Janet T. Mills
GOVERNOR

STATE OF MAINE
BOARD OF LICENSURE IN MEDICINE
137 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0137

Louisa Barnhart, MD
CHAIR

Dennis E. Smith, JD
EXECUTIVE DIRECTOR

Timothy E. Terranova
ASSISTANT EXECUTIVE DIRECTOR

February 12, 2021

Senator Heather B. Sanborn, Chair
Representative Denise A. Tepler, Chair
Committee on Health Coverage, Insurance and Financial Services
100 State House Station
Augusta, ME 04333

Re: ***LD 2133 An Act to Implement Recommendations for Review of the Licensing Laws for Certain Licensed Health Professionals Pursuant to the State Government Evaluation Act.***

Dear Senator Sanborn, Representative Tepler, and members of the Committee on Health Coverage, Insurance and Financial Services:

On March 18, 2020, the Maine Legislature passed LD 2133 into law following receipt and review of Government Evaluation Act (GEA) reports filed by a number of licensing boards, including the Board of Licensure in Medicine (BOLIM).

LD 2133 directed the BOLIM to review Title 32, Chapter 48 and any rules adopted by the board – in consultation with interested parties – and report recommended changes to the Committee on Health Coverage, Insurance and Financial Services (HCIFS) no later than February 15, 2021.

This letter is to inform the Committee that the board has reviewed its law and rules, in consultation with the interested parties listed below, regarding the recommended statutory changes to the laws affecting it in its GEA report to the Legislature (http://legislature.maine.gov/doc/3475); specifically, pages 27-30, and attachments O-T.

- Maine Hospital Association (MHA)
- Maine Medical Association (MMA)
- Maine Osteopathic Association (MOA)
- Maine Association of Physician Assistants (MEAPA)

The laws referenced in the BOLIM GEA report, pursuant to which it performs its duties of protecting the public, included:

1. Title 10 M.R.S. § 8003(5). The BOLIM proposes that this law be amended to allow it to revoke a license following a hearing in conformance with the Maine Administrative Procedure Act and without a de novo review in district court. This change will make the law consistent with the laws affecting licensing boards and commissions within the Office of Licensing and Regulation (OLR) and would eliminate the need to routinely pend license renewal applications

when an individual has an open complaint. The board received no comments from the interested parties opposing this proposed change.

3. Title 24 M.R.S. § 2506. The BOLIM proposes that this section be amended to eliminate the need for the board to request information from mandated reporters and instead require the mandated reporters to provide the information with their reports to the board. The board received no comments from the interested parties opposing this proposed change.

5. Title 32 M.R.S. Chapter 45. The BOLIM proposes updating its statute to include definitions, a requirement for licensure, and specific exemptions to licensure (e.g. medical students and physician assistant students). The board received comments from MEAPA regarding this statutory update, which resulted in changes to the proposed language. A copy of the proposed language changes is included with this report.

6. Title 32 M.R.S. Chapter 45. The BOLIM proposes updating its statute regarding complaint investigations and hearings to permit it to create separate "investigative committees" and "hearing committees." The board received no comments from the interested parties opposing this proposed change.

Chapter 2: Joint Rule Regarding Physician Assistants. The BOLIM undertook joint rulemaking with the Board of Osteopathic Licensure following the emergency passage of LD 1660. That joint rule making endeavor commenced in May 2020 and concluded in December 2020 with the adoption of the "Chapter 2: Joint Rule Regarding Physician Assistants." A copy of the joint rule, the Basis Statement and Response to Comments, and the comments received during the initial proposal and re-proposal of the rule is included with this report.

Thank you for the opportunity to provide this report and recommended changes to the Committee as directed by LD 2133.

Sincerely,

Dennis E. Smith, Esq.
Executive Director

Smith, Dennis E

From: Smith, Dennis E
Sent: Friday, February 5, 2021 10:47 AM
To: Laura Harper; Terranova, Tim E
Cc: Angela M. Leclerc; Jed Jankowski
Subject: RE: proposed bill langauge?
Attachments: Draft Amendment to Board Statute Regarding Definitions 02.05.21.pdf

Tracking:

Recipient	Delivery
Laura Harper	
Terranova, Tim E	Delivered: 2/5/2021 10:48 AM
Angela M. Leclerc	
Jed Jankowski	
Miller, Michael	Delivered: 2/5/2021 10:48 AM

Good morning everyone. Thanks again for speaking with Tim and me today regarding the draft legislation contained in the Board's GEA report. There were a number of possible draft changes to statutes contained in the Board's GEA report, but the focus of our conversation this morning was on the updates to the Board's definitions, licensure requirement and exemptions contained in Attachment S of the GEA Report.

As discussed, I have prepared draft changes to the Section S attachment to the GEA report to reflect the issues discussed, which is attached to this email. More specifically:

1. That the section 1(I) under the heading "Persons and practices not affected; Exemptions" (to licensure) in the GEA report. Looking at this now – it was a mistake to include that paragraph under exemptions as physician assistants must be licensed in order to practice. I apologize for any confusion it may have created. In hindsight, it does not make any sense to have included that language in the exemption to licensure section. As a result, that language would simply be removed.

2. That physician assistants did not have a paragraph similar to section 1(H) under the heading "Persons and practices not affected; Exemptions" (to licensure) that would allow them to append the initials of their professional degree to their name so long as their license has not been revoked, withdrawn while under investigation or suspended. A new section 1(I) has been created to create that exemption for physician assistants.

3. You concurred that the language regarding delegation by physician assistants to unlicensed personnel as reflected in the email below looked great. A new section 1(K) under the heading "Persons and practices not affected; Exemptions" (to licensure) has been added to include that language.

4. That section 1(C) under the heading "Persons and practices not affected; Exemptions" (to licensure) regarding medical and physician assistant students did not include a provision for performing duties assigned by a physician assistant. That section has been amended to include physician assistants who precept medical students and physician assistant students.

You also raised the question regarding "practicing medicine" versus "rendering medical services." While that distinction was not included in the draft statutory charges in the GEA report, I would point out that the recently enacted law pertaining to physician assistants – 32 M.R.S. § 3270-E and § 3270-G (from L.D. 1660) specifically includes the

terms/phrases: "render medical services" and "provide... medical services." If you think that it is important to include a definition of "rendering or providing medical services" in any draft legislation, please let me know.

Please let me know right away if the attached document with revisions does not address your concerns as we discussed this morning. Thank you.

Dennis

Dennis E. Smith, Esq.
Executive Director
Maine Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137
(207) 287-3605

From: Smith, Dennis E
Sent: Thursday, February 4, 2021 1:05 PM
To: Laura Harper <laura@mooseridgeassociates.com>; Terranova, Tim E <Tim.E.Terranova@maine.gov>
Cc: Angela M. Leclerc <LECLEA@mmc.org>; Jed Jankowski <jjankowski@me.com>
Subject: RE: proposed bill langauge?

Laura,

We don't have specific language – other than what is in the GEA report. Tim has already spoken with Jed Jankowski about this – and the fact that the language in the "updated definitions" section of the GEA report found in attachment S regarding "physician assistants" under the heading "Persons and Practices Not Affected" Section 1(I) is no longer in alignment with the new law. That particular section in the GEA report – which was created prior to the passage of the new law - stated:

I. This chapter may not be construed to prohibit an individual from rendering medical services as a physician assistant if these services are rendered under the supervision and control of a physician or surgeon and if that individual has satisfactorily completed a training program approved by the Board and a competency examination approved by the Board. Supervision and control may not be construed as requiring the personal presence of the supervising and controlling physician at the place where these services are rendered, unless a physical presence is necessary to provide patient care of the same quality as provided by the physician.

Any proposed legislation would not include this language, which was repealed and no longer in effect. Substitute language for this section could read along the lines of the following (which is taken out of the current 32 M.R.S. § 3270-E(4): http://legislature.maine.gov/statutes/32/title32sec3270-E.html.

I. This chapter may not be construed as prohibiting a physician assistant from delegating to the physician's assistant's employees or support staff or members of a health care team, including medical assistants relating to medical care and treatment carried out by custom and usage when the activities are under the control of the physician assistant. The physician assistant who delegates an activity permitted under this subsection is legally liable for the activity performed by an employee, a medical assistant, support staff or a member of a health care team.

Dennis

Dennis E. Smith, Esq.
Executive Director

Proposed Amendment to Board Statute Regarding Definition of "Practice of Medicine and Surgery"

§. DEFINITIONS

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Applicant. "Applicant" means an individual who submits an application for licensure or registration with the Board.

2. Board. "Board" means the Maine Medical Board.

3. Commissioner. "Commissioner" means the Commissioner of Professional and Financial Regulation.

4. Department. "Department" means the Department of Professional and Financial Regulation.

5. License. "License" means license or registration to practice medicine and surgery or to render medical services in this State pursuant to this chapter.

6. Licensed in good standing. "Licensed in good standing" means a full and unrestricted and unconditioned license with no prior discipline in any jurisdiction.

7. Licensee. "Licensee" means any individual licensed or registered pursuant to this chapter.

8. Practice of Medicine. "Practice of medicine" means:

A. Using the designation "Doctor," "Doctor of Medicine," "Physician," "Dr.," "M.D.," "D.O." or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition unless the designation additionally contains a description of another branch of the healing arts for which one holds a valid license in this State;

B. Advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine in this State;

C. Offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person;

D. Offering or undertaking to prevent, diagnose, correct, or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;

E. Offering or undertaking to perform any surgical operation upon any person;

F. Rendering a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient or the actual rendering of treatment to a patient within the State by a physician located outside the State as a result of the transmission of individual patient data by electronic or other means from within the State to the physician or his or her agent;

G. Rendering a determination of medical necessity or a decision affecting the diagnosis or treatment of a patient.

9. Physician. "Physician" means an individual who has graduated from an allopathic or osteopathic medical school approved by the Board and holds a valid license issued by the Board.

10. Physician Assistant. "Physician assistant" means an individual who has graduated from a program approved by the Board and holds a valid license issued by the Board.

11. Surgery. "Surgery" means any procedure, including but not limited to laser, in which human tissue is cut, shaped, burned, vaporized, or otherwise structurally altered, except that this section shall not apply to any person to whom authority is given by any other statute to perform acts which might otherwise be deemed the practice of surgery. "Laser" means light amplification by stimulated emission of radiation.

Subchapter 2: LICENSE; LICENSE REQUIRED; EXEMPTIONS

§. INDIVIDUAL LICENSE

Only an individual may be licensed or registered under this chapter and only a licensed individual may provide services for which a license is required under this chapter.

§. LICENSE REQUIRED

1. Unlicensed practice. Except as provided in section 5, a person may not practice or profess to be authorized to practice medicine or render medical services in this State without a license or during any period when that person's license has expired and/or lapsed or has been denied, suspended, revoked, or surrendered.

2. Penalties. A person who violates this section commits a Class E crime. Violation of this section is a strict liability crime as defined in Title 17-A, section 34, subsection 4-A.

3. Injunction. The Attorney General may bring an action in Superior Court pursuant to Title 10, section 8003-C, subsection 5 to enjoin an unlicensed person from violating this chapter.

§. PERSONS AND PRACTICES NOT AFFECTED; EXEMPTIONS

1. The requirement of a license under this chapter does not apply to:

A. A health care professional licensed, certified or registered by any board within or affiliated with the Office of Licensing and Professional Regulation or any other agency of this State when that person is practicing within the scope of his or her professional license;

B. A person serving in the United States Armed Forces, the National Guard, or the United States Department of Health and Human Services, Public Health Service or employed by the United States Department of Veterans Affairs or other federal agency while performing official duties, if the duties are limited to that service or employment;

C. A student enrolled in and attending an allopathic or osteopathic medical school or a physician assistant graduate program while performing duties assigned by a licensed physician or licensed physician assistant at any office of a licensed physician or licensed physician assistant, hospital, clinic or similar facility;

D. A person providing services in cases of emergency where no fee or other consideration is contemplated, charged or received by the physician or physician assistant or anyone on behalf of the physician or physician assistant;

E. A person fully licensed to practice medicine or render medical services in another jurisdiction of the United States who briefly render emergency medical treatment or briefly provide critical medical services in this State following an executive declaration of a state of emergency in this State;

F. A person accompanying a visiting athletic team and who holds a current unrestricted license to practice medicine and surgery in another state when the person, pursuant to a written agreement with an athletic team located in the state in which the person holds the license, provides medical services to any of the following while the team is traveling to or from or participating in a sporting event in this State:

1. A member of the athletic team;

2. A member of the athletic team's coaching, communications, equipment or sports medicine staff;

3. A member of a band or cheerleading squad accompanying the team; or

4. The team's mascot.

Restrictions. A person authorized to provide medical services in this State pursuant to this exemption may not provide medical services at a health care facility, including a hospital, ambulatory surgical facility or any other facility where medical care, diagnosis or treatment is provided on an inpatient or outpatient basis.

G. An individual licensed as a chiropractor licensed by this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Chiropractor," or a dentist duly licensed by this State may prefix the title "Doctor" or the letters "Dr." to that individual's name or a naturopathic doctor licensed by this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Naturopathy" or the words "Naturopathic Medicine" or an optometrist duly licensed under the laws of this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Optometrist" or a podiatrist licensed under the laws of this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Podiatrist" or "Chiropodist."

H. Nothing contained in this section prevents an individual who has received the degree "Doctor of Medicine" or "Doctor of Osteopathic Medicine" from a reputable college or university but who is not engaged in the practice of medicine or surgery or the treatment of a disease or human ailment, from prefixing the letters "Dr." or appending the letters "M.D." or "D.O." to that individual's name, as long as that individual's license to practice has never been revoked, withdrawn while under investigation or surrendered. Nothing in this chapter may be construed as to affect or prevent the practice of the religious tenets of a church in the ministration to the sick or suffering by mental or spiritual means.

I. Nothing contained in this section prevents an individual who has received a degree from an accredited physician assistant program but who is not engaged in rendering medical services from appending the letters "P.A." to that individual's name, as long as that individual's license has never been revoked, withdrawn while under investigation or surrendered. Nothing in this chapter may be construed as to affect or prevent the practice of the religious tenets of a church in the ministration to the sick or suffering by mental or spiritual means.

~~I. This chapter may not be construed to prohibit an individual from rendering medical services as a physician assistant if these services are rendered under the supervision and control of a physician or surgeon and if that individual has satisfactorily completed a training program approved by the Board and a competency examination approved by the Board. Supervision and control may not be construed as requiring the personal presence of the supervising and controlling physician at the place where these services are rendered, unless a physical presence is necessary to provide patient care of the same quality as provided by the physician.~~

J. This chapter may not be construed as prohibiting a physician or surgeon from delegating to the physician's or surgeon's employees or support staff certain activities relating to medical care and treatment carried out by custom and usage when the activities are under the control of the physician or surgeon. The physician delegating these activities to employees or support staff, to program graduates or to participants in an approved training program is legally liable for the activities of those individuals, and any individual in this relationship is considered the physician's agent. This section may not be construed to apply to registered nurses acting pursuant to chapter 31.When the delegated activities are part of the practice of optometry as defined in chapter 34-A, then the individual to whom these activities are delegated must possess a valid license to

practice optometry in Maine, or otherwise may perform only as a technician within the established office of a physician, and otherwise acting solely on the order of and under the responsibility of a physician skilled in the treatment of eyes as designated by the proper professional board, and without assuming evaluation or interpretation of examination findings by prescribing corrective procedures to preserve, restore or improve vision.

K. This chapter may not be construed as prohibiting a physician assistant from delegating to the physician's assistant's employees or support staff or members of a health care team, including medical assistants relating to medical care and treatment carried out by custom and usage when the activities are under the control of the physician assistant. The physician assistant who delegates an activity permitted under this subsection is legally liable for the activity performed by an employee, a medical assistant, support staff or a member of a health care team.

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Smith, Dennis E

From: Andrew MacLean <amaclean@mainemed.com>
Sent: Wednesday, February 3, 2021 2:52 PM
To: Smith, Dennis E; Dan Morin
Cc: Terranova, Tim E
Subject: RE:

Follow Up Flag: Follow up
Flag Status: Flagged

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.
Hi Dennis & Tim:

Thanks for being so persistent in ensuring we have a chance to review & comment on this! I think we're fine with "1" below, enthusiastic about "2," & concur with "3." I don't recall the political/legislative circumstances of the "de novo" review of license revocations, but I do remember that it came about as a result of testimony I gave to the BRED Committee many years ago. I think John Richardson may have been the House Chair at that time. I don't remember if it was our bill or yours, or someone else's! Will these be in an agency bill this session? Lastly, were some of the lawyers who regularly practice before the board, such as Emily Bloch, on the interested parties list?

Thanks again for the opportunity to have input!

Andy

From: Smith, Dennis E <dennis.e.smith@maine.gov>
Sent: Friday, January 29, 2021 9:19 AM
To: Dan Morin <DMorin@mainemed.com>; Andrew MacLean <amaclean@mainemed.com>
Cc: Terranova, Tim E <Tim.E.Terranova@maine.gov>; Andrew MacLean <amaclean@mainemed.com>
Subject: RE:

Thanks for your thoughts and feedback Dan. I wanted to give you some background on the proposed statutory changes:

1. License revocation. In the past, the Board had the authority to revoke licenses. Then that authority was removed. Then it was put back in under Title 10 (the one cited in the GEA report) with a *de novo* review. I've attempted to articulate in the GEA report why the *de novo* review is not necessary given the low number of revocations in the previous 10 years. In addition to that, the Board has a policy to pend renewal applications for licensees who have an open complaint. This policy allows the Board to deny the renewal if the complaint is sufficiently serious. The standard of review for denying a renewal of a license is not *de novo* – it is whether there is substantial evidence in the record to support the Board's decision. Simply put, denying a license eliminates the need for a new trial in court. However, pending a license also has implications for the licensee when the renewal date passes. The law allows the existing license to continue pending final action by the Board so the individual will still be able to practice. Sometimes, however, credentialing agencies (insurance companies, hospitals, etc.) become confused by the pending status and it can cause issues for the person. Andy and I have discussed this issue – and whether it would make sense for the Board to have the ability to revoke without *de novo* hearing and eliminate the pending of license renewals when a complaint is filed against a licensee.

2. Complaint & Hearing Committees. As you know, there are various models for the composition and functioning of state medical boards. One model is the one that currently exists in Maine. Another is the one included in the

statutory draft that would allow the complaint/investigative functions to be separated from the hearing functions via the creation of standing committees. At present, the entire Board both investigates and adjudicates a complaint. Although this process has been upheld by courts, attorneys always raise the issue of prejudgment and confirmatory bias in decision making. In addition, they raise the issue of the assistant attorney general both advising the investigation and then prosecuting the matter in front of the same Board members. That is the legal side. The practical side is that allowing committees to perform these tasks would allow a standing hearing committee to adjudicate complaints without having to deal with other issues such as licensing and investigations. The Board members – particularly the physicians and physician assistants have current jobs and practices that keep their knowledge current but also make it challenging to schedule and complete hearings. Right now, we have a case that is going on its 3rd day of hearing on a regularly scheduled monthly Board meeting. The proposed changes are designed/intended to make the hearing process more efficient for licensees, their attorneys, and the Board.

3. The definitions section is really a long overdue update. It has nothing to do with the type of license.

I hope this has explained the purpose of the prosed draft changes. Please let me know if the MMA has any objection to any of them. Thank you. Have a safe and restful weekend.

