician relationships with other licensed professionals and in the context of the provision of care to patients, but in every relationship, the Code emphasizes physicians' obligation to uphold the "values and norms of medicine" in the best interests of the public. The Code specifically addresses the potential tension between this obligation and a medical director's obligations to a non-physician employer. (Opinion 10.2) Informative sections (called "opinions" in the Code) include the following:

2.3.6 Surgical Co-Management

"Surgical co-management refers to the practice of allotting specific responsibilities of patient care to designated clinicians. Such arrangements should be made only to ensure the highest quality of care. When engaging in this practice, physicians should allocate responsibilities among physicians and other clinicians according to each individual's expertise and qualifications," and refrain from participating in unethical or illegal financial agreements, such as fee-splitting.

9.2.1 Medical Student Involvement in Patient Care

This section emphasizes the importance of communicating the scope of participants' responsibilities to fully inform patients.

9.2.2 Resident & Fellow Physicians' Involvement in Patient Care

This section emphasizes the fact that residents and fellows are "physicians first and foremost" and should always regard the interests of patients as paramount. They should interact honestly with patients, clearly identifying their respective roles and who is responsible for which aspects of the care, and follow "established mechanisms for reporting and analyzing errors." Again emphasis is repeated as to promoting patients' welfare and dignity.

10.1 Ethics Guidance for Physicians in Nonclinical Roles

"Even when they fulfill roles that do not involve directly providing care for patients in clinical settings, physicians are seen by patients and the public, as well as their colleagues and coworkers as professionals who have committed themselves to the values and norms of medicine. Whatever roles they may play in the system of health care delivery, when physicians use the knowledge and values they gained through medical training and practice in roles that affect the care and well-being of individual patients or groups of patients, they are functioning within the sphere of their profession."

10.1.1 Ethical Obligations of Medical Directors

"Physicians' core professional obligations include acting in and advocating for patients' best interests. When they take on roles that require them to use their medical knowledge on behalf of third parties, physicians must uphold these core obligations.

When physicians accept the role of medical director and must make benefit coverage determinations on behalf of health plans or other third parties or determinations about individuals' fitness to engage in an activity or need for medical care, they should . . . (e) put patient interests over personal interests (financial or other) created by the nonclinical role.

10.2 Physician Employment by a Nonphysician Supervisee

"Physicians' relationship with midlevel practitioners must be based on mutual respect and trust as well as their shared commitment to patient well-being. Health care professionals recognize that clinical tasks should be shared and delegated in keeping with each practitioner's training, expertise, and scope of practice. Given their comprehensive training and broad scope of practice, physicians have a professional responsibility for the quality of overall care that patients receive, even when aspects of that care are delivered by nonphysician clinicians.

Accepting employment to supervise a nonphysician employer's clinical practice can create ethical dilemmas for physicians. If maintaining an employment relationship with a midlevel practitioner contributes significantly to the physician's livelihood, the personal and financial influence that employer status confers creates an inherent conflict for a physician who is simultaneously an employee and a clinical supervisor of his or her employer.

Physicians who are simultaneously employees and clinical supervisors of nonphysician practitioners must (a) and (b) give precedence to their ethical obligations to act in the patient's best interest and exercise independent professional judgment, even if it puts the physician at odds with the employer-supervisee. . . ."

10.5 Allied Health Professionals

When physicians practice with other allied health professionals, they share a common commitment to patient well-being. They should delegate provision of medical services to appropriately trained and credentialed professionals within the individual's scope of practice.

III. CASES ADDRESSING PROFESSIONAL JUDGMENT

Cases that address professional judgment invariably do so in the context of finding whether or not the respondent's actions demonstrated such a lack of judgment as to endanger patients. Their utility is mostly in exploring the outer boundaries of appropriate judgment. Some examples are:

- *ITMO Ilardi*, OAH No. 10-0114-MED (2010), finding that having a relationship with patient, failing to admit that she was his patient, and claiming that it was "no big deal" is of a type of poor professional judgment that could endanger the health of a future patient.