Dennis

Dennis E. Smith, Esq.
Executive Director
Maine Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137
(207) 287-3605

From: Dan Morin <DMorin@mainemed.com>
Sent: Wednesday, January 27, 2021 1:20 PM
To: Smith, Dennis E <dennis.e.smith@maine.gov>; Diane McMahon <amaclean@mainemed.com>
Cc: Terranova, Tim E <Tim.E.Terranova@maine.gov>
Subject: RE:

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.
Maybe Andy—the lawyer—will want to jump in but here's my lay-look and observations

Wouldn't eliminating de novo review in district court for revocation wouldn't be required to defer to the findings of the board? I also don't understand the connection between that and making a license "pending." Likely my ignorance

Separate investigatory committees have pros and cons the way I see it:

- It's seems good to me when the board members who investigated the complaint with staff and make the recommendation to other members on discipline don't get to vote on their own recommendations. The members can spend more time digging into things because time is a huge challenge on the medical board.
- But, don't members routinely defer to the investigation committee anyway. The benefit then wouldn't be as strong as one might hope.
- In Kansas, The Board of Healing Arts didn't always follow the recommendations of the investigatory committees but its few and far between.

The hard part is that if you have a large number of folks on an investigatory committee, those same people can't be on an adjudicatory hearing committee. If they are taking out one person from the board to present the complaint it doesn't seem like an issue but if you are going to remove several people, the docs (and attorneys) before the board may have a

problem with that I suspect. It all depends on whether they remove people from the pool. Better for time management but people may poke holes in those situations concerning due process.

I have no opinion on the alterations in the definition of practice. Does that have to do with limiting physicians who have an administrative practice?

Signed,
Not a Lawyer (Thank God)

From: Smith, Dennis E <dennis.e.smith@maine.gov>
Sent: Friday, January 22, 2021 8:40 AM
To: Andrew MacLean <amaclean@mainemed.com>; Dan Morin <DMorin@mainemed.com>
Cc: Terranova, Tim E <Tim.E.Terranova@maine.gov>
Subject: FW:

Andy/Dan,

I am following up on this email I sent out last week. I know you are busy with all that is going on. Do either of you have any concerns regarding any of the proposed statutory changes outlined in the email and GEA report? Would you like to have a Zoom meeting to discuss? Thanks.

Dennis

Dennis E. Smith, Esq.
Executive Director
Maine Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137
(207) 287-3605

From: Smith, Dennis E
Sent: Wednesday, January 13, 2021 11:01 AM
To: Andrew MacLean (amaclean@mainemed.com) <amaclean@mainemed.com>; Dan Morin <DMorin@mainemed.com>; arichards@mainedo.org; awesthoff@mainedo.org; Angela M. Leclerc <LECLEA@mmc.org>; Jeffrey A. Austin <jaustin@themha.org>
Cc: Terranova, Tim E <Tim.E.Terranova@maine.gov>
Subject:

Good morning,

You are receiving this email because you have been identified as a potential interested party regarding possible changes to the laws affecting the Maine Board of Licensure in Medicine (BOLIM).

On March 18, 2020, the Maine Legislature passed LD 2133 (attached) into law following receipt and review of Government Evaluation Act (GEA) reports filed by a number of licensing boards, including the BOLIM. A copy of the BOLIM GEA report may be found at: http://legislature.maine.gov/doc/3475.

The law directs the boards to review their laws – in consultation with interested parties – and report recommended changes to the laws no later than February 15, 2021.

Northern Light Health

Northern Light Health
Government Relations
43 Whiting Hill Road
Brewer, Maine 04412

Office 207-861-3282
Fax 207-872-2030

Northern Light Health
Acadia Hospital
A.R. Gould Hospital
Beacon Health
Blue Hill Hospital
C.A. Dean Hospital
Eastern Maine Medical Center
Home Care & Hospice
Inland Hospital
Maine Coast Hospital
Mercy Hospital
Northern Light Health Foundation
Sebasticook Valley Hospital

January 28, 2021

Dennis E. Smith, Esq.
Executive Director
Maine Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Subject: Possible changes to the laws affecting the Maine Board of Licensure in Medicine (BOLIM)

Dear Mr. Smith,

Thank you for the opportunity to provide feedback on potential legislative revisions to Title 24 M.R.S. Chapter 21 – Mandated Reporting by Health Care Entities.

The proposed change removes the current standard "upon written request from the Board of Licensure in Medicine, specific information must be released to the board or authority within 20 days of receipt of request". Our understanding of the change is to require the health care entity to report all of the required information in the initial report to the Board. We are in full support of reporting all available information but want to highlight a potential challenge. Normally, Northern Light Health files initial reports in advance of the 60 day deadline. In our experience when communicating an initial report to the board on actions involving licensed providers that are contracted providers from an outside organization, reports are often filed by both Northern Light Health and the contracted employer of the individual. The two reports are not always provided to the board at the same time, and we expect this new requirement may result in Northern Light Health filing its report later than it has historically to allow us to gather the requisite information. Thus, it may be that the board receives a report from an outside organization before it receives a report from Northern Light Health. We raise this situation to the board to raise awareness. We are confident that all of the required information will be provided within 60 days.

Thank you for the opportunity to provide comment on the proposed changes.

Sincerely,

Lisa Harvey-McPherson RN, MBA, MPPM
Vice President Government Relations

Memo

Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333
(207) 287-3603 voice (207) 287-6590 fax
maureen.s.lathrop@maine.gov

To: Don Wismer, APA Coordinator
Secretary of State

From: Maureen S. Lathrop, Administrative Assistant
Board of Licensure in Medicine

Subject: Adopted Rule: Chapter 2 – Joint Rule Regarding Physician Assistants

Date: December 10, 2020

Enclosed please find duplicate packets of the Chapter 2 Joint Rule Regarding Physician Assistants, a joint rule adopted by the Board of Licensure in Medicine and the Board of Osteopathic Licensure. I will e-mail a copy of the adopted rule and notice of adoption (MAPA-4) to you.

Please contact me at 287-3603 if you have any questions.

Board of Licensure in Medicine

Rulemaking Cover Sheet

MAPA-1

TO: **Secretary of State**
ATTN: **Administrative Procedure Officer,**
State House Station 101, Augusta, Maine 04333.

1. **Agency:** Board of Licensure in Medicine

2. **Agency umbrella and unit number:** 02-373
(2 digit umbrella # and 3 digit unit #)

3. **Title of rule:** Joint Rule Regarding Physician Assistants

4. **Chapter number assigned to the rule** 2
(must be 3 digits or less)

5. **Date(s)/method(s) of notice - Initial rule proposal:** newspaper advertisement by Secretary of State on July 8, 2020; sent to interested parties July 8, 2020; posted to Board's website July 8, 2020; and article in the Board's Summer 2020 newsletter July 24, 2020

Re-proposal with substantive changes: newspaper advertisement by Secretary of State on September 30, 2020; sent to interested parties September 30, 2020; and posted on Board's website September 30, 2020.

6. **Date(s)/place(s) of hearing(s):** none held

7. **Type:** ☐ new rule ☒ partial amendment(s) of existing rule

☐ suspension of existing rule ☐ repeal of rule ☐ emergency rule

☐ repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. **Name/phone of agency contact person:** Dennis E. Smith, Executive Director; 287-3605

9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**

☐ **Provisional adoption** (prior to Legislative review) ☐ **Final adoption**

☐ **emergency adoption of major-substantive rule**

10. **Certification Statement:** I, Louisa Barnhart, M.D., Board Chair, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by

Board of Licensure in Medicine (name of agency) on November 10, 2020 (date).

I further certify that all portions of this rule are adopted in compliance with the requirements of the Maine Administrative Procedure Act.

Signature: _____
(original signature, personally signed by the head of agency)

Printed name & title: Louisa Barnhart, M.D., Board Chair

11. **Approved as to form and legality by the Attorney General on** 12/08/2020 .
(date)

Signature Thomas C. Sturtevant .
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Thomas C. Sturtevant, JR. .

Rulemaking Cover Sheet

MAPA-1

TO: **Secretary of State**
ATTN: **Administrative Procedure Officer,**
State House Station 101, Augusta, Maine 04333.

1. **Agency:** Board of Licensure in Medicine

2. **Agency umbrella and unit number:** 02-373
(2 digit umbrella # and 3 digit unit #)

3. **Title of rule:** Joint Rule Regarding Physician Assistants

4. **Chapter number assigned to the rule** 2
(must be 3 digits or less)

5. **Date(s)/method(s) of notice - Initial rule proposal:** newspaper advertisement by Secretary of State on July 8, 2020; sent to interested parties July 8, 2020; posted to Board's website July 8, 2020; and article in the Board's Summer 2020 newsletter July 24, 2020

Re-proposal with substantive changes: newspaper advertisement by Secretary of State on September 30, 2020; sent to interested parties September 30, 2020; and posted on Board's website September 30, 2020.

6. **Date(s)/place(s) of hearing(s):** none held

7. **Type:** ☐ new rule ☒ partial amendment(s) of existing rule

☐ suspension of existing rule ☐ repeal of rule ☐ emergency rule

☐ repeal and replace; complete replacement of existing chapter, with former version simultaneously repealed.

8. **Name/phone of agency contact person:** Dennis E. Smith, Executive Director; 287-3605

9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**

☐ **Provisional adoption** (prior to Legislative review) ☐ **Final adoption**

☐ **emergency adoption of major-substantive rule**

10. **Certification Statement:** I, Louisa Barnhart, M.D., Board Chair, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by

Board of Licensure in Medicine (name of agency) on November 10, 2020 (date).

I further certify that all portions of this rule are adopted in compliance with the requirements of the Maine Administrative Procedure Act.

Signature: _____
(original signature, personally signed by the head of agency)

Printed name & title: Louisa Barnhart, M.D., Board Chair

11. **Approved as to form and legality by the Attorney General on** 12/08/2020 (date).

Signature Thomas C. Sturtevant (original signature, personally signed by an Assistant Attorney General).

Printed Name: Thomas C. Sturtevant, JR.

Adopted Rule

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE
a joint rule with
383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 2: JOINT RULE REGARDING PHYSICIAN ASSISTANTS

SUMMARY: Chapter 2 is a joint rule pertaining to the licensure, scope of practice, continuing clinical competency, consultation, collaborative agreements, practice agreements, notification, and continuing education requirements for physician assistants who are licensed in Maine. Chapter 2 also establishes a Physician Assistant Advisory Committee.

SECTION 1. DEFINITIONS

1. "AAPA" means the American Academy of Physician Assistants.

2. "Active Unrestricted Physician License" means an active Maine physician license to practice medicine that does not include any restrictions or limitations on the scope of practice or ability to consult with or collaborate with physician assistants.

3. "Administratively Complete Application" is a uniform application for licensure as developed by the Boards, which when submitted to one of the Boards has: a) all questions on the application completely answered; b) signature and date affixed; c) all required notarizations included; d) all required supplemental materials provided in correct form; e) all requests for additional information submitted; and f) all fees, charges, costs or fines paid.

4. "AMA" means the American Medical Association.

5. "AOA" means the American Osteopathic Association.

6. "Board" means the Board of Licensure in Medicine or the Board of Osteopathic Licensure.

7. "BOL" means the Board of Osteopathic Licensure as defined in 32 M.R.S. §2561.

8. "BOLIM" means the Board of Licensure in Medicine as defined in 32 M.R.S. §3263.

9. "Collaborative Agreement" means a document agreed to by a physician assistant and a physician that describes the scope of practice for the physician assistant as determined by the practice setting and describes the decision-making process for a health care team, including communication and consultation among health care team members. A collaborative agreement is subject to review and approval by the Board.

10. "Consultation" means engagement in a process in which members of a health care team use their complimentary training, skill, knowledge and experience to provide the best care for a patient.

11. "Health care facility" means a facility, institution or entity licensed pursuant to State law or certified by the United States Department of Health and Human Services, Health Resources and Services Administration that offers healthcare to persons in this State, including hospitals and any clinics or offices affiliated with hospitals and any community health center, each of which has a system of credentialing and granting of privileges to perform health care services and that follows a written professional competence review process.

12. "Health care team" means 2 or more health care professionals working in a coordinated, complementary and agreed upon manner to provide quality, cost-effective, evidence-based care to a patient and may include a physician, physician assistant, advance practice nurse, nurse, physical therapist, occupational therapist, speech therapist, social worker, nutritionist, psychotherapist, counselor or other licensed professional.

13. "Inactive Status License" means the physician assistant has an inactive license and cannot render medical services in Maine.

14. "License" means a document issued by the Board to a physician assistant that identifies the physician assistant as qualified by training and education to render medical services.

15. "NCCPA" means the National Commission on Certification of Physician Assistants.

16. "Physician" means a person licensed as a physician by the Maine Board of Licensure in Medicine or the Maine Board of Osteopathic Licensure.

17. "Physician Assistant" means a person who has graduated from a physician assistant program accredited by the American Medical Association Committee on Allied Health Education and Accreditation, or the Commission for Accreditation of the Allied Health Education Programs, or the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or their successors; and/or who has passed the certifying examination administered by the National Commission on Certification of Physician Assistants (NCCPA) or its successor and possesses a current license issued by the Board. Only physician assistants who are currently certified by the NCCPA may use the initials PA-C.

18. "Physician Group Practice" means an entity composed of 2 or more physicians that offers healthcare to persons in this State and that has a system of credentialing and granting of privileges to perform health care services and that follows a written professional competence review process.

19. "Practice agreement" means a document agreed to by a physician assistant who is the principal clinical provider in a practice and a physician that states the physician will be

available to the physician assistant for collaboration or consultation. A practice agreement is subject to review and approval by the Board.

SECTION 2. UNIFORM QUALIFICATIONS FOR LICENSURE

1. **License Required**

   An individual must hold an active license issued by the Board in order to render medical services as a physician assistant in the State of Maine.

2. **Uniform Application for Licensure**

   A. The Boards shall develop a uniform application form for licensure.

   B. Applicants for physician assistant licensure shall complete the Board-approved application forms and submit them to the Board together with all required fees and required documentation.

3. **Uniform Requirements for Temporary/New Graduate License**

   A. The Board, or if delegated, Board staff may issue a one-time, non-renewable temporary license to practice as a physician assistant to an applicant who:

      (1) Submits an administratively complete application;

      (2) Pays the appropriate uniform licensure fee;

      (3) Has successfully completed an educational program for physician assistants accredited by the American Medical Association Committee on Allied Health Education and Accreditation, or the Commission for Accreditation of the Allied Health Education Programs, or their successors;

      (4) Has no license, certification or registration as a physician assistant, or any other type or classification of health care provider license, certification or registration under current discipline, revocation, suspension, restriction or probation;

      (5) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law;

      (6) Passes, at the time of license application, a jurisprudence examination administered by the Board; and

      (7) Is currently scheduled to take, but has not yet taken, the national certifying examination administered by the NCCPA (NCCPA examination) or its successor organization or has taken the NCCPA examination and is awaiting

the results. **An applicant who has taken the NCCPA examination and failed to pass is not eligible to apply for a temporary license.**

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding the applicant's qualifications, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

C. A temporary license is valid until one of the following occurs:

(1) A period not to exceed six (6) months from the date of issuance has elapsed;

(2) The Board and/or physician assistant receive notice of the failure to pass the NCCPA examination; or

(3) Board staff receives notice of the passage of the NCCPA examination, upon which Board staff shall issue a full license so long as all other qualifications have been met and no cause exists that may be considered grounds for disciplinary action or denial of licensure as provided by law.

D. Incomplete Application

Any application for a temporary license that has been on file without action for three (3) months shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process in order to proceed to licensure.

4. **Uniform Requirements for Full License**

A. The Board, or if delegated, Board staff may issue a full license as a physician assistant to an applicant who:

(1) Submits an administratively complete application form;

(2) Pays the appropriate uniform licensure fee;

(3) Has successfully completed an educational program for physician assistants accredited by the American Medical Association Committee on Allied Health Education and Accreditation, or the Commission for Accreditation of the Allied Health Education Programs, or their successors;

(4) Has no license, certification or registration as a physician assistant, or any other type or classification of health care provider license, certification or registration under current discipline, revocation, suspension, restriction or probation;

(5) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law;

(6) Passes, at the time of license application, a jurisprudence examination administered by the Board; and

(7) Has passed the NCCPA certification examination and holds a current certification issued by the NCCPA that has not been subject to disciplinary action by the NCCPA at the time the license application is acted upon by the Board.

(8) Demonstrates current clinical competency as required by this rule.

(9) A new licensee who is scheduled to renew three (3) months or less from the date of original licensure will be issued a license through the next renewal cycle.

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding the applicant's qualifications, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

C. Incomplete Application

Any application that has been on file without action for one (1) year shall be deemed administratively incomplete and shall be discarded. The applicant must restart the application process in order to proceed to licensure.

SECTION 3. UNIFORM REQUIREMENTS FOR RENEWAL/INACTIVE STATUS/REINSTATEMENT/ WITHDRAWAL OF LICENSE

1. License Expiration and Renewal

Except for temporary licenses, the license of every physician assistant born in an odd-numbered year expires at midnight on the last day of the month of the physician assistant's birth every odd-numbered year. The license of every physician assistant born in an even-numbered year expires at midnight on the last day of the month of the physician assistant's birth every even-numbered year. The physician assistant must renew the license every two (2) years prior to the expiration of the license by submitting an administratively complete application to the Board on forms approved by the Board.

2. Renewal Notification

At least sixty (60) days prior to the expiration of a current license, the Board shall notify each licensee of the requirement to renew the license. If an administratively complete re-licensure application has not been submitted prior to the expiration date of the existing license, the license immediately and automatically expires. A license may be reinstated up to 90 days after the date of expiration upon payment of the renewal fee and late fee. If an administratively complete renewal application is not submitted within 90 days of the date of the expiration of the license, the license immediately and automatically lapses. The Board may reinstate a license pursuant to law.

3. Criteria for Active License Renewal

A. The Board, or if delegated, Board staff may renew the active license of a physician assistant who meets the following requirements:

(1) Submits an administratively complete license renewal application form;

(2) Pays the appropriate license renewal fee and/or late fee (if any);

(3) Affirms that the licensee has met the CME requirements. In the event that the required CME is not complete, the physician assistant may request an extension of time for good cause to complete the CME. The Board Secretary, Board Chair, or their designee has the discretion to grant or deny a request for an extension of time to complete the required CME credits;

(4) Demonstrates continuing clinical competency as required by this rule;

(5) Successfully completes the Board's jurisprudence examination when directed by the Board; and

(6) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding the applicant's qualifications, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

C. Timeliness of Application

If an application for renewal of license is not administratively complete and postmarked or received electronically by the date of expiration of the license, the late fee shall be assessed.

4. Criteria for Inactive License Renewals

A. The Board, or if delegated, Board staff may renew the inactive license of a physician assistant who meets all of the following requirements:

(1) Submits an administratively complete license application form;

(2) Pays the appropriate license renewal fee and/or late fee (if any); and

(3) Has no cause existing that may be considered grounds for disciplinary action or denial of renewal of licensure as provided by law.

B. Timeliness of Application

If an application for renewal of license is not administratively complete and postmarked or received electronically by the date of expiration of the license, the late fee shall be assessed.

5. License Status Conversions Between Scheduled Renewal Dates

A. Process for Conversion from Active to Inactive License

A physician assistant may convert an active license to an inactive license between scheduled renewal dates by filing a written request with the Board. Upon receipt of a written request, the Board staff shall convert the active license to an inactive license. The biennial renewal date remains unchanged.

B. Process for Conversion from Inactive to Active License

The Board, or if delegated, Board staff may convert the status of a physician assistant's license from inactive to active for an applicant who:

(1) Files an administratively complete application with the Board;

(2) Pays the appropriate conversion fee;

(3) Provides evidence of having met the Board's requirements for CME;

(4) Demonstrates continuing clinical competency as required by this rule;

(5) Meets the jurisprudence examination requirement; and

(6) Has no cause existing that may be considered grounds for disciplinary action or denial of licensure as provided by law.

C. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding an applicant's qualifications, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

6. Uniform Process for Withdrawal of License or Withdrawal of an Application for License

A. A physician assistant may request to withdraw a license by submitting an administratively complete renewal application which states the reason for requesting the withdrawal of the license.

B. An applicant may request to withdraw their application for a license by submitting a written request which states the reason for requesting to withdraw the application.

C. The Board staff may approve an application to withdraw a license or a request to withdraw an application if the Board has no open investigation or complaint regarding the applicant, and no cause exists that may be considered grounds for disciplinary action or denial or licensure as provided by law.

D. If a request to withdraw a license or an application for a license is presented to the Board, the Board shall determine whether to grant the request and whether the request was made while the applicant was under investigation by the Board.

7. Requirements for License Reinstatement

A. The Board, or if delegated, Board staff may reinstate a lapsed or withdrawn license of a physician assistant who meets all of the following requirements:

(1) Submits an administratively complete reinstatement application;

(2) Pays the appropriate reinstatement fee(s);

(3) Provides a written statement explaining why he/she withdrew or allowed the license to lapse and a detailed listing of his/her activities since that time;

(4) Held a Maine physician assistant license or was deemed to have held a valid Maine physician assistant license prior to filing an application for reinstatement;

(5) Passes, at the time of license application, a jurisprudence examination administered by the Board;

(6) Has passed the NCCPA certification examination and holds a current certification issued by the NCCPA that has not been subject to disciplinary action by the NCCPA at the time the license application is acted upon by the Board;

(7) Demonstrates current clinical competency as required by this rule; and

(8) Has no cause existing that may be considered grounds for disciplinary action or denial of license reinstatement as provided by law.

B. In the event that the Board delegates licensing decisions to Board staff and there is any question regarding reinstatement of the license, Board staff shall consult with the Board Secretary, Board Chair, or their designee who may approve the application or defer action on the application to the full Board.

C. A physician assistant whose license has lapsed or been withdrawn for more than five (5) years shall apply for a new license.

D. The applicant's license may not be reinstated if the applicant has not provided evidence satisfactory to the Board of having actively engaged in active rendering of medical services continuously for at least the past 12 months under the license of another jurisdiction of the United States or Canada unless the applicant has first satisfied the Board of the applicant's current competency by passage of written examinations or practical demonstrations as the Board may prescribe, including but not limited to meeting the continued clinical competency requirements of this rule.

SECTION 4. UNIFORM CONTINUING CLINICAL COMPETENCY REQUIREMENTS

1. Requirements

A. General

If an applicant has not engaged in the active rendering of medical services during the 24 months immediately preceding the filing of the application, the Board may determine on a case by case basis in its discretion whether the applicant has adequately demonstrated continued competency to render medical services.

B. Demonstrating Current Competency

The Board may require an applicant to submit to any competency assessment(s) or evaluation(s) conducted by a program approved by the Board. If the assessment/evaluation identifies gaps or deficiencies, the applicant must complete an educational/remedial program to address them or engage in supervised practice as required by the Board. The Board retains the discretion regarding the method of determining continued competency based upon the applicant's specific circumstances. The methodology may include but is not limited to successful passage of examination(s), completion of additional training, and successful completion of a formal reentry to practice plan approved by the Board.

C. If the Board determines that an applicant requires a period of supervised practice and/or the completion of an educational or training program, the Board may at its discretion issue the applicant a probationary license pursuant to a consent agreement or issue an applicant a temporary license in conjunction with a reentry to practice plan.

D. All expenses, including but not limited to, expenses associated with the assessment, evaluation, test, supervision and/or training requirements are the sole responsibility of the applicant.

SECTION 5. UNIFORM FEES

A. Board staff shall collect the following fees prior to the issuance of any license or certificate:

(1) Initial License Application $300

(2) Late Fee	$50
(3) License Renewal	$250
(4) License Reinstatement after Withdrawal	$200
(5) License Reinstatement after Lapse	$400

B. Board staff may prorate the fees for any license that will expire less than six (6) months after its issuance.

SECTION 6. UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS

1. General

A physician assistant may provide any medical service for which the physician assistant has been prepared by education, training and experience and is competent to perform. The scope of practice of a physician assistant is determined by the practice setting. Physician assistant scope of practice delineated in collaborative agreements or practice agreements are subject to review and approval by the Board.

2. Practice Setting

A physician assistant may render medical services in the following settings including, but not limited to a physician employer setting, physician group practice setting or independent private practice setting, or in a health care facility setting, by a system of credentialing and granting of privileges.

3. Consultation

Physician assistants shall, as indicated by a patient's condition, the education, competencies and experience of the physician assistant and the standards of care, consult with, collaborate with or refer the patient to an appropriate physician or other health care professional. The level of consultation required is determined by the practice setting, including a physician employer, physician group practice, or private practice, or by the system of credentialing and granting of privileges of a health care facility. A physician must be accessible to the physician assistant at all times for consultation. Consultation may occur electronically or through telecommunication and includes communication, task sharing and education among all members of a health care team. Upon request of the Board, a physician assistant shall identify the physician who is currently available or was available for consultation with the physician assistant.

4. Delegation by Physician Assistants

A physician assistant may delegate to the physician assistant's employees or support staff or members of a health care team, including medical assistants, certain activities relating to medical care and treatment carried out by custom and usage when the activities are under the control of the physician assistant. The physician assistant who delegates an activity is legally liable for the activity performed by the employee, medical assistant, support staff or a member of a health care team.

5. Dispensing Drugs

Except for distributing a professional sample of a prescription or legend drug, a physician assistant who dispenses a prescription or legend drug:

A. Shall comply with all relevant federal and state laws and federal regulations and state rules; and

B. May dispense the prescription or legend drug only when:

(1) A pharmacy service is not reasonably available;

(2) Dispensing the drug is in the best interests of the patient; or

(3) An emergency exists.

6. Legal Liability

A physician assistant is legally liable for any medical service rendered by the physician assistant.

7. Collaborative Agreements/Practice Agreements

Physician assistants who are required to have either a collaborative agreement or a practice agreement with an actively licensed Maine physician shall conform their scope of practice to that which has been reviewed and approved by the Board. Such agreements must be kept on file at the physician assistant's main location of practice and be made available to the Board or the Board's representative upon request. Upon any change to the parties in a practice agreement or other substantive change to the practice agreement, the physician assistant shall submit the revised practice agreement to the Board for review and approval.

8. Criteria for Requiring Collaborative Agreements or Practice Agreements

A. **Collaborative Agreement**. Physician assistants with less than 4,000 hours of documented clinical practice must have one (1) of the following in order to render medical services under their Maine license:

(1) A Board-approved collaborative practice agreement with a Maine physician holding an active, unrestricted physician license; or

(2) A scope of practice agreement through employment with a health care system or physician group practice as defined by this rule that has a system of credentialing and granting of privileges.

B. **Practice Agreement**. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner or who own and/or operate an independent practice must have the following in order to render medical services under their Maine license:

(1) A Board-approved practice agreement with a Maine physician holding an active, unrestricted physician license.

C. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and are employed with a health care facility or with a practice that includes a physician partner – regardless of whether or not the facility or practice have a system of credentialing and granting of privileges - are not required to have either a collaborative agreement or practice agreement.

D. Acceptable documentation of clinical practice includes, but is not limited to the following:

(1) Copies of previous plans of supervision, together with physician reviews;

(2) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

(3) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

(4) Attestation of completion of 4,000 hours of clinical practice, together with an employment history;

(5) Verification of active licensure in the State of Maine or another jurisdiction for 24 months or longer.

9. **Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements**

A. In reviewing a proposed scope of practice delineated in a collaborative agreement or a practice agreement, the Board may request any of the following from the physician assistant:

(1) Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;

(2) Copies of previous plans of supervision, together with physician reviews;

(3) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

(4) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

(5) Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA or its successor organization;

(6) Preparation of a plan for rendering medical services for a period of time under the supervision of a physician;

(7) Successful completion of an educational and/or training program approved by the Board.

B. Physician assistants who work outside of a health care facility or physician group practice may not render medical services until their scope of practice is reviewed and approved by the Board.

SECTION 7. UNIFORM ELEMENTS OF WRITTEN COLLABORATIVE AND PRACTICE AGREEMENTS

1. All written collaborative agreements and practice agreements shall include at a minimum:

A. The physician assistant's scope of practice and practice setting, including the types of patients and patient encounters common to the practice, a general overview of the role of the physician assistant in the practice setting, and the tasks that the physician assistant may be delegating to medical assistants.

B. Identify any and all active Maine physician(s) who are signatories to a collaborative or practice agreement that describes the physician assistants' scope of practice;

C. Identify the method(s) of consultation with the active Maine physicians who are signatories to a collaborative or practice agreement, and any limitations regarding the ability of the physician(s) to provide consultation, including limitations as to scope of practice or availability. The physician(s) who are signatories to a collaborative or practice agreement shall provide consultation only within their scope of practice and must be available for consultation with the physician assistant at all times and for all medical services rendered by the physician assistant.

D. Maintenance and production of collaborative and practice agreements

(1) Physician assistants licensed to practice in accordance with these rules must prepare and have on file in the main administrative office of the practice or practice location a written, dated collaborative or practice agreement that is signed by both the physician(s) and the physician assistant and contains the elements as required by this rule.

(2) Failure to have a current written collaborative or practice agreement on file and/or failure to produce a current collaborative or practice agreement upon request of the Board or Board staff shall result in a citation and/or possible disciplinary action.

SECTION 8. UNIFORM NOTIFICATION REQUIREMENTS FOR PHYSICIAN ASSISTANTS

1. Change of Collaborative Agreement or Practice Agreement

A physician assistant licensed by the Board shall notify the Board in writing within ten (10) calendar days of any change to a collaborative agreement or practice agreement by submitting a revised collaborative agreement or practice agreement to the Board for review and approval.

2. Termination of Collaborative or Practice Agreement

A physician assistant licensed by the Board shall notify the Board in writing within ten (10) calendar days regarding the termination of any collaborative or practice agreement. Such notification shall include the reason for the termination.

3. **Change of Contact Information**

A physician assistant licensed by the Board shall notify the Board in writing within ten (10) calendar days of any change in work or home address, email, phone, or other contact information.

4. **Death/Departure of Collaborating Physician**

A physician assistant licensed by the Board shall notify the Board in writing within ten (10) calendar days of the death or permanent or long-term departure of a collaborating physician who is a signatory to either a collaborative agreement or a practice agreement.

5. **Failure to Pass NCCPA Examination**

A physician assistant issued a temporary license by the Board shall notify the Board in writing within ten (10) calendar days of the failure to pass the NCCPA examination.

6. **Criminal Arrest/Summons/Indictment/Conviction**

A physician assistant shall notify the Board in writing within ten (10) calendar days of being arrested, summonsed, charged, indicted or convicted of any crime.

7. **Change in Status of Employment or Hospital Privileges**

A physician assistant shall notify the Board in writing within ten (10) calendar days of termination of employment, or any limitation, restriction, probation, suspension, revocation or termination of hospital privileges.

8. **Disciplinary Action**

A physician assistant shall notify the Board in writing within ten (10) calendar days of disciplinary action taken by any licensing authority including, but not limited to, warning, reprimand, fine, suspension, revocation, restriction in practice or probation.

9. **Material Change**

A physician assistant shall notify the Board in writing within ten (10) calendar days of any material change in qualifications or the information and responses provided to the Board in connection with the physician assistant's most recent application.

10. **Name Change**

A physician assistant licensed by the Board shall notify the Board in writing within thirty (30) calendar days regarding any legal change in her/his name and provide the Board with a copy of the pertinent legal document (e.g. marriage certificate or court order).

SECTION 9. UNIFORM CITATION

1. The board, or if delegated, board staff may issue citations in lieu of taking disciplinary action for:

   A. The failure to have a current written collaborative or practice agreement that conforms to the requirements of this rule on file at the location specified. The administrative fine for each violation is $200; or

   B. The failure to file a written notification form with the relevant Board as required by this rule. The administrative fine for each violation is $100.

2. **Service of Citation**

   The citation may be served on the licensee by mail sent from the Board office.

3. **Right to Hearing**

   The citation shall inform the licensee that the licensee may pay the administrative fine or request in writing a hearing before the Board regarding the violation. If the licensee requests a hearing, the citation shall be processed in the same manner as a complaint pursuant to 32 M.R.S. §3282-A, or 32 M.R.S. §2591-A except that the licensee's written response to the citation must be filed at the same time as the written request for hearing.

4. **Time for Payment or Request for Hearing**

   The licensee shall either pay the administrative fine within thirty (30) days following issuance of the citation or request a hearing in writing within thirty (30) days following issuance of the citation. Failure to take either action within this thirty-day (30-day) period is a violation of the Board's rules that may subject the licensee to further disciplinary action by the Board for unprofessional conduct, including but not limited to an additional fine and action against the license.

5. **Citation Violations Not Reportable**

   Administrative fines paid solely in response to citations issued pursuant to this rule do not constitute discipline or negative action or finding and shall not be reported to the

Federation of State Medical Boards or the National Practitioner Databank or to any other person, organization, or regulatory body except as allowed by law. Citation violations and administrative fines are public records within the meaning of 1 M.R.S. §402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. §408-A.

SECTION 10. CONDUCT SUBJECT TO DISCIPLINE

Violation of this rule by a physician assistant constitutes unprofessional conduct and is grounds for discipline of a physician assistant's license.

SECTION 11. UNIFORM CONTINUING MEDICAL EDUCATION (CME) REQUIREMENTS AND DEFINITIONS

In order to qualify to renew a license, a physician assistant must meet the following CME requirements:

1. **Requirements**

   A. Each physician assistant who possesses an active license shall complete, during each biennial licensing period, a minimum of one hundred (100) credit hours of continuing medical education subject to the following:

      (1) At least fifty (50) hours must be in Category 1 (as defined by this rule);

      (2) The total one hundred (100) hours may be in Category 1.

      (3) Fifty (50) credit hours may be in Category 2 (as defined by this rule).

   B. If the required CME is not completed and submitted, then an inactive status license renewal will be issued unless the Board has granted an extension of time or deferment as described in Subsection 2C below.

   C. Proof of current NCCPA certification at the time an application for renewal is submitted satisfies CME requirements.

   D. CME for Opioid Prescribing

   Physician assistants must complete 3 hours of Category 1 credit CME every two years on the prescribing of opioid medication as required by Board Rule Chapter 21 "Use of Controlled Substances for Treatment of Pain."

2. **Definitions of CME Categories**

A. Category 1 CME includes:

(1) CME programs sponsored or co-sponsored by an organization or institution accredited by: the American Academy of Physician Assistants (AAPA); the American Medical Association Council on Medical Education (AMA); the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Practice (AAFP); the Committee on Continuing Medical Education of the Maine Medical Association (MMA); the American Osteopathic Association (AOA); or the Maine Osteopathic Association (MOA). Programs will be properly identified as such by approved sponsoring or co-sponsoring organizations. VALUE: One (1) credit hour per hour of participation. VERIFICATION: Certificate of completion, if requested by the Board as part of a CME audit.

(2) Papers or articles published in peer reviewed medical journals (journals included in Index Medicus) VALUE: Ten (10) credit hours for each article. Limit one article per year. VERIFICATION: Copy of first page of article, if requested by the Board as part of a CME audit.

(3) Poster preparation for an exhibit at a meeting designated for AMA/AOA/AAPA category 1 credit, with a published abstract. VALUE: Five (5) credit hours per poster. Limit one poster per year. VERIFICATION: Copy of program with abstract and presenter identified, if requested by the Board as part of CME audit.

(4) Teaching or presentation in activities designated for AMA/AOA/AAPA category 1 Credit, VALUE: Two (2) credit hours for each hour of preparation and presentation of new and original material. Limit ten (10) hours per year. VERIFICATION: Copy of program from activity, if requested by the Board as part of CME audit.

(5) Medically related degrees, i.e. MPH, Ph.D. VALUE: Twenty-five (25) credit hours per year. VERIFICATION: Certified copy of diploma or transcript, if requested by the Board as part of CME audit.

(6) Postgraduate training or advanced specialty training. VALUE: Fifty (50) credit hours per year. VERIFICATION: Certified copy

of diploma or transcript, if requested by the Board as part of CME audit.

(7) Other programs developed or approved from time to time by the Board. VALUE: Determined by the Board at the time of approval. VERIFICATION: Determined by the Board at the time of approval.

B. Category 2 CME includes:

(1) CME programs with non-accredited sponsorship, i.e. those not meeting the definition of Category 1 as defined in Subsection 2(A) above. VALUE: One (1) credit hour per hour of participation.

(2) Medical teaching of medical students, interns, residents, fellows, practicing physicians, or allied professionals. VALUE: One (1) credit hour per hour of teaching.

(3) Authoring papers, publications, books, or book chapters, not meeting the definition of Category 1 as defined in Subsection 2(A) above. VALUE: Ten (10) credit hours per publication. Limit ten (10) hours per year.

(4) Non-supervised individual activities, i.e. journal reading, peer review activities, self-assessment programs which are not sponsored by an accredited Category 1 organization. VALUE: One (1) credit hour per hour of participation.

C. Exceptions to CME requirements

(1) The Board, at its discretion, may grant an extension of time or deferment to a licensee who because of prolonged illness, undue hardship, or other extenuating circumstances has been unable to meet the requirements of CME.

(2) CME will be prorated during the first licensure period.

(3) CME requirements will be stayed for physician assistants called to active military duty according to current Board policy.

D. Evidence of completion

Board staff shall perform random audits of CME.

SECTION 12. IDENTIFICATION REQUIREMENTS

1. Physician assistants licensed under this rule shall:

   A. Keep their licenses available for inspection at the location where they render medical services;

   B. When rendering medical services, wear a name tag identifying themselves as physician assistants; and

   C. Verbally identify themselves as physician assistants whenever greeting patients during initial patient encounters and whenever patients incorrectly refer to them as "doctors."

SECTION 13. PHYSICIAN ASSISTANT ADVISORY COMMITTEE

1. The Boards shall appoint a Physician Assistant Advisory Committee (the Advisory Committee) comprised of such persons as it deems appropriate, but the Advisory Committee shall include at least two physicians and two physician assistants licensed by either the BOLIM or the BOL. The PA members of the BOL and the BOLIM shall also be members of the committee. The Boards may also appoint such Advisory Committee members it deems appropriate.

2. The duties of the Advisory Committee shall be to review matters and make recommendations pertaining to physician assistants which the Boards request the Advisory Committee to consider.

3. Members of the Advisory Committee shall be appointed by the Boards for terms of up to four years. A member may be appointed by the Board for a second, and final four-year term. If a member is appointed to complete a term created by the premature departure of another member, the appointed member may still serve two full terms. The Boards may, at their discretion, remove any member from the Advisory Committee.

4. Members of the Advisory Committee shall not hold a leadership position or be an officer in a professional association regarding any professional occupation(s) licensed or regulated by the Boards.

5. The Chairperson of the Advisory Committee shall be a physician assistant member and shall not be a regular member of the Board of Licensure in Medicine or the Board of Osteopathic Licensure and shall be elected by a vote of the members of the Advisory Committee. The Chairperson shall serve for a term of two years and may not be re-elected.

6. The Advisory Committee shall meet at the request of either Board. Five (5) members of the Advisory Committee shall constitute a quorum for the purpose of holding a meeting and conducting business.

STATUTORY AUTHORITY: 32 M.R.S. §§ 2562 and 2594-E(5); §§ 32 M.R.S. 3269(7) and 3270-E(5); 10 M.R.S. §8003(5)(C)(4).

EFFECTIVE DATE:
November 1, 1994

EFFECTIVE DATE (ELECTRONIC CONVERSION):
October 22, 1996

NON-SUBSTANTIVE CHANGES:
January 29, 1999 - converted to Microsoft Word.