- *ITMO Bartling,* OAH No. 12-0221-MED (2013), considering whether judgment was lacking where respondent made the decision to change medication where patient's condition is getting worse, without examining the patient (no violation found).

- *ITMO Korn*, OAH No. 20-0696-NUR (2021), finding prescribing controlled substances oblivious to their effect on patients showed poor professional judgment.

State Medical Board
Prioritized list of Action Items
Based on July 1, 2024, Board Survey Results

#1. Establish new guidelines for malpractice reviews

#2. Explore statute changes to increase board membership to decrease workload on individual members and / or advocate to allow board members to be notified of subpoenas, summary suspension or cease and desist orders by email (or telephone.)

#3. Issue position statements / practice guidance on special topics. Topics identified to date include:

a) Gender-affirming treatment for minors.
b) Insurance restrictions on physician care.

#4. Explore updating CME requirements

 # 5. Partner with the Board of Pharmacy to address opioid shortages.

#6. Explore updating regulations related to Physician-Pharmacy agreements to either eliminate or streamline the existing process

#7. Explore creating a telemedicine license apart from full medical license.

#8. Explore and adopt a definition of "physician-patient relationship" relationship

Department of Commerce, Community
and Economic Development

Division of Corporations, Business
and Professional Licensing

Alaska State Medical Board

Annual Report

Fiscal Year 2025

Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

P.O. Box 110806
Juneau, Alaska 99811-0806
Email: *License@Alaska.Gov*

This report is required under Alaska Statute 08.01.070(10).

Alaska State Medical Board
FY 2025 Annual Report

Table of Contents

Alaska State Medical Board
FY 2025 Annual Report

Board Membership *(as of the Date This Report was Approved)*

Date of Final Board Approval: [Click or tap to enter a date.]

Brent Taylor, MD
Board Chair

David Barnes, DO

Matt Heilala, DPM

David Paulson, MD

David Wilson, Public Member

Alaska State Medical Board
FY 2025 Annual Report

Accomplishments

The Alaska State Medical Board (ASMB) is responsible for protecting the public through the licensing, regulation, and discipline of allopathic and osteopathic physicians, podiatrists, and physician assistants. The Board establishes and evaluates licensing standards for applicants to practice medicine in Alaska.

During FY2025 the Board finalized and implemented multiple regulation changes aimed at efficiencies and streamlining the licensure process for physicians. These changes have significantly reduced the overall processing and wait times for applicants to obtain full licensure. The Board also engaged in a second round of work groups aimed at soliciting stakeholder input to revise and modernize the regulations that govern the practice of physician assistants in Alaska. Based on this feedback a new set of draft regulations were approved by the board in October 2024. These proposed changes are still being worked through the regulatory change process, and are now halted by the Governor's May 9, 2025 Executive Order.

Alaska State Medical Board
FY 2025 Annual Report

Activities

Board Investigators received and opened 106 new investigative cases and closed 211 cases on behalf of the Medical Board during this fiscal year. Out of those 211 cases, 144 cases were referred to board members to review and make recommendations.

Licensed board members are tasked with reviewing all case documents (medical records, interviews, documents, etc.) and making recommendations to resolve the matter, which may include either no further action or imposing a sanction on the licensee. In cases that involve standard of care violations, two licensed board members must review the case to ensure a thorough review is completed. Standard of Care violations, comprising 20% of the cases brought to the board, were the most common types of violations; while violations of reporting requirements and failing to meet continuing education requirements were the next most common types of violations.

The Board reviewed 35 malpractice cases reported by licensees, screening for gross negligence and avoidable patient harm. Following their case review, licensees were notified regarding recommended follow up actions.

During FY 2025 (July 1, 2024 through May 12, 2025), the board issued 891 licenses, including:

- 641 allopathic physicians
- 111 osteopathic physicians
- 4 podiatrists
- 51 residents
- 1 locum tenens
- 83 physician assistants

Needs

The State Medical Board currently has three vacancies (physician, physician assistant and public member).