REPEALED AND REPLACED:
May 8, 2001
August 22, 2005 – filing 2005-333
August 23, 2006 – filing 2006-390
March 9, 2013 – filing 2013-056
July 18, 2016 – filing 2016-122 (*a joint rule with* 02-383 – Board of Osteopathic Licensure)

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE
IN MEDICINE
Chapter 2

383 BOARD OF OSTEOPATHIC
LICENSURE
Chapter 2

JOINT RULE REGARDING PHYSICIAN ASSISTANTS

ADOPTED BY BOARD OF LICENSURE IN MEDICINE NOVEMBER 10, 2020
ADOPTED BY BOARD OF OSTEOPATHIC LICENSURE NOVEMBER 12, 2020

BASIS STATEMENT AND RESPONSE TO COMMENTS

Basis Statement

The Board of Licensure in Medicine and the Board of Osteopathic Licensure (boards) were created by the Legislature with the sole purpose of protecting the public. 10 M.R.S. § 8008 provides:

> **§8008. Purpose of occupational and professional regulatory boards**
> **The sole purpose of an occupational and professional regulatory board is to protect the public health and welfare.** A board carries out this purpose by ensuring that the public is served by competent and honest practitioners and by establishing minimum standards of proficiency in the regulated professions by examining, licensing, regulating and disciplining practitioners of those regulated professions. **Other goals or objectives may not supersede this purpose.**

It is with this purpose in mind that the boards approach the current rule making regarding Chapter 2.

On March 18, 2020 L.D. 1660, a bill entitled "An Act to Improve Access to Physician Assistant Care" was emergently enacted into law in the State of Maine. Prior to its enactment by the full Legislature, L.D. 1660 was reviewed by the Joint Standing Committee on Health Coverage, Insurance and Financial Services (HCIFS), including oral and written testimony in support of and in opposition to the bill. Several individuals and organizations opposed the bill arguing that removing physician delegation and supervision over physician assistants would result in less oversight of physician assistant practice, unnecessary risk to the public, and independent practice by physician assistants who lack post-graduate residency training in a given medical specialty. Individual physician assistants and the Maine Association of Physician Assistants supported the bill arguing that physician assistants are trained medical professionals who should be treated as colleagues and work "in collaboration" with physicians – not under their supervision. In

addition, the HCIFS Committee was presented with testimony regarding the differences between the education and training of physicians (4 years of medical school followed by at least 3 years of residency training in a medical specialty) and physician assistants (2 years of school and no residency training) as well as the administrative paperwork burden placed on physician assistants, physicians, and health care systems regarding physician supervision requirements and written plans of supervision.

The Board of Licensure in Medicine and Board of Osteopathic Licensure (boards) submitted joint written testimony informing the HCIFS Committee that the bill would "represent a significant paradigm shift for the regulation and oversight of physician assistants in Maine," convert physician assistants from "dependent" practitioners to "independent" practitioners, and remove significant physician oversight and accountability. In addition, the boards pointed out to the HCIFS Committee that physician assistants working outside of health care facilities and physician group practices represented the most significant risk to the public as without physician oversight, supervision, and delegation the bill allowed physician assistants to define their own "scope of practice" with the risk that they could choose to perform services that are beyond their education and training. The HCIFS Committee amended the bill to require that certain physician assistants working outside of health care systems or physician group practices have collaborative agreements or practice agreements with scopes of practice approved by the boards. The significant changes of the new law include:

- Elimination of physician supervision and oversight of physician assistants;
- Elimination of the delegation of medical acts by physicians to physician assistants;
- Elimination of the requirement of plans of supervision and replaced them with collaborative agreements and practice agreements;
- Creation of an exception to the need for either a collaborative agreement or practice agreement for physician assistants with 4,000 hours or more of clinical experience who are working within a health care facility or physician group practice;
- Authorizing physician assistants with less than 4,000 hours of clinical experience to work within health care facilities or physician group practices pursuant to a privileging and credentialing document that delineates the scope of practice (in lieu of a collaborative agreement); and
- Authorizing the Boards to approve or deny the scope of practice delineated in a collaborative agreement or practice agreement.

In sum, the new law created the following four categories of physician assistant practice models in Maine:

1. Physician assistants with **less than 4,000 hours** (post-graduate) of documented clinical experience **working in a health care facility or physician group practice** under a system of credentialing and granting of privileges and pursuant to a written scope of practice agreement.

2. Physician assistants with **less than 4,000 hours** (post-graduate) of documented clinical experience working in a private practice setting **other than** a health care facility or

physician group practice under a system of credentialing and granting of privileges pursuant to a written collaborative agreement with a Maine licensed physician.

3. Physician assistants with **more than 4,000 hours** (post-graduate) of documented clinical experience and the principal clinical provider in a practice that does not include a physician partner (own or operate an independent practice) pursuant to a practice agreement with a Maine licensed physician.

4. Physician assistants with **more than 4,000 hours** (post-graduate) of documented clinical experience and practicing in a setting **other than** as the principal clinical provider in a practice that does not include a physician partner (do not own or operate an independent practice) such as a health care facility or physician group practice. **No credentialing and privileging document, no collaborative agreement, and no practice agreement is required** to be maintained or produced to the boards.

Nearly all stakeholders concurred that the vast majority of physician assistants in Maine worked within health care facilities, which operate pursuant to protocols for educating and training them as well as for evaluating and monitoring the quality of medical services rendered by physician assistants. Therefore, decreasing the administrative burdens in these settings, which provide both oversight and a safety net for physician assistants, arguably did not pose a significant risk to the public. In addition, health care facilities are ultimately legally liable and responsible for any medical services rendered by physician assistants employed by them, which should lead to appropriate education, training, and oversight. Finally, health care facilities are mandated by law to report to the boards any adverse employment or privileging decisions regarding physician assistants that are based upon unprofessional conduct or competency issues.

Similarly, nearly all stakeholders agreed that physician assistants who worked alone outside of health care facilities or physician group practices represent the greatest risk to the public due to the lack of oversight and evaluation. Therefore, the Legislature gave the boards the responsibility of reviewing and approving the scopes of practice for these physician assistants who may perform medical services pursuant to a collaborative agreement or practice agreement. As indicated earlier, prior to the enactment of this law that responsibility fell to the physician(s) supervising the physician assistant(s). **As evidence of this intent, the new law specifically provided that both collaborative agreements and practice agreements must include the scope of practice for the physician assistant and specifically provided that both collaborative agreements and practice agreements "shall be submitted to the board for approval" by the physician assistant.**

The new law specifically provides that "scope of practice" for physician assistants "is determined by the practice setting" and that a physician assistant "**may provide any medical service for which the physician assistant has been prepared by education, training and experience and is competent to perform.**" Thus, in evaluating any proposed scope of practice, the legislation requires the boards to consider the physician assistant's education, training and experience, and competency as well as the practice setting. This is to ensure that the public is competently and safely served. For example, the public would not be safely or competently served by a physician assistant with more than 4,000 hours of clinical experience and who has

been practicing for ten (10) years in orthopedics, and who decides to open a private practice in which she is the principal clinical provider without a physician partner providing general family practice services. Because orthopedics is a medical specialty that is significantly different from family practice, allowing a physician assistant to make such a change – without oversight, additional training and/or re-education – may endanger the public.

In addition, to emphasize the HCIFS Committee's (and hence the Legislature's) intent to implement this new model of physician assistant oversight in Maine, the new law included the following language:

> **Construction**. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, **this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings**.

With the foregoing Legislative mandate and statutory changes in mind, the boards convened a workgroup to review the draft amendments to the Chapter 2 rule (and accompanying licensing applications and collaborative agreements/practice agreements forms). The work group consisted of the staff and membership of the boards as well as their respective legal counsel:

Members/staff of the BOLIM

- Dr. Louisa Barnhart, M.D., Board member
- Mr. Christopher Ross, P.A., Board Member
- Ms. Lynne Weinstein, Public Board Member
- Timothy E. Terranova, Assistant Executive Director
- Dennis E. Smith, Esq., Executive Director

Members/staff of the Osteopathic Board of Licensure

- Dr. John Brewer, D.O., Board Member
- Ms. Melissa Michaud, P.A., Board Member
- Susan E. Strout, Executive Secretary

Members of the Attorney General's Office

- Assistant Attorney General Michael Miller
- Assistant Attorney General Lisa Wilson

The draft amendments to the rule:

- Add new definitions (e.g. "Health Care Facility," Health Care Team," Inactive Status License," and "Physician Group Practice") and eliminate old definitions (e.g. "Supervision" and "Written Plan of Supervision");
- Eliminate registration and supervision requirements;
- Establish criteria for "Inactive Status Licenses;"
- Establish uniform continuing clinical competency requirements;
- Amend the uniform fees;
- Establish criteria for collaborative agreements and practice agreements;
- Amend the uniform notification requirements to include legal change of name; and
- Amend the continuing medical education (CME) requirements, including 3 hours of CME every 2 years regarding opioid prescribing.

The boards published the amendments to the rule for public comment on July 8, 2020. The amendments organized the rule as follows:

SECTION 1. Definitions
SECTION 2. Uniform Qualifications for Licensure
SECTION 3. Uniform Requirements for Renewal/Inactive Status/Reinstatement/Withdrawal of License
SECTION 4. Uniform Continuing Competency Requirements
SECTION 5. Uniform Fees
SECTION 6. Uniform Scope of Practice for Physician Assistants
SECTION 7. Uniform Elements of Written Collaborative and Practice Agreements
SECTION 8. Uniform Notification Requirements for Physician Assistants
SECTION 9. Uniform Citation
SECTION 10. Conduct Subject to Discipline
SECTION 11. Uniform Continuing Medical Education (CME) Requirements and Definitions
SECTION 12. Identification Requirements
SECTION 13. Physician Assistant Advisory Committee

Before delving into the comments, the boards wish to convey their sincere appreciation for the feedback, comments, suggestions and questions regarding the proposed rule amendments. In addition, the boards want to clarify for the commenters and stakeholders that the boards are State agencies created by the Legislature and derive their very existence, membership and authority from the laws enacted by the Legislature. The boards must implement the newly enacted law, and cannot act contrary to law or promulgate a rule or amendments to a rule that conflict with the law. Several of the comments submitted to the boards expressed general opposition to the new law and advocated for continued physician supervision and oversight of physician assistants in the rule amendments. The Legislature has spoken, and the boards are legally bound to enact rules that are both within the law and congruent with the Legislative intent. The boards express their appreciation for the commenters' and stakeholders' understanding concerning this issue.

The comment period for the rule as originally proposed closed on August 7, 2020. The boards received 19 written comments from 23 individuals and organizations regarding the proposed rule, which are attached to this Basis Statement and Response to Comments. The boards subsequently reviewed the comments received regarding the proposed rule, and voted to make

several substantive changes to the rule based upon the concerns expressed in the comments, including:

- Adding a definition for "physician."
- Adding a new sub-paragraph D to Section 6, paragraph 8 that identifies acceptable documentation of clinical practice.
- Adding a new paragraph 9 to Section 6 that identifies criteria which the boards will employ in reviewing and evaluating the scope of practice for physician assistants in collaborative agreements or practice agreements.
- Adding a provision in Section 12 that requires physician assistants to verbally identify themselves as physician assistants to patients and to correct patients who refer to them as "doctors."

The proposed rule with the foregoing substantive changes was re-published for public comment on September 30, 2020. The comment period for the re-proposed rule closed on October 30, 2020. The boards received additional comment(s) regarding the re-published rule which are identified below.

Original Comments Following Proposal of the Rule on July 8, 2020

List of Commenters:

1. Sarah Calder, Dir. of Gov't Affairs, *on behalf of* MaineHealth
2. Saul M. Levin, MD, CEO & Med. Dir., *on behalf of* American Psychiatric Association
3. Stuart Glassman, M.D., Chair, *on behalf of* State Advocacy Committee, American Academy of Physical Medicine and Rehabilitation
4. Alan Hull, P.A.
5. Jeffrey Austin, V.P. of Gov't Affairs, *on behalf of* Maine Hospital Association
6. Angela Leclerc, P.A., President, *on behalf of* Me. Assoc. of Physician Assistants (MEAPA)
7. Andrew Nicholson, M.D.
8. Christine Thomas, P.A.
9. Corey Cole, D.O.
10. Maria Paone, M.D.
11. Megan Selvitelli, M.D., President, *on behalf of* Maine Neurological Society
12. Garreth Debiegun, M.D., President, Maine Chapter, *on behalf of* American College of Emergency Physicians (ACEP)
13. Lisa Harvey-McPherson, R.N., V.P. Gov't Relations, *on behalf of* Northern Light Health
14. Dana L. Greene, P.A.
15. Lisa A. Moreno, M.D., President, *on behalf of* American Academy of Emergency Medicine (AAEM)
16. Purvi Parikh, M.D., *on behalf of* Physicians for Patient Protection
17. Alyson Maloy, M.D., *on behalf of* Portland Cognitive and Behavioral Neurology
18. Dan Morin, Dir. Comm. And Gov't Affairs, *on behalf of* Maine Medical Association (MMA), Maine Society of Eye Physicians and Surgeons (MSEPS), Maine Chapter of the

American College of Emergency Physicians (MEACEP), and the Maine Neurological Society (MNS)
19. Amanda Richards, Exec. Dir., *on behalf of* Maine Osteopathic Association
20. Ann Robinson, Esq., *on behalf of* Spectrum Healthcare Partners
21. Robert Grover, M.D.
22. Scott C. Ellis, P.A.
23. Anthony Curro, P.A.

Response to Comments

Comments and Board Responses:

I. General Comments Opposing the Law and Rule Amendments

The boards received a number of general comments in opposition to the new law and the rule amendments eliminating physician oversight and supervision of physician assistants despite the clear intent of the Legislature. In addition, the boards received a number of comments requesting changes to the rule that are beyond the boards' authority or which would contradict the law or conflict with the intent of the law.

1. Saul Levin, M.D. *on behalf of* American Psychiatric Association

   WRITTEN COMMENT: This rule changes the terminology of the relationship between the physician and the physician assistant from "supervision" to "collaborative agreement" and "practice agreement." As a result, this rule authorizes physician assistants to practice far more freely, however it renders a physician no less liable for the actions of a physician assistant. This could be ameliorated by adding language indicating that physicians shall not be held liable in cases where physician assistants are the primary patient contact unless the collaborating physician was willfully negligent.

   - BOARDS' RESPONSE: Comment not accepted. The rule amendment follows the law. The boards do not have the authority to affect the legal liability of physicians collaborating with physician assistants.

2. Stuart Glassman, M.D. *on behalf of* State Advocacy Committee, American Academy of Physical Medicine and Rehabilitation

   WRITTEN COMMENT: AAPM&R writes in opposition to the proposed amendments to remove the physician supervision requirements for physician assistants. Physiatrists work collaboratively with many allied and advanced practice health care providers, who are valued members of the rehabilitation team. However, we believe that physician-led, patient-centered, team-based care is the best approach to providing optimized care for patients. We have great concern that providers who have not gone through the extensive training and medical education that a physician has, would be allowed to practice independently of a physician to provide patient care. Physician assistants, while skilled, knowledgeable, and important to patient care, are not physicians. The role of physician

assistants on the health care team is determined by many factors, including education and training level and individual experience and proficiency. Physician assistants should provide patient care to the extent of their education and training, subject to the oversight of a supervising physician.

There is a significant disparity in the education and training between a physician and physician assistant. Physicians spend over 11 years in medical training in order to ensure they are properly trained and educated to diagnose and treat patients. The skills, knowledge, and abilities of physician assistants and physicians are not equivalent, but instead are complementary. The most effective way to maximize the talents of the complementary skill sets of both professionals is to work as a team to care for patients in the physician-led, team-based approach.

- BOARDS' RESPONSE: Comment not accepted. The rule amendments follow the law. The boards do not have the authority to change a law nor to enact rule amendments that conflict with the law or contradict the intent of the law.

3. Maria Paone, M.D.

WRITTEN COMMENT: I am highly concerned about the language of the new law allowing independent practice for PAs. It will set a dangerous precedent for other states. PAs have only 2 years of graduate education and no residency training. This bill essentially permits them the same rights and privileges as a physician who went to school for 4 years and trained for another 3-7 years after. This bill allows PAs to practice in any specialty of their choice. Even if their 4000 hours are spent in pediatrics, they can get a job in the ICU as an independent practitioner without a single hour of extra training. There should be language in the law mandating another training period before being allowed independent practice in another specialty. The law allows PAs to "collaborate" with physicians and takes out all reference to "supervision" even when they first graduate. This is unsafe. At the very least, their initial post graduate period should be required to be "under direct supervision." How do they expect to learn medicine without guidance? The public should not be experimented on for the satisfaction of their ego and the greed of the corporations who want to hire them in place of physicians. PAs and NPs like to say they want to practice to the "top of their license." In the case of a PA, their license is to practice as a Physician Assistant, not as a Physician. This law enables them to bypass 2 years of school and 3-7 years of training, board specialty exams and recertification and practice to the full extent of a Physician's license. More, actually, because, unlike a physician, they are permitted to switch specialties at will. Either medical school and physician training has value or it doesn't. If a law permitting medical students the same rights as this law does PAs, there would be a public outcry that dangerously undereducated and poorly trained doctors were being licensed. And that would be correct. There should be no shortcuts to the practice of medicine.

- BOARDS' RESPONSE: Comment not accepted. The rule amendments follow the law. The boards do not have the authority to change a law nor to enact rule amendments that conflict with the law or contradict the intent of the law.

4. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
   Garreth Debiegun, M.D. *on behalf of* Maine Chapter of American College of Emergency Physicians

   WRITTEN COMMENT: We have concerns that the removal of requirements related to supervision potentially compromises patient safety in our practice setting.

   - BOARDS' RESPONSE: Comment not accepted. The rule amendments follow the law. The boards do not have the authority to change a law nor to enact rule amendments that conflict with the law or contradict the intent of the law.

5. Robert Grover, M.D.

   WRITTEN COMMENT: If PAs don't need to be supervised, then surely physicians who had 2 years clinical training in medical or osteopathic school shouldn't need to do a residency to practice either.

   - BOARDS' RESPONSE: Comment not accepted. The law establishes the criteria for licensure of physicians and physician assistants in Maine.

6. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
   Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
   Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
   Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

   WRITTEN COMMENT: The scope of practice of physicians is determined by completion of a Liaison Committee on Medical Education (LCME)-accredited medical school, followed by highly competitive acceptance into and completion of an Accreditation Council of Graduate Medical Education (ACGME)-approved residency program. This nearly decades-long process to become a physician is most often followed by passing multi-day specialty exams to earn "board-certification." Certification in one's American Board of Medical Subspecialties (ABMS) specialty is determined by a 3 to 7 year-long residency, some with an additional 1 to 3-year long fellowship. This process ensures rigorous standardization of skills and includes multiple overlapping determinants of competence. No similar oversight in PA training exists. The draft appears to show that the BOLIM has opted to forego the need for this rigorous determination of safe scope of practice and opt instead to allow PAs to claim expertise based on practice location or whatever training and education the PA decides is sufficient. Under this system, a PA could legally claim to be a "specialist" in dermatology after working for a few weeks in a dermatology practice, while a physician with many years more training in dermatology is legally barred from such claims. The confusion created by this double standard communicates to patients that the training of a PA "specialist" exceeds that of a physician, and yet this deception is legal on a state level. Likewise, a PA could decide he/she is competent to perform a thoracentesis after watching one in the emergency department. This PA with no formal training in this procedure could decide to perform this procedure on a patient, who has no idea of the lack of training of this clinician and

the associated risk. No true informed-consent is possible, as the risks of the procedure being performed by an untrained individual are additive to the inherent risks of the procedure. Relying on the employer to ensure and/or provide the training and oversight for PAs' scope of practice places the responsibility on to employers, who practice in a business model, not in an altruistic one of educator or supervisor. The BOLIM does not determine scope of practice for physicians through the licensing process because there is already a rigid system in place that determines physician scope of practice. However, since a similar system is not in place for PAs, how is the BOLIM going to protect public safety by ensuring PAs are competent to perform in the scope of practice they self-declare? If there is no answer, perhaps this needs to be carefully established as part of the rule-making process. The speed of the law-making seems to demand more from the medical system than currently exists to determine scope of practice of PAs in a manner commensurate with public safety.

- BOARDS' RESPONSE: Comment not accepted. The law establishes the criteria for licensure of physicians and physician assistants in Maine. The rule amendments follow the law. The boards do not have the authority to change a law nor to enact rule amendments that conflict with the law or contradict the intent of the law. Physician assistants must be prepared by education, training and experience to perform a medical service and the rule does not permit physician assistants to provide medical services that they are not competent to perform.

7. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

WRITTEN COMMENT: **Collaboration**
The term collaboration is used when discussing work between nurses and physicians because they belong to different professions. In contrast, physicians and physician assistants both belong to the profession of medicine. Because both physicians and PAs are now being allowed to practice medicine independently, but PAs complete significantly less training than physicians, physicians will continue to be held liable unless they are working in a consultation capacity. When a physician and a PA work together, the physician is either supervising (e.g. the physician shares responsibility for the patient) or the physician is consulting (e.g. not primarily responsible for the patient). When a physician "collaborates" with a PA on a case, the physician will be held liable. Therefore, we propose the term consultation agreement be used instead of collaboration agreements to more clearly define the roles and responsibilities of each party. Simply stating in the amendment that PAs are liable for their own mistakes will not make it so. Changes in language as proposed here, as well as other changes not relevant here (such as holding equal malpractice insurance) will be necessary. In addition to the above discussion of language, we would like to comment on the omission of a consultation agreement (collaborative agreement, as per the draft) requirement for PAs hired by facilities that credential them. We believe this is a dangerous oversight in patient safety

that assumes employers provide physician staff to meaningfully review their work, which is widely known to not occur. Furthermore, it continues to make physicians liable for the work done by PAs at those institutions. We do not see any justifiable reason to exclude inexperienced PAs hired by facilities from the consultation/collaborative agreement proposed by the Board. This is an issue of ensuring ongoing supervision to ensure safety in licensure and we do not believe oversight of that can safely be left to employers whose goal is maximum productivity of employees.

- BOARDS' RESPONSE: Comment not accepted. The rule amendments follow the law. The boards do not have the authority to change a law nor to enact rule amendments that conflict with the law or contradict the intent of the law. The rule amendments cannot define a term to conflict with a definition that already exists in the law ("collaborative agreement") nor can the rule amendments limit the legal liability of physicians providing collaboration or consultation to physician assistants. Finally, the law specifically provides for physician assistants to be able to provide medical services without a collaborative agreement when working in a health care facility or physician group practice pursuant to a credentialing and privileging document that identifies the physician assistant's scope of practice.

8. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
   Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
   Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
   Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

   WRITTEN COMMENT: **Pay Parity**
   We based our comments on the BOLIM draft, but do want to say that a paragraph in the osteopathic version appears to require pay parity for PAs. We do not see a similar statement in the BOLIM version. Various interests have promoted the false narrative that a generic "health care provider" provides uniform medical services independent of the training of the "provider." This falsity is actualized by an insurance industry coding system that distinguishes the care of other specialties, such as occupational therapists, social workers, audiologists, chiropractors, and nutritionists, but makes no similar distinction between the nature of the service provided by physicians, nurse practitioners, and PAs, other than by a slight *percentage* reduction for nonphysician providers (NPPs). Pay parity laws gloss over the fact that physicians, NPs, and PAs, actually provide different medical services based on their expertise. The only public agencies that truly understand the differences in training and thus can protect the public from a false belief in equivalency are the medical boards. For the osteopathic medical board to promote pay parity is to equate the training and education of PAs with that of physicians. The downstream consequences of this false equivalency in the business-of-medicine model would be devastating to patient safety as lower-cost PAs are hired to provide "the same" medical care as physicians, when in fact the care is not the same. Furthermore, patients lose the right to see a physician when HMOs fill their panels with PAs and insist that rather than see a family practice physician as a PCP, the patient MUST see a PA who works in family practice because they provide "the same" medical service. Our concern with the draft as it stands is that rather than permit a specific type of clinician to work

independently, it functionally gives PAs a license to practice medicine in the same capacity as physicians, without them actually completing the education and training necessary to achieve that level of competence. The practice of medicine would thus be largely performed by people without medical degrees, while the public continues to be lost in confusion about the actual training and oversight of these clinicians, which they understandably assume others (the employers, the BOLIM) are doing.

- BOARDS' RESPONSE: Comment not accepted. The rule amendments follow the law. The boards do not have the authority to change a law nor to enact rule amendments that conflict with the law or contradict the intent of the law. The rule is a joint rule and there are not two versions with one addressing pay parity. Financial reimbursement regarding medical services provided by physician assistants is beyond the scope of the rule and the jurisdiction of the boards.

9. Corey Cole, DO

WRITTEN COMMENT: I feel that there should be a comment about the PA needing to have malpractice insurance whether it be provided by themselves or their employer.

- BOARDS' RESPONSE: Comment not accepted. The HCIFS Committee was made aware that no law exists in Maine requiring physicians or physician assistants to obtain medical malpractice insurance. Despite this, the HCIFS Committee and the Legislature declined to make this a requirement in the new law.

II. General Comments Supporting the Law and Rule Amendments

1. Jeffrey Austin, VP of Gov't Affairs *on behalf of* Maine Hospital Association

WRITTEN COMMENT: MHA supports the Chapter 2 Joint Rule Regarding Physician Assistants. MHA participated in the legislative process in connection with the underlying bill. Maine hospitals employ many physician assistants all across the state. A hospital will be considered a "health care facility" under the terms of the rule and will be impacted by the rule. We believe the rule is consistent with the underlying law and addresses the issues in the manner expected by the legislature.

- BOARDS' RESPONSE: Comment accepted for the reasons stated.

2. Christine Thomas, P.A.

WRITTEN COMMENT: As a Physician Assistant who has practiced in Maine for 24 years, I would like to support the proposed Joint Rule Regarding Physician Assistants I believe the changes to the current regulations will allow better access to health care for all Mainers by removing limitations. It will also put us on equal footing with other professionals who can work independently despite having less experience.

- BOARDS' RESPONSE: Comment accepted for the reasons stated.

3. Dana L. Green, P.A.

   WRITTEN COMMENT: I would like to thank you for all your professional work during such challenging and uncertain times. I am also thankful for the proposed revisions to the physician assistant medical practice rules of the newly approved Chapter 2. This will provide expansion of physician assistant services in the coming years for Maine's medical communities.

   - BOARDS' RESPONSE: Comment accepted for the reasons stated.

4. Scott C. Ellis, P.A.

   WRITTEN COMMENT: With the growing demands for healthcare services in Maine and around the country, the role of the Physician Assistant as a member of the healthcare provider team has never been more necessary. That is why LD1660 has been such an important step forward in Maine to insure that patients, especially in underserved parts of our state with significant physician shortages, have access to quality healthcare. Thank you for all your hard work during this Covid-19 Pandemic to craft these accurate, clear and thoughtful proposed revisions to Chapter 2. The revisions to Chapter 2 Joint Rule Regarding Physician Assistants addresses the growing needs for healthcare providers in Maine by removing the physician supervisory requirements for PAs and establishing collaborative and practice agreements with physicians and other healthcare professionals. Overall, the Rules reflect the intent of LD1660 by eliminating language that implies physician liability for PA care, and allows the PA scope of practice to be determined at the practice level based on the PA's individual education, training, and experience.

   - BOARDS' RESPONSE: Comment accepted for the reasons stated.

III. **Section 1 – Definitions**

1. Saul Levin, M.D. *on behalf of* American Psychiatric Association

   WRITTEN COMMENT: In LD 1660, "physician" is defined as "a person licensed as a physician under this chapter or chapter 48." "This chapter" refers to chapter 36, Osteopathic Physician licensure and chapter 48 is licensure provided by the Board of Licensure in Medicine. The proposed rule has a definition section but does not provide a definition for "physician." To retain the intent of the law, the definition for physician should be echoed in the regulation: "'physician' is a person licensed as a physician under chapter 36 or chapter 48."

   - BOARDS' RESPONSE: Comment accepted for the reason stated. The following definition will be added to Section 1 Definitions: "Physician" means a person licensed as a physician by the Maine Board of Licensure in Medicine or the Maine Board of Osteopathic Licensure. The boards removed the definition of

"physician" previously contained in the rule following the amendment to the definition of "active unrestricted physician license" but will reinsert a definition for that term as stated above.

2. Andrew Nicholson, M.D.

   WRITTEN COMMENT: Maine physician is undefined. This implies a physician licensed and residing in Maine, but it is not defined. Given the movement to telehealth, and the practice of medicine across state lines, I think it is important that "Maine physician" be someone locally available and licensed.

   - BOARDS' RESPONSE: Comment accepted for the reason stated. The following definition will be added to Section 1 Definitions: "Physician" means a person licensed as a physician by the Maine Board of Licensure in Medicine or the Maine Board of Osteopathic Licensure. The boards removed the definition of "physician" previously contained in the rule following the amendment to the definition of "active unrestricted physician license" but will reinsert a definition for that term as stated above.

3. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
   Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
   Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
   Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

   WRITTEN COMMENT: When a physician and a PA work together, the physician is either supervising (e.g. the physician shares responsibility for the patient) or the physician is consulting (e.g. not primarily responsible for the patient). When a physician "collaborates" with a PA on a case, the physician will be held liable. Therefore, we propose the term consultation agreement be used instead of collaboration agreements to more clearly define the roles and responsibilities of each party.

   - BOARDS' RESPONSE: Comment not accepted. The rule amendments follow the law. The boards do not have the authority to change a law nor to enact rule amendments that conflict with the law or contradict the intent of the law. The rule amendments cannot define a term to conflict with a definition that already exists in the law ("collaborative agreement"). The term "collaborative agreement" in the rule amendments is based upon the definition of that term in the law.

IV. **Section 2 – Uniform Qualifications for Licensure:**

1. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
   Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
   Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
   Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

WRITTEN COMMENT: Point (8) on page 6 of the BOLIM draft under "Uniform Requirements for Full License" requires for licensure that a physician assistant (PA) "demonstrates current clinical competence as required by this law." (This requirement is also found on page 11 under license reinstatement.) Clinical competence is not explicitly defined under the law, per se, but on page 15, under Uniform Scope of Practice for Physician Assistants, PAs are granted the authority to provide "any medical service for which the physician assistant has been prepared by education, training, and experience and is competent to perform. The scope of practice of a physician assistant is determined by the practice setting."

- BOARDS' RESPONSE: Comment accepted. The rule as drafted requires physician assistants who have not rendered medical services within the 24 months prior to application to demonstrate current clinical competency. Section 4 of the amended rule identifies various ways in which an applicant may attempt to demonstrate current clinical competency, which the boards will evaluate based upon the specific facts and circumstances of the applicant.

2. Anthony Curro, P.A.

WRITTEN COMMENT: Can the criteria for demonstrating clinical competency [be] included as part of the proposed Chapter 2 amendments?

- BOARDS' RESPONSE: Comment accepted. The rule as drafted requires physician assistants who have not rendered medical services within the 24 months prior to application to demonstrate current clinical competency. Section 4 of the amended rule identifies various ways in which an applicant may attempt to demonstrate current clinical competency, which the boards will evaluate based upon the specific facts and circumstances of the applicant.

V. Section 3 – Uniform Requirements for Renewal/Inactive Status/Reinstatement/ Withdrawal of License

1. Anthony Curro, P.A.

WRITTEN COMMENT: Section 3 indicates the use of an approved form while Item 4 page 10 has "approved by the board" crossed out. The use of an approved form makes sense to me and I suggest Item 4 on page 10 be changed to remove the strikethrough.

- BOARDS' RESPONSE: Comment not accepted. The language was stricken from the amended rule as redundant. "Administratively complete application" defined in Section 1 of the amended rule includes "a uniform application for licensure as developed by the boards."

2. Anthony Curro, P.A.

WRITTEN COMMENT: Can the criteria for demonstrating continuing clinical competency [be] included as part of the proposed Chapter 2 amendments? The same suggestion applies to item 7.A.(7) on page 16 which addresses demonstrating clinical competency for license reinstatement.

- BOARDS' RESPONSE: Comment accepted. The rule as drafted requires physician assistants who have not rendered medical services within the 24 months prior to application to demonstrate current clinical competency. Section 4 of the amended rule identifies various ways in which an applicant may attempt to demonstrate current clinical competency, which the boards will evaluate based upon the specific facts and circumstances of the applicant.

VI. Section 6 - Uniform Scope of Practice for Physician Assistants

1. Saul Levin, M.D. *on behalf of* American Psychiatric Association

WRITTEN COMMENT: We are concerned that the proposed rule would authorize a facility or the Board to determine the scope of practice for a physician assistant. This does not correspond with physician scope of practice; for instance, a psychiatrist cannot decide to suddenly become a dermatologist one day and have the facility or Board solely determine the physician's scope of practice. A physician's scope of practice is based on years of training, including Accreditation Council of Graduate Medical Education (ACGME)-approved residency programs and multiple exams proving the physician has the skills needed to be a medical specialist. Similarly, a facility or Board should not unilaterally determine a physician assistant's scope of practice without specific evidence that a physician assistant has completed additional education and training to be certified in that specialty. To address these concerns, we suggest including detailed regulatory language requiring certification in the specialty in which a physician assistant will be practicing **and** defining the specific education and training of each specialty for those physician assistant "specialties" that do not have certification programs.

- BOARDS' RESPONSE: Comment not accepted. The new law authorizes: (1) the boards to review "collaborative agreements" and "practice agreements" to approve or not approve a physician assistant's scope of practice; and (2) physician assistants with less than 4,000 hours of clinical experience to work within health care facilities or physician group practices pursuant to a written credentialing and privileging plan that identifies the physician assistant's scope of practice. In addition, the new law exempts physician assistants with more than 4,000 hours of clinical experience and who are working within a health care facility or physician group practice to render medical services without a collaborative agreement or a written credentialing and privileging plan that identifies the physician assistant's scope of practice. In crafting the new law, the Legislature intentionally eliminated the legal requirement for physician delegation of medical acts to physician assistants, and shifted the responsibility

for approving the scope of practice for certain physician assistants (depending upon clinical experience and practice setting) to either the boards or the health care facilities/physician group practices employing them. The Legislature was well-aware of the lack of post-graduate training for physician assistants as well as the fact that physician assistants receive additional education and training "on the job" in physician group practices or health care facilities. While it is true that physicians receive post-graduate training in a specific medical specialty, the boards do not license physicians to practice medicine within a particular medical specialty. Physicians are expected to practice medicine within the parameters of their education and training. In addition, a law specifically prohibits the Board of Licensure in Medicine from requiring national board specialty certification for physicians as a condition of licensure or re-licensure (See 32 M.R.S. § 3271(2)). Therefore, the comment suggesting that the boards should require all physician assistants desiring to practice in a specific medical field obtain specialty certification is one that is actually prohibited for physicians. The evaluation of a physician assistant's education and training is appropriate as part of the boards' review of a proposed scope of practice; however, the ways in which physician assistants may be able to demonstrate competency in a specific medical field should – like the current clinical competency requirement and re-entry to practice guidelines – be flexible. Unlike physicians, some physician assistants may work in various practices rendering medical services in a variety of medical specialties. Requiring specialty certifications for physician assistants who have rendered medical services competently for years in several different specialty areas of medicine would be unduly burdensome. On the other hand, requiring physician assistants who have never rendered medical services in a specific medical specialty to demonstrate current competency in that medical specialty is not unduly burdensome and protects the public. Like the current clinical competency requirement, there may be a variety of ways to meet the requirement based upon the specific circumstances of the applicant. For example, physician assistants who obtain additional education and training regarding a new medical specialty while working within a health care facility or physician group practice would be subject to oversight and accountability. In contrast, physician assistants who work outside of such practices (e.g. own their own practice) and contemplate rendering medical services in a novel medical specialty field would likely have to develop and complete a plan for education and training prior to being granted authorization by the boards to render medical services in the novel medical specialty. Such a plan could include specialty certification, education and training under the supervision of a physician or group of physicians who then attest to their competency, or employment for a period of time within a health care facility or physician group practice. Delineating with exclusive specificity all of the ways in which to demonstrate competency runs the risk of unnecessarily limiting the ways in which to so do. Nonetheless, the boards do agree that the rule should include some criteria for the review of a physician assistant's proposed scope of practice in a collaborative or practice agreement, and address that issue in response to other comments below.

2. Corey Cole, D.O.

   WRITTEN COMMENT: Would there be any procedures or scope of practice that they would be restricted from performing such as "major surgery", perimortem c-sections, endovascular procedures, etc.? I realize that there is still a credentialing process as outlined later in the statue but as it written it seems too broad.

   - BOARDS' RESPONSE: Comment accepted. Any physician assistants rendering medical services outside of a health care facility or physician group practice are required to have either a "collaborative agreement" or a "practice agreement" with a scope of practice approved by one of the Boards. This language was specifically inserted into the law – and the rule – due to concerns exactly as those raised by the commenter.

3. Maria Paone, M.D.

   WRITTEN COMMENT: PAs and NPs like to say they want to practice to the "top of their license." In the case of a PA, their license is to practice as a Physician Assistant, not as a Physician. This law enables them to bypass 2 years of school and 3-7 years of training, board specialty exams and recertification and practice to the full extent of a Physician's license. More, actually, because, unlike a physician, they are permitted to switch specialties at will.

   - BOARDS' RESPONSE: Comment accepted. Any physician assistants rendering medical services outside of a health care facility or physician group practice are required to have either a "collaborative agreement" or a "practice agreement" with a scope of practice approved by one of the boards. This language was specifically inserted into the law – and the rule – due to concerns exactly as those raised by the commenter.

4. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
   Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
   Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
   Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

   WRITTEN COMMENT: [W]e would like to comment on the omission of a consultation agreement (collaborative agreement, as per the draft) requirement for PAs hired by facilities that credential them. We believe this is a dangerous oversight in patient safety that assumes employers provide physician staff to meaningfully review their work, which is widely known to not occur. Furthermore, it continues to make physicians liable for the work done by PAs at those institutions. We do not see any justifiable reason to exclude inexperienced PAs hired by facilities from the consultation/collaborative agreement proposed by the Board. This is an issue of ensuring ongoing supervision to ensure safety in licensure and we do not believe oversight of that can safely be left to employers whose goal is maximum productivity of employees.

- BOARDS' REPONSE: Comment not accepted. As stated previously, the Legislature enacted the law that provided that physician assistants are able to render medical services within a health care facility or physician group practice pursuant to either a collaborative practice agreement or pursuant to "a system of credentialing and granting of privileges and scope of practice agreement." The boards are unable to promulgate a rule that conflicts with or contradicts the law.

5. Lisa Harvey-McPherson, R.N., V.P. Gov't Relations *on behalf of* Northern Light Health

   WRITTEN COMMENT: **Section 6. 8. Criteria for Requiring Collaborative Agreements or Practice Agreements.** The proposed rule refers to agreement requirements for physician assistants with more than or less than 4,000 hours of documented clinical practice. We request that the final rule provide more detail on what qualifies as documented clinical practice. Is the standard as basic as the number of hours generally employed as a physician assistant or it is more complex relating to the number of hours performing clinical tasks as a licensed physician assistant.

   - BOARDS' RESPONSE: Comment accepted for the reasons stated. As indicated in their response to comment 5 below, the Legislature made a clear distinction between physician assistants rendering medical services within a health care facility or physician group practice practices pursuant to "a system of credentialing and granting of privileges and scope of practice agreement" and physician assistants working in private practice who require collaborative agreements or practice agreements. For the former, the health care facilities and physician group practices must determine what "documentation" is acceptable for physician assistants to demonstrate that they have 4,000 hours of clinical experience. These entities, which employ a plethora of health care workers, are in a unique position to oversee and evaluate physician assistant practice and to vet their credentials and qualifications for privileges to render medical services. The boards expect that these entities will perform due diligence in requesting and reviewing documentation from the physician assistants, their former employers, and former colleagues (including any prior supervising physician(s)) regarding their work history and clinical experience. These entities grant written privileges to physician assistants regardless of the number of hours of clinical experience, and therefore provide oversight of physician assistants regardless of the number of hours of clinical experience.

     The boards' review of scope of practice and documentation of 4,000 hours of clinical experience will focus on physician assistants who work in settings other than health care facilities or physician group practices pursuant to "a system of credentialing and granting of privileges and scope of practice agreement." As indicated in their response to comment 5 below, the boards have added a new subsection 9 to add criteria for reviewing physician assistants' scope of practice in certain settings. In addition, in response to the present comment, the boards add the following new paragraph to Section 6(8) entitled "Criteria for Requiring Collaborative Agreements or Practice Agreements":

D. Acceptable documentation of clinical practice includes, but is not limited to the following:

(1) Copies of previous plans of supervision, together with physician reviews;

(2) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

(3) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

(4) Attestation of completion of 4,000 hours of clinical practice, together with an employment history;

(5) Verification of active licensure in the State of Maine or another jurisdiction for 24 months or longer.

It should be noted that the documentation of 4,000 hours of clinical practice is a separate and distinct issue from "scope of practice." Physician assistants with more than 4,000 hours of documented clinical practice who render medical services outside of a health care facility or physician group practice still must have their scope of practice delineated in a written "practice agreement" and reviewed and approved by the boards.

6. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society

WRITTEN COMMENT: The terms of Chapter 627 allow a physician assistant to essentially provide medical services independent of meaningful physician oversight if they wish to open a solo practice after 4,000 hours of clinical experience. We would urge the Board to give additional attention to defining "scope of practice" in these rules, particularly what constitutes appropriate education, training, and experience in order to provide a particular medical service. Clearly delineated requirements for detailed and meaningful collaborative agreements and practice agreements that take into consideration practice and clinical settings are essential to promote high quality care and patient safety.

- BOARDS' RESPONSE: Comment accepted for the reasons stated. First, the boards want to once again emphasize that in enacting the law the Legislature was well-aware of the significant changes that would occur in the licensing and regulation of physician assistants. The Legislature – and indeed all of the stakeholders agreed – that the vast majority of physician assistants in Maine worked within health care facilities that have their own processes for educating and training and for evaluating and credentialing medical professionals, including physician assistants. Physician assistants working within health care facilities or physician group practices have the safety net of other medical and nursing colleagues and support staff. Health care facilities have quality control measures

and systems to review medical decision making and treatment and, when necessary, take corrective action. That is why the Legislature enacted the law that allowed physician assistants with less than 4,000 hours of clinical experience and working within health care facilities or physician group practices to render medical services pursuant to either a "collaborative agreement" or "under a system of credentialing and granting of privileges and scope of practice agreement." It is also why the Legislature did not require physician assistants with more than 4,000 hours of clinical experience and working within health care facilities or physician group practices to render medical services pursuant to either of these documents. The Legislature recognized that this would allow physician assistants working in those settings (as well as the hospitals and group practices) the maximum flexibility to move and work within different departments and medical specialties. These settings contain other medical personnel who may review the services rendered by physician assistants, operate pursuant to a system of credentialing and privileging, and are ultimately responsible for all medical services rendered by physician assistants in their employ. In other words, these settings – as the Legislature recognized - provide a safety net for physician assistant practice. Notably, the Legislature did not authorize the boards to review or approve the scopes of practice for physician assistants working within a health care system or physician group practice pursuant to "a system of credentialing and granting of privileges and scope of practice agreement." Thus, the boards will not typically be reviewing or approving these privileging and scope of practice agreements, but may request them when conducting a specific investigation. Therefore, the boards decline to issue specific requirements for delineating the scope of practice of physician assistants working within health care facilities or physician group practices pursuant to "a system of credentialing and granting of privileges and scope of practice agreement."

The boards do, however, agree that the rule should include some minimum criteria for reviewing the proposed scope of practice of physician assistants who render medical services in settings other than health care facilities or physician group practices (e.g. independent practice) pursuant to a "collaborative agreement" or "practice agreement." The Legislature recognized the potential risk to the public posed by physician assistants working outside of a health care facility by authorizing the boards to review and approve the physician assistants' scopes of practice. In formulating these standards, the boards are mindful of the importance of striking a balance between protecting the public and creating unduly burdensome and inflexible criteria. In order to provide transparency to the public and stakeholders regarding the standards for reviewing proposed scopes of practice, the boards add the following new subsection to Section 6, Uniform Scope of Practice for Physician Assistants:

9. **Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements**

A. In reviewing a proposed scope of practice delineated in a collaborative agreement or a practice agreement, the Board may request any of the following from the physician assistant:

(1) Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;

(2) Copies of previous plans of supervision, together with physician reviews;

(3) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

(4) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

(5) Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA or its successor organization;

(6) Preparation of a plan for rendering medical services for a period of time under the supervision of a physician;

(7) Successful completion of an educational and/or training program approved by the Board.

B. Physician assistants who work outside of a health care facility or physician group practice may not render medical services until their scope of practice is reviewed and approved by the Board.

7. Garreth Debiegun, M.D. *on behalf of* Maine Chapter of American College of Emergency Physicians

WRITTEN COMMENT: we would urge the Board to give additional attention to the need to define "scope of practice." Properly defined, an emergency physician is one who has completed residency training and passed rigorous examinations in emergency medicine in order to become a specialist in the field. The requirements for practice in a specialty setting contemplated for independent physician assistants under the proposed rules contain far less rigor and, in fact, would allow for specialty practice largely based on self-reporting related to practice settings but largely independent of actual reportable accomplished training. We believe that this is not in the best interest of patients and that a more rigorous means for determining scope of practice would be appropriate. We advise that the Board in its Rule Making should define what constitutes appropriate education, training and experience in order to provide a particular medical service. Medical training for physicians consists of medical education followed by postgraduate education, generally a minimum of three years or longer. This post graduate training is curriculum

based and training programs are reviewed by the ACGME or the AOA for their ability to provide adequate training to ensure the public that graduates of these programs can provide safe specialty care. Before closing, we should emphasize that we value the training and experience of physician assistants who are an important part of the emergency department environment. None of these comments are intended in any way to denigrate their training and experience. However, it is important that their training and experience be practiced in the context of a health care team that is organized to provide high quality care to our patients. As such, we would suggest that the rules for Chapter 2 should

a. describe the nature of the training that should occur during the 4000 hours of practice in which a physician assistant must have a collaborative agreement. The Rules should include the requirement that any Scope of Practice agreement should be based on evidence of curricula-based training.

b. specify that an additional 4000 hours of training should be necessary if the Physician Assistant elects to practice in a different medical specialty than the one in which the initial training occurred.

- BOARDS' RESPONSE: Comment accepted in part. See the boards' response to comments 4-6.

8. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

WRITTEN COMMENT: The BOLIM does not determine scope of practice for physicians through the licensing process because there is already a rigid system in place that determines physician scope of practice. However, since a similar system is not in place for PAs, how is the BOLIM going to protect public safety by ensuring PAs are competent to perform in the scope of practice they self-declare? If there is no answer, perhaps this needs to be carefully established as part of the rule-making process. The speed of the law-making seems to demand more from the medical system than currently exists to determine scope of practice of PAs in a manner commensurate with public safety. In the absence of an existing system to determine the bounds of PA scope of practice, two options are:

1. to disallow PA claims of specialization based on practice location; see also "Truth in Advertising" below

2. to require consultation with physicians that occurs in person, on-site while practicing, to determine and approve scope of practice. Due to their rigorous standardization of education, physicians *are* in a position to determine safe scope of practice by PAs on a case-by-case basis. This suggestion is different than the on-paper approval provided by BOLIM staff, who are removed from observing

the actual provision of care, that is being proposed in the current draft. Furthermore, this suggestion is *different* from "collaboration" (which suggest equal but complementary expertise between a physician and a PA) or "supervision" (which is not permitted by the statute). The PA would be legally liable for his or her own work, but would be required by the BOLIM to document external validation of safety to function safely within a defined scope of practice. We understand that the BOLIM has attempted to achieve this via collaboration agreements, which we believe does not accomplish one of the stated goals of LD1660 of removing physician liability from PAs' practice. We address this specific issue in greater detail in the section "Collaboration" below.

- BOARDS' RESPONSE: Comment accepted in part. See the boards' response to comments 4-6.

9. Dan Morin, Dir. of Comm. & Gov't Affairs *on behalf of* MMA, MSEPS, MEACEP, MNS
   Amanda Richards, Exec. Dir. *on behalf of* Maine Osteopathic Association
   Ann Robinson, Esq. *on behalf of* Spectrum Healthcare Partners

   WRITTEN COMMENT: One of our principal criticisms of the legislation was its delegation of overly broad authority to the licensing boards and its failure to specifically enumerate standards for determination of scope of practice and other important parameters for medical services provided by physician assistants. Chapter 627, and these and subsequent regulations, could have far-reaching implications for patient care. Therefore, under any construct of collaborative or practice agreements, we propose the following amendments to the joint rule:

   Amend Section 6 (Uniform Scope of Practice for Physician Assistants), in subsection 1 (General), by establishing a joint subcommittee of physician and physician assistants by the Boards of Licensure in Medicine and Osteopathic Licensure to lead the development of standard agreements and appropriate regulatory oversight. Because physician assistant services until enactment of Chapter 627 were technically medical services under the delegation and supervision of a person licensed to practice medicine, the boards should also develop standard forms and review the appropriateness of certain collaborative and practice agreements in various clinical settings. Such an approach would create a more formal structure and process and promote better communication, coordination, and expectations between the physician and physician assistant communities, and between the two licensing boards. In addition to potentially reviewing individual agreements prior to forwarding them for board review, joint committee members could first establish the proposal of basic standards and criteria that would be applicable to a given type of physician assistant practice setting.

   - BOARDS' RESPONSE: Comment accepted in part. See the boards' response to comments 4-6.

10. Andrew Nicholson, M.D.

WRITTEN COMMENT: The BOLIM must evaluate and approve each collaboration and practice agreement. I am not sure the Board has the capability to properly evaluate, oversee, update and enforce these agreements. This is critical to the safety of patients. Physicians move, change jobs, and retire. The scope of practice for independently practicing PA's may be on constant flux. It may be much harder to keep an updated collaboration or practice agreement than anticipated by the proposed rule. I am afraid these agreements may just become a "check the box" document that is filed, but never updated or reviewed until after a problem occurs.

- BOARDS' RESPONSE: Comment accepted in part. See the Boards' response to comments 4-6, 9. The Legislature gave the Boards the responsibility for reviewing physician assistant scope of practice in certain settings. The rule amendment also requires physician assistants to maintain a copy of any collaborative agreement or practice agreement and to notify the Boards in writing within 10 days of any change to a collaborative agreement or practice agreement, thereby triggering review.

11. Scott C. Ellis, P.A.
Alan Hull, P.A.
Angela Leclerc, P.A., President *on behalf of* Maine Association of Physician Assistants
Jeffrey Austin, VP of Gov't Affairs *on behalf of* Maine Hospital Association

WRITTEN COMMENT: In section 6, UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS, subsection 3, "Consultation," the last sentence reads: "Upon request of the Board, a physician assistant shall identify the physician who is currently available ***or was available*** for consultation with the physician assistant." I would ask that "or was available" be modified to read: "or was available within 1 year of the request from the Board." As written, the rule presents an unlimited time frame. The proposed 1 year time frame allows PAs and administrators an appropriate length of time to keep records of available working and on-call physicians in tact.

includes the phrase "or was available for consultation" in the last sentence. This phrase is problematic as there is no addressed time frame as to how far in the past, the physician "available for consultation" will have to be identified. Will these records have to be maintained for 10 days, 10 weeks, 10 months, 10 years, or in perpetuity? Long-term maintenance of these records would be burdensome, and onerous. There should be a definitive timeframe for these records to be maintained.

With our current technology, medical records programs change relatively frequently, and unfortunately, importing all the data from the old system into the new system is expensive, extremely time-consuming, and frequently does not happen. Schedules whether electronic or hard copy, can be misplaced, or inadvertently discarded.

I would ask the physicians on the Boards to see if they can identify who the physician preceptor was on August 7 during the second year of their residency. Could they do so readily? Could they gain access to the records to identify that preceptor? If they were to name the residency director as a default preceptor, could they be assured that that physician would not have been on vacation or out ill that day? To expect a Maine PA to be able to identify the consultant available at five years, 10 years, or 20 years in the past is spurious.

I would respectfully suggest and hope that the phrase "or was available for consultation" can be modified to include a definitive timeframe in the past. One year seems to be reasonable duration of time for the maintenance of those records.

Request for addition of timeframe to identify available physician: MEAPA supports PAs being able to identify which physicians are available for consultation, however, requests that the language be adjusted to include a specific timeframe, and would suggest:

[...] Upon request of the Board, a physician assistant shall identify the physician who is currently available **or was available for consultation** with the physician assistant ***up to one year from the date of care***.[...]

We do agree with the PA Association that the provision in Section 6(3) may present challenges with respect to retrospective requests. A limit of some time seems warranted.

- BOARDS' RESPONSE: Comment not accepted. In response to a complaint received or as part of an investigation, the boards may be required to review the medical services rendered by a physician assistant for any time period that the physician assistant was licensed by a board. While a large percentage of complaints or investigations occur within a relatively short period of time following the provision of services, the boards have the obligation to investigate any complaint received notwithstanding when the medical services were rendered. Therefore, a physician assistant may be requested by the boards to identify the physician(s) that were available to them for consultation in connection with medical services they have rendered during any period in which they have held a license. One way to preserve this information is to document the identity of the consulting physician(s) in the medical record.

12. Anthony Curro, P.A.

WRITTEN COMMENT: Two of my current practice locations have a service, PDRx, which provide a small variety of non-narcotic medications to be prescribed and dispensed

to patients. This can be done for patient convenience when local pharmacies are open as well as when pharmacies are closed. Will this type of service continue to be allowed under the proposed amendment language? In addition the WMHC seasonal clinic at Sunday River has "To go packs" which include narcotics and can be prescribed and provided to patients with orthopedic injuries. Will the proposed amendment allow continuation of that practice?

- BOARDS' RESPONSE: Comment not accepted. The rule follows the law.

13. Anthony Curro, P.A.

WRITTEN COMMENT: While I understand that the PA is responsible for services rendered I would have thought that the legislation and the courts would establish liability rather than in the rules governing PA practice. With a quick electronic search of the version of LD1660 I found on line I did not find language establishing PA liability. Is the proposed language about PA liability part of the final version of LD1660?

With the exception of PA's without a physician partner or who own and/or operate an independent practice PA's practicing under the proposed amendment will have one of the following: a collaborative or practice agreement, a physician partner who is required to be available at all times and who must be named by the PA if requested to do so by the board, or they will be part of a healthcare facility or physician group practice which grants privileges and defines scope of practice. In all of those latter circumstances the delivery of healthcare is a joint responsibility between the PA, physician partner, and their employers.

Unless liability is specified in the final version of LD1660 I request that the language on page 23 section 6 be amended to reflect a joint responsibility between PA, physician partner, and their employer. This suggestion would not apply if the PA were the owner/operator of an independent practice.

- BOARDS' RESPONSE: Comment not accepted. The rule follows the law which specifically provides that physician assistants are legally liable for all medical services they render. This language was specifically included in the new law which eliminated physician delegation and liability for medical acts rendered by physician assistants under their supervision.

14. Dan Morin, Dir. of Comm. & Gov't Affairs *on behalf of* MMA, MSEPS, MEACEP, MNS
Amanda Richards, Exec. Dir. *on behalf of* Maine Osteopathic Association
Ann Robinson, Esq. *on behalf of* Spectrum Healthcare Partners

WRITTEN COMMENT: We also support the requirement that, "*a physician assistant is legally liable for any medical service rendered by the physician assistant.*"

- BOARDS' REPONSE: Comment accepted. The language of the amended rule is consistent with the law.

15. Scott C. Ellis, P.A.
Alan Hull, P.A.
Angela Leclerc, P.A., President *on behalf of* Maine Association of Physician Assistants

WRITTEN COMMENT: In section 8. Criteria for Requiring Collaborative Agreements or Practice Agreements, B. Practice Agreement, the rule reads: "Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner **or who own and/or operate an independent practice** must have the following in order to render medical services under their Maine license:"... I ask that the phrase "or who own and/or operate an independent practice" be deleted. This phrase is not appropriate as it identifies a business relationship and doesn't pertain to the regulation of the practice of medicine.

The bolded language above references regulation of a structure of business rather than regulation of practice and appears to be inappropriate. It is not in the revised statute. In addition, using the term "independent" is confusing (when thinking of PA practice vs PA business). MEAPA recommends this language be deleted in its entirety, and the revised language read:

> B. **Practice Agreement**. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner must have the following in order to render medical services under their Maine license:

- BOARDS' RESPONSE: Comment not accepted. The language at issue in the amended rule does not constitute a comment regarding the structure of a business (e.g. sole proprietorship, limited liability corporation, professional service corporation) but rather clarifies and interprets the statutory language.

16. Anthony Curro, P.A.

WRITTEN COMMENT: 8. **Criteria for Requiring Collaborative Agreements or Practice Agreements Sub-Section C Physician Assistants with more than 4000 hours of documented clinical practice**
Comment/Suggestion: My suggestion would be to amend the language to say that "are not required to have, but may enter into, either a collaborative agreement or a practice agreement."
Rationale: Although examples of the collaborative and practice agreements are not included with the proposed amendment the description of the collaborative agreement appears to be similar to current plans of supervision. In my practice I believe a collaborative agreement would provide the safest and most effective care for my patients. As it would be similar to the current POS system it has the advantage of being a known method of delivering patient care.

- BOARDS' RESPONSE: Comment not accepted. Nothing in the law nor rule prevents a physician assistant from entering into a collaborative agreement or a practice agreement with a physician or physicians.

VII. **Section 7 - Uniform Elements of Written Collaborative and Practice Agreements**

1. Sarah Calder, Dir. of Gov't Affairs *on behalf of* MaineHealth

   WRITTEN COMMENT: With a growing health care workforce shortage, we truly appreciate the intent of the proposed amendments to Board Rule Chapter 2 Physician Assistants. We have concerns, however, and proposed suggested revisions, based primarily on the fact that, as drafted, the amendments do not, in some areas, provide the necessary flexibility to implement these changes within a large health care system like MaineHealth. Also, as drafted, the amendments in some instances place the burden on physician assistants to undertake actions that we, as their employer, are better equipped to undertake. The minor revisions we propose below do not take away the intent and/or goals of the proposed amendments, but rather are requested in order to add flexibility to some requirements of collaborative and practice agreements and to enable an employer, in addition to and/or instead of an individual physician assistant, to perform some of the mandated tasks.

   Our requested changes to the proposed rule amendments are as follows:
   Section 7 – Uniform Elements of Written Collaboration and Practice Agreements. Subsection 1. (A): Requested Change: We request the language reflect Public Law, Chapter 627 and state as follows: "the tasks that the physician assistant may be delegating" instead of "will be delegating." This change will still allow for a collaborative agreement and practice agreement to itemize all of the tasks that a physician assistant (PA) may ask a medical assistant (MA) to do (all of which would still be in compliance with the remaining legal obligations and scope of relevant practices), but will not be so restrictive as to require a PA to always ask a MA to do a certain task (via the phrase of commitment "will be"). Flexibility in day-to-day practice is important, including if a PA determines that a particular MA (including a new MA, for example) is unable to do a particular task on a particular day and circumstances under which a PA determines in his/her judgment that it is best, for patient safety, to undertake the task himself/herself. The "will do" language does not afford for that flexibility, and any deviation from the collaborative agreement and/or practice agreement subjects the PA to potential discipline under the current rules as written.

   - BOARDS' RESPONSE: Comment accepted for the reason stated. Section 7(1)(A) will be changed to "may be" to be consistent with the law.

2. Stuart Glassman, M.D. *on behalf of* State Advocacy Committee of the American Academy of Physical Medicine and Rehabilitation (AAPMR)
   Dan Morin, Dir. of Comm. & Gov't Affairs *on behalf of* MMA, MSEPS, MEACEP, MNS

Amanda Richards, Exec. Dir. *on behalf of* Maine Osteopathic Association (MOA)
Ann Robinson, Esq. *on behalf of* Spectrum Healthcare Partners (Spectrum)

WRITTEN COMMENTS:

(AAPMR) Given the proposed amendment to remove the physician supervision requirements for physician assistants is maintained, a collaborative agreement between the physician and physician assistant must be upheld. Collaborative agreements may allow physician assistants to provide quality patient care to the extent of their education and training, as agreed upon by their health care team to ensure patient safety. A collaborative agreement may also allow the physician to provide more complex patient care and leadership duties suited to their level of expertise. AAPM&R believes that the consultation provision should be enforced to the fullest extent to ensure that physician assistants, based on the patient's condition, the education, competencies and experience of the physician assistant and the standards of care, consult with, collaborate with, or refer the patient to an appropriate physician or other health care professional. Furthermore, we firmly agree that a physician must be accessible to the physician assistant at all times for consultation and that a physician assistant, upon request of the Board, shall identify the physician who is currently available or was available for consultation with the physician assistant.

(MMA, MSEPS, MEACEP, MNS, MOA, Spectrum) We appreciate the opportunity to submit the following comments on the proposed amendments to the proposed joint rule pertaining to the licensure and practice of physician assistants in response to Public Law 2019, Chapter 627. Maine needs physician assistants. They are a vital part of our physician-led health care teams. However, it is critical for the public to understand that physician assistants and physicians are *NOT* essentially interchangeable, and that the two professions *DO NOT* have a body of knowledge and clinical skills that are equivalent. Each member of a physician-led health care team has an important role to play, working together to provide the best outcomes for patients while also driving improvements in patient care. While there is no question about the level of service and professionalism physician assistants bring to a health care team, they are not physicians. Any other characterization underestimates the clinical complexity that often accompanies a medical determination and plan of care.
Nevertheless, the terms of Chapter 627 allow a physician assistant to essentially provide medical services independent of meaningful physician oversight if they wish to open a solo practice after 4,000 hours of clinical experience. While we continue to have strong reservations about aspects of the legislation, we support the provision outlining that, for all physician assistants, in every clinical setting, "*a physician must be accessible to the physician assistant at all times for consultation,*" and that upon request of the Board, "*a physician assistant shall identify the physician who is currently available or was available for consultation with the physician assistant.*"

- BOARDS' RESPONSE: Comments accepted for the reason stated. The boards agree that consultation is very important to ensure safe rendering of medical

services by physician assistants and that the consulting physician(s) should be available at all times to the physician assistant.

3. Sarah Calder, Dir. of Gov't Affairs *on behalf of* MaineHealth
   Anthony Curro, PA

   WRITTEN COMMENTS:

   (MaineHealth): **Subsection 1 (D)**: Requested change: Allow a PA's employer, and not just a PA, to prepare, maintain and produce/have on file the required collaborative and practice agreements. The current proposed rule places the burden on the PA exclusively to prepare, maintain and keep on file the collaborative or practice agreements, and subjects the PA to penalties/potential discipline if he/she falls short in these regards. Within large and/or organized healthcare systems, which employ PAs and which also place accountabilities on PAs and physicians under credentialing and privileging processes, the burden may be better assumed by the employer to develop/prepare, maintain and produce the collaborative and practice agreements. Also, such employers are able to better track when changes are necessary to such agreements, including if and where changes may be needed due to transitions in employment of consulting/collaborating physicians. MaineHealth's request is to make the following change to the proposed rule under Section 7, Subsection (1)(D): "Physician assistants licensed to practice in accordance with these rules, and/or the employers of such physician assistants, must prepare and have on file in the main administrative office of the practice or practice location a written, dated collaborative or practice agreement ..." The requested change does not take away from the intent of the original proposed rule to ensure that required collaborative and practice agreements are prepared, filed and maintained, but rather affords healthcare systems some flexibility in where to place this burden including to ensure that such agreements are prepared, maintained, updated, and filed appropriately.

   Anthony Curro, PA: D. C. **Maintenance and production of plan of supervision collaborative and practice agreements**
   Comment/Suggestion: My suggestion would be to amend the language to say that: ") Physician assistants licensed to practice in accordance with these rules and their employer must prepare...."
   Rationale: All parties to the agreement should have a stake in the preparation and execution of agreements. Out of a need to become cost efficient there has been significant consolidation in the number of groups delivering healthcare. This has led to fewer independent job opportunities, including for physician assistants, and greater leverage on the part of the employers. Essentially a few large groups now dominate the market for healthcare delivery and employment opportunities. A requirement by the board that both the physician assistant, and their employer, be responsible for the preparation of collaborative and practice agreements will insure that both parties to those agreements have equal standing in, and incentive to prepare, such agreements. For clarity I think it would be reasonable to continue to have the PA responsible to submit the agreement once it is prepared.

- BOARDS' RESPONSE: Comments not accepted. First, while the boards understand the intent of the comments, the boards lack the authority to promulgate rules regarding the employers of physician assistants. The boards' authority extends only to its licensees. Second, as medical professionals it is the personal and professional responsibility of physician assistants to comply with the laws and rules of the boards. Third, there is nothing in the rule amendment that prohibits physician assistants from coordinating with their employer(s) regarding this issue, with the understanding that the physician assistants are ultimately responsible for complying with the rule.

4. Stuart Glassman, M.D. *on behalf of* State Advocacy Committee of the American Academy of Physical Medicine and Rehabilitation
   Lisa Harvey-McPherson, RN, VP of Gov't Relation *on behalf of* Northern Light Health

   WRITTEN COMMENTS:

   (AAPMR) To create a formal structure that would promote standardization of the process for establishing collaborative agreements, we believe that the both licensing boards should develop standard forms and review the appropriateness of collaborative and practice agreements in various clinical settings.

   (Northern Light Health) We ask that the respective boards develop standardized collaborative and practice agreement templates for optional use by physician assistants.

   - BOARDS' RESPONSE: Comments accepted for the reason stated. The boards have developed model collaborative agreements and practice agreement forms for use by physician assistants and their consulting physicians. These model forms are not included in the rule amendments to allow for flexibility in modifying or updating them if necessary.

5. Dan Morin, Dir. of Comm. & Gov't Affairs *on behalf of* MMA, MSEPS, MEACEP, MNS
   Amanda Richards, Exec. Dir. on behalf of Maine Osteopathic Association (MOA)
   Ann Robinson, Esq. on behalf of Spectrum Healthcare Partners (Spectrum)

   WRITTEN COMMENTS: The collaborative agreement and/or practice agreement should contain the following:
   - A requirement that each physician assistant and physician shall jointly review the authorization for collaborative or practice agreements annually,
   - Each authorization for collaborative or practice agreements shall include a cover page containing the date of the annual review by the physician assistant and physician and an acknowledgement and signature of the same,
   - Each authorization for collaborative or practice agreement shall be maintained in either hard copy or electronic format at the physician's and physician assistants' principal place of practice, and

- Medical services performed by a physician assistant under a collaborative or practice agreement must be appropriate to the skills and practice area of the physician as well as the physician assistant's level of competence, as determined by the physician, to ensure that accepted standards of medical practice are followed.

  - BOARDS' RESPONSE: Comments accepted in part for the reason stated. The rule amendments already provide for the physician assistant and collaborating/consulting physician sign a collaborative agreement or practice agreement, and require that physicians providing consultation do so "only within their scope of practice." In addition, the amendments already require the maintenance and production of collaborative agreements and practice agreements by the physician assistants. However, the boards do not agree that there needs to be an annual "joint review" by the physician assistant(s) and collaborating/ consulting physicians and an accompanying cover page with their signatures and the date. Review of a physician assistant's practice is on on-going process involving daily interactions and feedback.

VIII. **Section 8 – Uniform Notification Requirements for Physician Assistants**

1. Sarah Calder, Dir. of Gov't Affairs *on behalf of* MaineHealth

   WRITTEN COMMENT: **Subsections (1) & (2):** Requested changes: First, allow the PA's employer (in addition to and/or instead of the PA) to make the required notifications of any changes to and/or terminations of collaborative or practice agreements, including by submitting revisions and notifications to the Board(s). This request is made in the same spirit as that set forth above under Subsection (1)(D) of Section 7 – specifically, the burden on these matters may better fall to a PA's employer within an organized healthcare system including when the system has its own employment rules and its own credentialing and privileging requirements and processes. The second change is to add some flexibility in the number of days to submit changes to collaborative and practice agreements in writing to the Board(s), due to the immense challenges and work burdens that PAs, physicians and healthcare systems are already facing in delivering and prioritizing patient care. The requested changes are therefore to add the following language in the following areas: Subsection (1) – Change of Collaborative Agreement or Practice Agreement "A physician assistant licensed by the Board and/or the employer for such physician assistant shall notify the board in writing within thirty (30) calendar days of any change to a collaborative agreement or practice agreement to the Board for review and approval." Subsection (2) – Termination of Collaborative or Practice Agreement "A physician assistant licensed by the Board and/or the employer for such physician assistant shall notify the Board in writing within thirty (30) calendar days regarding the termination of any collaborative or practice agreement. Such notification shall include the reason for termination."

   - BOARDS' RESPONSE: Comment not accepted. First, while the boards understand the intent of the comment, the boards lack the authority to promulgate

rules regarding the employers of physician assistants. The boards' authority extends only to its licensees. Second, as medical professionals it is the personal and professional responsibility of physician assistants to comply with the laws and rules of the boards. Third, there is nothing in the rule amendment that prohibits physician assistants from coordinating with their employer(s) regarding this issue, with the understanding that the physician assistants are ultimately responsible for complying with the rule.

2. Sarah Calder, Dir. of Gov't Affairs *on behalf of* MaineHealth

WRITTEN COMMENT: **Subsection 4 – Death/Departure of Collaborating Physician**
MaineHealth's requested changes to Section 8, Subsection 4 have both practical and legal considerations behind it. First – the primary requested change is to eliminate this subsection altogether, as the death or permanent/long term departure of a collaborating physician is already encompassed in a required change to a collaborative agreement under subsection (1) of Section 8. If a physician is no longer able to be a collaborating physician pursuant to death and/or permanent or long term departure, the PA is already required to notify the Board(s) of a change to the relevant collaborative or practice agreements (including for example by changing the agreement to reflect a new collaborative physician) under Section 8, Subsection (1). Moreover, PAs and Hospital systems may learn of death or disability resulting in permanent/long term departures of physicians through conversations, communications or events protected by HIPAA, state privacy laws and/or state or federal employment privacy laws, where further disclosure of such matters by such PAs and/or Hospital systems are legally prohibited. Subsection 4 is therefore not only arguably unnecessary in light of Subsection (1), but also legally complicating.

If Subsection 4 must and is legally able to be retained, then a separate requested change is, again, to enable the PA's employer to undertake the burden of notifying the Board(s) of the death or permanent or long-term departure of a collaborating physician who is a signatory to either a collaborative or practice agreement. Also, we the request that the time limit for making such requested notification be extended to 30 days from the date that the death or disabling condition of the physician became known. MaineHealth therefore requests that Subsection 4 of Section 8 read as follows: "A physician assistant licensed by the Board, and/or the employer for such physician assistant, shall notify the Board in writing within thirty (30) calendar days upon learning of the death or permanent or long term departure of a collaborating physician who is a signatory to either a collaborative agreement or a practice agreement."
The reason behind the requested change(s) are that an employing entity, versus an individual PA, is much more likely (and in the case of MaineHealth, is likely always going to be) knowledgeable about whether and under what specific circumstances a collaborating physician may have a permanent or long term departure from employment. In this regard, typically a long term and/or permanent departure is caused by either a medically disabling condition, and/or termination of employment, which matters are deemed confidential by both federal and state law as well as by employer policy and

practice. Employers are therefore precluded, and/or do not share by policy, this particular kind of information with individual employees, including PAs. It would be unfair to subject a PA to discipline under the new proposed rules for failure to provide information to the Board(s) if the nature of the information is not something that the PA himself/herself would be privy to, whether by law or by operation of employer policy. Further, the request for the extension of time to 30 days from date of notice to notify the Board(s) of the death or permanent/long term departure of a collaborating physician is to enable allowance for the natural period of time that passes in order for an employer to collect underlying information related to health conditions, leaves of absence and/or basis for employment separations as to such physicians (and other employees). For example, as related to permanent and/or long term departures occasioned by medical conditions, the process to obtain documentation of the underlying condition and/or the basis for any alleged period of time needed away from work typically takes numerous weeks, and often more than 10 days. The proposed 10 day notice requirement, therefore, may not be practicably met. MaineHealth would not want its PAs sanctioned or disciplined for events outside of their (as well as the employer's
control).

- BOARDS' RESPONSE: Comment not accepted. First, while the boards understand the intent of the comment, the Boards lack the authority to promulgate rules regarding the employers of physician assistants. The boards' authority extends only to its licensees. Second, as medical professionals it is the personal and professional responsibility of physician assistants to comply with the laws and rules of the boards. Third, there is nothing in the rule amendment that prohibits physician assistants from coordinating with their employer(s) regarding this issue, with the understanding that the physician assistants are ultimately responsible for complying with the rule. Fourth, the boards are health oversight entities under HIPAA. This specific notification requirement does not require the disclosure of protected care information: physician assistants can merely inform the boards that the physician is permanently no longer available without disclosing protected health care information. Fifth, the boards do not agree that 10 days is overly burdensome – especially in the case of physician assistants who own or operate their own practices and render medical services in consultation with a physician. Finally, this notification requirement should affect only a small percentage of physician assistants working within health care facilities. Only those physician assistants with less than 4,000 hours of clinical experience and working within health care systems are required to render medical services pursuant to either a collaborative agreement" or "under a system of credentialing and granting of privileges and scope of practice agreement." In other words, physician assistants working within health care facilities "under a system of credentialing and granting of privileges and scope of practice agreement" are not required to have collaborative agreements – and thus this notification provision does not apply to them. Likewise, physician assistants with more than 4,000 hours of clinical experience and working within health care facilities are not required to have either a collaborative agreement nor a scope of practice agreement – and thus this notification provision does not apply to them. In conclusion, the regulatory impact of this notification provision upon physician

assistants and health care facilities is minimal compared to the importance of the public safety factor for physician assistants working in private practice settings.

IX. Section 11 – Uniform Continuing Medical Education (CME) Requirements and Definitions

1. Anthony Curro, PA

   WRITTEN COMMENT: I wanted to clarify CME requirements as they pertain to NCCPA. My Maine license renewal is in November 2020 while my most recent NCCPA certification cycle ended in December 2019 with my submitting at least 100 hours of CME to NCCPA. Will completion of NCCPA CME requirements for a two year cycle ending December 2019 meet the board's requirement for license renewal in November 2020?

   - BOARDS' RESPONSE: Comment not accepted. Rule Section 11(1)(C) provides that proof of current NCCPA certification at the time an application for renewal is submitted satisfies CME requirements.

2. Anthony Curro, PA

   WRITTEN COMMENT: Item 1 under definition of CME Categories includes a list of approved organizations for category 1 CME. In addition NCCPA has used categories of CME which included self-assessment (SA) and Process improvement (PI). Each of those categories was granted more than one hour of CME for each hour spent in the activity; for example self-assessment CME were granted 1.5 hours of CME for each hour of participation. I suggest that we align the list of organizations approved for Category 1 CME, and the value of those activities with current NCCPA requirements. Any future modifications by NCCPA would then be included in the State of Maine requirements and would simplify record keeping for physician assistants.

   - BOARDS' RESPONSE: Comment not accepted. The proposed rule identifies any number of organizations that provide qualifying Category 1 CME opportunities for physician assistants.

X. Section 12 – Identification Requirements

1. Saul Levin, M.D. *on behalf of* the American Psychiatric Association

   WRITTEN COMMENT: In 2013 and 2015, Governor LePage signed health care practitioner transparency legislation into law (24 M.R.S.A. § 2988), requiring a health care practitioner to disclose the license under which the health care practitioner is practicing. We recommend including similar language in this rule requiring physician assistants to identify the license under which they practice. We also strongly advise that physician assistants be required to say aloud that they are physician assistants, especially during the pandemic when telehealth patients will not be able to see practitioners' name

badges. Patients should be provided this information in a clear manner so that they can make informed decisions about their medical care.

- BOARDS' RESPONSE: Comment accepted for the reason stated. See the boards' response to comment 3 below.

2. Megan Selvitelli, M.D. *on behalf of* Maine Neurological Society
Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
Purvi Parikh, M.D. *on behalf of* Physicians for Patient Protection
Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

WRITTEN COMMENT: **Truth in Advertising**
As discussed above, the draft proposal as written allows PAs to define their own scope of practice. This option not only lacks safeguards for patient safety, but also allows misleading self-promotion on specialization. The AMA performed a longitudinal Truth in Advertising survey that found that 61% of patients thought that PAs with a doctorate of medicine science were physicians (https://www.ama-assn.org/sites/amaassn.org/files/corp/media-browser/premium/arc/tia-survey_0.pdf). We believe as regulators of both physician and PA practice, the BOLIM is in a unique position and indeed obligated to clear up the confusion and thereby empower them to make autonomous, educated decisions about healthcare purchasing. In the Truth in Advertising campaign stated above, 91% of respondents said that a physician's years of medical education and training are vital to optimal patient care. PAs should not be allowed to claim to be a "dermatology specialist" simply because they work in a dermatology office, which implies to patients that they have more experience in dermatology than the patient's primary care physician. Additionally, a PA with a medical science doctorate who passed the National Commission on Certification of Physician Assistants (NCCPA) certification program should not be allowed to claim she is a "board-certified family medicine doctor." These claims are misleading and dangerous. We propose that the rule-making process include truth in advertising language that includes, but is not limited to, requirements for disclosure of licensure title to every patient, as well as require PAs to explicitly correct patients who refer to them as "doctor."

- BOARDS' RESPONSE: Comment accepted for the reason stated. See the boards' response to comment 3 below.

3. Dan Morin, Dir. of Comm. & Gov't Affairs *on behalf of* MMA, MSEPS, MEACEP, MNS
Amanda Richards, Exec. Dir. *on behalf of* Maine Osteopathic Association
Ann Robinson, Esq. *on behalf of* Spectrum Healthcare Partners

WRITTEN COMMENT: We also respectfully request amending Section [12] of the joint rule under Identification Requirements to include: • Physician assistants licensed under these rules shall keep their license available for inspection at the location where they render medical services and shall, when rendering medical services, wear a name tag identifying themselves as a physician assistant. Physician assistants shall also verbally

identify themselves as a physician assistant to each new patient. Despite the enactment of Public Law 2019, Chapter 627, state law still clearly defines physicians as engaging in the "practice of medicine or surgery", while describing physician assistants as rendering "medical services." Studies have increasingly shown patients are confused about the qualifications of different health care professionals. Many non-physicians earn advanced degrees, and some degree programs now confer the title "doctor." As a result, patients often mistakenly believe they are meeting with physicians (medical doctors or doctors of osteopathic medicine) when they are not. As non-physicians increasingly seek to expand their scope of practice, there should come the added responsibility of visually, and verbally, disclosing their education, qualifications, and training. The latter also is necessary for the visually impaired. Maine can leverage the knowledge and skills of physician assistants, and the increased availability of convenient settings for care delivery, to meaningfully expand access to services, while maintaining a clear focus on patient safety and quality in care coordination and integration. Developing clear parameters and uniform expectations for allowing physician assistants to practice at the highest level of their knowledge and clinical training, while recognizing the important role physicians play in a physician-led care team, is the right path to take.

- BOARDS' RESPONSE: Comment accepted for the reasons stated. This section of the proposed amended rule will be changed to read as follows:

SECTION 12. IDENTIFICATION REQUIREMENTS

Physician assistants licensed under this rule shall:

1. Keep their licenses available for inspection at the location where they render medical services;

2. When rendering medical services, wear a name tag identifying themselves as physician assistants; and

3. Verbally identify themselves as physician assistants whenever greeting patients during initial patient encounters and whenever patients incorrectly refer to them as "doctors."

Response to Additional Comments Following Re-Proposal of the Rule on September 30, 2020

Before delving into the comments, the boards wish to again convey their sincere appreciation for the feedback, comments, suggestions and questions regarding the proposed rule amendments. In addition to the specific comments identified below, the boards received and reviewed information from the Federal Trade Commission (FTC) for the boards to consider as they undertake the current rule making regarding Chapter 2. The boards intent in promulgating the new rule and the criteria for reviewing physician assistant scope of practice is to protect the public by ensuring that the scope of practice is consistent with the education, training and experience of the physician assistant as required by the new law.

Once again, the boards want to clarify for the commenters and stakeholders that the boards are State agencies created by the Legislature and derive their very existence, membership and authority from the laws enacted by the Legislature. The boards must implement the newly enacted law, and cannot act contrary to law or promulgate a rule or amendments to a rule that conflict with the law. The Legislature has spoken, and the boards are legally bound to enact rules that are both within the law and congruent with the Legislative intent. The boards express their appreciation for the commenters' and stakeholders' understanding concerning this issue as well as the new paradigm for physician assistant licensure and regulation in Maine as enacted by the Legislature.

In addition, the boards reminds all stakeholders that their sole purpose is to protect the public and that the current rule making regarding Chapter 2 is being undertaken with that mandate in mind, and that the re-proposed rule was open for comments regarding the new language identified in the re-proposed rule – and not regarding the entire language of the proposed rule.

List of Commenters:

1. Pamela Barter-Chessman, P.A.
2. Angela Coton, P.A.
3. David Duchin, P.A.
4. Amy Hoffman, P.A. licensed in Maryland
5. Jed Jankowski, P.A.
6. Tillie Fowler, J.D. *on behalf of* the American Academy of Physician Assistants (AAPA)
7. Scott Ellis, P.A.
8. Angela Leclerc, P.A. *on behalf of* Maine Association of Physician Assistants
9. Gretchen Morrow, P.A.
10. Scott Ellis, P.A.
11. Kristi Kalajian, P.A.
12. Ryan Trosper, P.A.
13. Lisa Allen, P.A.
14. Erwin Morse, P.A.
15. Alan Hull, P.A.
16. Dan Morin *on behalf of* The Maine Medical Association
17. Amanda Richards *on behalf of* The Maine Osteopathic Association
18. Ann Robinson, Esq. *on behalf of* Spectrum Healthcare Partners
19. Andrew Dionne, M.D.
20. Rebekah Bernard *on behalf of* Physicians for Patient Protection
21. Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
22. Matthew Davis, M.D. *on behalf of* Maine Association of Psychiatric Physicians
23. Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology
24. Erin Muthig, P.A.
25. Cynthia Davies, P.A.
26. Charles Dingman, Esq. *on behalf of* Maine Primary Care Association

Comments and Board Responses:

I. **Section 1 – DEFINITIONS, paragraph 11 "Health Care Facility"**

1. Charles F. Dingman, Esq. *on behalf of* Maine Primary Care Association

WRITTEN COMMENT: The definition of "health care facility" should be amended to include community health centers that are not licensed by the State of Maine such as federally qualified health centers that have a system of credentialing and granting of privileges to perform health care services. The current definition appears to have unintentionally omitted these types of facilities that employ physician assistants.

- BOARDS' RESPONSE: Comment accepted for the reason stated. The language of paragraph 11 shall be changed to read as follows:

"Health care facility" means a facility, institution or entity licensed pursuant to State law or certified by the United States Department of Health and Human Services, Health Resources and Services Administration that offers health care to persons in this State, including hospitals, any clinics or offices affiliated with hospitals and any community health center, each of which has a system of credentialing and granting of privileges to perform health care services and that follows a written professional competence review process.

II. **Section 6 – UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS, paragraph 8.C.**

1. Allan Hull, P.A.
Jed Jankowski, P.A.
Angela Leclerc, P.A. *on behalf of* Maine Association of Physician Assistants
Tillie Fowler, J.D. *on behalf of* the American Academy of Physician Assistants (AAPA)

WRITTEN COMMENT: The commenters state that this subsection does not appear to be consistent with the law and may be confusing. One commenter suggests removing the reference to "practice agreements" as it is unnecessary. The other commenter suggests clarifying this subsection to include physician assistants with more than 4,000 hours of documented clinical experience and who work within a physician-owned practice or physician group practice that lack a credentialing system.

- BOARDS' RESPONSE: Comments accepted. The boards agree that this subsection omitted a category of physician assistants and make the following non-substantive clarification to the subsection:

C. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and are employed with a health care facility or with a practice that includes a physician partner – regardless of whether or not the facility or practice have a system of credentialing and granting of privileges - are not required to have either a collaborative agreement or a practice agreement.

III. **Section 6 – UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS, "9. Criteria for Requiring Collaborative Agreements or Practice Agreements."**

1. Dan Morin *on behalf of* The Maine Medical Association
   Amanda Richards *on behalf of* The Maine Osteopathic Association
   Ann Robinson, Esq. *on behalf of* Spectrum Healthcare Partners

   WRITTEN COMMENTS: "We appreciate the boards' willingness to better establish basic standards and criteria under a new paragraph to Section 6(8) entitled 'Criteria for Requiring Collaborative Agreements or Practice Agreements.'"

   - BOARDS' RESPONSE: Comments accepted for the reasons stated.

IV. **Section 6 – UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS, "8.D Acceptable documentation of clinical practice includes, but is not limited to the following:"**

1. Alan Hull, P.A.

   WRITTEN COMMENTS: The commenter suggests this subsection "provides some welcome guidance" regarding the types of acceptable documentation but nonetheless also states "the wording suggests an overly complex, burdensome, and lengthy process." The commenter also suggests that the wording of the subsection is "unclear if ALL of the 'acceptable documentation'… is required." The commenter also suggests some minor changes to the language.

   - BOARDS' RESPONSE: Comments not accepted.

     First, the language of the proposed rule, including this subsection, is both brief and clear. The language of this proposed subsection states:

     D. Acceptable documentation of clinical practice <u>includes, but is not limited to the following</u>:

        (1) Copies of previous plans of supervision, together with physician reviews;

        (2) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

        (3) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

        (4) Attestation of completion of 4,000 hours of clinical practice, together with an employment history;

        (5) Verification of active licensure in the State of Maine or another jurisdiction for 24 months or longer.

Second, this specific subsection was added in response to comments requesting guidance from the boards regarding the types of documentation that would be accepted to demonstrate 4,000 hours of clinical practice. It is not intended to be nor is it "overly complex, burdensome, and lengthy." The language of this subsection actually provides transparency, guidance and flexibility to the boards, physician assistants, and the public regarding the types of documentation not specifically identified in the subsection; hence the language "includes, but is not limited to the following." The types of documentation required may actually differ upon the specific circumstances of the physician assistant. By identifying what type of documentation is acceptable, the boards are also streamlining the process – not lengthening it.

Third, the language as proposed is sufficiently clear and concise, while also allowing physician assistants to submit - and the boards to consider – other types of documentation not specified within the language of the subsection.

V. **Section 6 – UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements", Subparagraph A.**

1. Pamela Barter-Chessman, P.A.
   Angela Coton, P.A.
   David Duchin, P.A.
   Scott Ellis, P.A.
   Amy Hoffman, P.A.
   Jed Jankowski, P.A.
   Angela Leclerc, P.A. *on behalf of* Maine Association of Physician Assistants
   Gretchen Morrow, P.A.
   Kristi Kalajian, P.A.
   Ryan Trosper, P.A.
   Lisa Allen, P.A.
   Erwin Morse, P.A.
   Alan Hull, P.A.
   Tillie Fowler, J.D. *on behalf of* the American Academy of Physician Assistants (AAPA)
   Edward D. Burbach *on behalf of* AAPA
   Rebekah Bernard *on behalf of* Physicians for Patient Protection
   Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
   Matthew Davis, M.D. *on behalf of* Maine Association of Psychiatric Physicians
   Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology
   Cynthia Davies, P.A.
   Gretchen Morrow, P.A.
   Erin Muthig, P.A.

   WRITTEN COMMENTS: The commenters expressed concern with the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements." Some commenters assert that the law distinguishes between collaborative agreements and practice agreements, and that the

criteria for evaluating the scope of practice for physician assistants with collaborative agreements may not be the same as that for physician assistants with practice agreements. Some commenters assert that the boards are attempting to combine collaborative agreements and practice agreements when the Legislature created two different agreements. Some commenters believe that the criteria for evaluating the scope of practice for physician assistants under each type of agreement should not be combined as each scenario requires unique regulation and may cause confusion. Therefore, some commenters believe that the rule should set out separate criteria for each type of agreement. Some commenters believe the proposed wording may possibly be a result of misunderstanding of these two very different agreements and one commenter asserts it would be detrimental to Maine's most vulnerable underserved population for which healthcare is often limited. Some commenters believe that the language of the new subsection should be changed from "may request" to "shall be required" to create more uniformity in scope of practice determinations. Finally, some commenters believe that this section should be eliminated in its entirety.

- BOARDS' RESPONSE: Comments not accepted.

  First, the boards fully understand the distinction between the two agreements – which is based upon the practice setting and whether a physician assistant has achieved 4,000 hours of documented clinical experience. While the majority of "new" or "recent" physician assistant graduates may fall within those that may require a collaborative agreement, there may be many physician assistants who are not new or recent graduates and who still have not achieved 4,000 hours of clinical practice. For one example, a physician assistant could graduate from an approved PA program, yet fail to pass the national certification examination – resulting in a delay in clinical practice until the passage of the examination. For another example, a physician assistant may graduate from an approved PA program but not enter clinical practice for several years for any number of reasons (e.g. health reasons, additional education, different field of employment, raising a family) or have an interruption in their clinical practice. Therefore, the criteria regarding "Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement" *may* be relevant for the boards to consider – depending upon the specific circumstances of the physician assistant. The operative point is that the boards will be able to request the relevant information to specific circumstances of the individual physician assistant. To be clear, the boards are not requiring all of these types of criteria for "new" or "recent" graduates of approved physician assistant programs; therefore, they will not be barriers to employment or practice.

  Second, the boards are not "combining" collaborative agreements and practice agreements. The title of the new section should inform everyone that the purpose of the section is to establish criteria for reviewing a physician assistant's scope of practice – whether that scope of practice is set out in a collaborative agreement or a practice agreement.

Third, the proposed rule aligns with the law and establishes criteria that the boards *may* use in evaluating a physician assistant's scope of practice under either type of agreement. As indicated earlier, the law shifted the responsibility for determining the scope of practice of physician assistants working outside of a health care facility or physician group practice (where there is oversight and accountability) to the boards. Before the enactment of the law, that responsibility fell to physicians who supervised physician assistants. The law specifically authorizes the boards to review the scopes of practice for physician assistants working pursuant to either a collaborative agreement or a practice agreement. By including this language in the law, the legislature recognized the risk posed to the public by physician assistants who may attempt to render medical services in specialty areas outside of their training and experience. For example, a physician assistant who has rendered clinical medical services for 10 years in orthopedics may not be qualified to safely treat patients as the principal clinical provider in a practice rendering family medicine services – at least not without additional education, training, and oversight.

Fourth, as the boards are required to review the scope of practice of physician assistants who work pursuant to either a collaborative agreement or a practice agreement, there is no rational basis for having a separate and distinct set of criteria for each. The boards added the "criteria" in response to comments received during the initial publication of the rule so that physician assistants and the public would know what information that the boards *may* consider in deciding whether or not to approve a proposed scope of practice of a physician assistant who works pursuant to either a collaborative agreement or a practice agreement. Identifying the criteria in the rule provides for transparency and avoids allegations that the decisions made by the boards regarding scope of practice are arbitrary or capricious. The rule does not require the boards to apply each and every criteria listed – only those that are relevant to the particular circumstances of the physician assistant and the particular agreement. The criteria are not confusing, do not impact access to care, and are specifically designed to ensure access to "safe" care. Finally, the language "may request" is sufficient for the boards to obtain information needed to conduct scope of practice reviews. Requiring ALL of the types of information to be provided every time the boards are reviewing scope of practice does not necessarily result in uniformity and deprives the boards of flexibility in making such determinations based upon the individual circumstances of the physician assistant.

2. Edward D. Burbach *on behalf of* AAPA

WRITTEN COMMENT: This new section imposes "more stringent requirements regarding collaborative agreements and practice agreements."

- BOARDS' RESPONSE: Comment not accepted. The law shifted the responsibility for determining the scope of practice of physician assistants working outside of a health care facility or physician group practice (where there is oversight and accountability) to the boards. Before the enactment of the law,

that responsibility fell to physicians who supervised physician assistants. The law specifically authorizes the boards to review the scopes of practice for physician assistants working pursuant to either a collaborative agreement or a practice agreement. The law specifically states that the scope of practice of a physician assistant must be delineated in each type of agreement and that each agreement must be submitted to the boards "for approval."

By including this language, the legislature recognized the risk posed to the public by physician assistants who may attempt to render medical services in specialty areas outside of their training and experience. For example, a physician assistant who has rendered clinical medical services for 10 years in orthopedics may not be qualified to safely treat patients in a family medicine setting – at least not without additional education, training, and oversight.

The proposed rule aligns with the law and establishes criteria that the boards *may* use in evaluating a physician assistant's scope of practice under either type of agreement when submitted to the boards for approval. The boards added the "criteria" in response to comments so that physician assistants and the public would know what information that the boards *may* consider in deciding whether or not to approve a proposed scope of practice of a physician assistant who works pursuant to either a collaborative agreement or a practice agreement. Identifying the criteria in the rule does not impose stringent requirements, provides for transparency and avoids allegations that the decisions made by the boards regarding scope of practice are arbitrary or capricious. The rule does not require the boards to apply each and every criteria listed – only those that are relevant to the particular circumstances of the physician assistant and the particular agreement.

VI. **Section 6 – UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements", Subparagraph B.**

1. Alan Hull, P.A.

   WRITTEN COMMENT: "The way this is written, a single unclear or controversial item on a proposed Scope of Practice, could delay approval of the Collaborative Agreement for a considerable amount of time. This section could cause hardship for an underserved community and/or the practice and PA if the process is delayed. Please consider modifying this sentence to provide for a partial approval of a Scope of Practice until such time as the items of debate could be addressed."

   - BOARDS' RESPONSE: Comments not accepted. The rule aligns with the law, which requires physician assistants to submit Collaborative Agreements or Practice Agreements to the boards for review and approval. The boards already have the authority to approve or not approve any proposed agreement submitted to them for review. It is only logical that the boards can already do what the

commenter suggests – namely approve a modified agreement. Finally, even underserved communities deserve to have the credentials of its medical professionals – of whatever background – thoroughly vetted to ensure that safe and competent care is provided. The boards understand the health care challenges facing all Mainers, and will employ due diligence in implementing this rule.

VII. Section 12 – Identification Requirements

1. Pamela Barter-Chessman, P.A.
   Scott Ellis, P.A.
   Amy Hoffman, P.A.
   Jed Jankowski, P.A.
   Andrew Dionne, M.D.
   Angela Leclerc, P.A. *on behalf of* Maine Association of Physician Assistants
   Lisa Allen, P.A.
   Cynthia Davies, P.A.
   David Duchin, P.A.
   Alan Hull, P.A.
   Kristi Kalajian, P.A.
   Gretchen Morrow, P.A.
   Erin Muthig, P.A.
   Ryan Trosper, P.A.

   WRITTEN COMMENTS: The commenters expressed concern over a new requirement in Section 12 that licensed physician assistants: "Verbally identify themselves as physician assistants whenever greeting patients during initial patient encounters and whenever patients incorrectly refer to them as 'doctors.'" The commenters assert that this is "demeaning" and "onerous and detracts from patient centered care." The commenters believe that this requirement is "excessive and unnecessary," "difficult and detracts from patient care," and that physician assistants should "correct and move on." The commenters state that physician assistants are professionals, that no other Maine health care providers have such a requirement and that "repeatedly correcting a patient would lead to further harm and confusion… [and] undermine patient care." In addition, one commenter was concerned about the requirement of a name tag identifying him as a physician assistant, and one commenter noted that some physician assistants have "PhD or doctorates in a different field."

   - BOARDS' RESPONSE: Comments not accepted. The intent of this requirement is to ensure that the public is informed about the actual credentials of the individuals who are providing their care. The boards understand that some patients may care more or less about credentials than others and/or that some patients may lack the ability to understand or appreciate the differences in credentials of health care providers due to medical issues (e.g. neurocognitive or psychological issues). Therefore, the boards do not expect that physician assistants will correct patients each and every time during a single patient encounter. However, the boards expect that physician assistants will employ

judgment and tact during patient clinical encounters during which this issue may arise – and as one commenter stated, "correct and move on." The rule already included a requirement for physician assistants to wear a name tag identifying themselves as physician assistants. Such a requirement is also mandated by Maine law: 24 M.R.S. § 2988(3).[1] http://legislature.maine.gov/statutes/24/title24sec2988.html. The requirement that physician assistants verbally introduce themselves to new patients as physician assistants is not onerous, is informative, and does not negatively impact patient care. Similarly, the requirement that physician assistants "correct" patients who refer to them as "doctors" is not onerous and will not negatively impact patient care. Finally, Maine law prohibits a physician assistant with a doctorate and who is actively engaged in rendering medical services from referring to herself as "doctor." See 32 M.R.S. § 3270.[2] http://legislature.maine.gov/statutes/32/title32sec3270.html.

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[1] **3. Identification.** A health care practitioner shall comply with the following identification requirements.

A. [PL 2015, c. 35, §1 (RP).]

B. A health care practitioner seeing patients on a face-to-face basis shall wear a name badge or some other form of identification that clearly discloses:

(1) The health care practitioner's first name or first and last name, except that if the health care practitioner is a physician, the name badge or identification must disclose the physician's first and last name; and

(2) The type of license, registration or certification the health care practitioner holds, including the common term for the health care practitioner's profession.

[2] **§3270. Licensure required**

Unless licensed by the board, an individual may not practice medicine or surgery or a branch of medicine or surgery or claim to be legally licensed to practice medicine or surgery or a branch of medicine or surgery within the State by diagnosing, relieving in any degree or curing, or professing or attempting to diagnose, relieve or cure a human disease, ailment, defect or complaint, whether physical or mental, or of physical and mental origin, by attendance or by advice, or by prescribing or furnishing a drug, medicine, appliance, manipulation, method or a therapeutic agent whatsoever or in any other manner unless otherwise provided by statutes of this State. An individual licensed under chapter 36 may prefix the title "Doctor" or the letters "Dr." to that individual's name, as provided in section 2581, or a chiropractor licensed by this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Chiropractor," or a dentist duly licensed by this State may prefix the title "Doctor" or the letters "Dr." to that individual's name or a naturopathic doctor licensed by this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Naturopathy" or the words "Naturopathic Medicine" or an optometrist duly licensed under the laws of this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Optometrist" or a podiatrist licensed under the laws of this State may prefix the title "Doctor" or the letters "Dr." to that individual's name when accompanied by the word "Podiatrist" or "Chiropodist."

Whoever, not being duly licensed by the board, practices medicine or surgery or a branch of medicine or surgery, or purports to practice medicine or surgery or a branch of medicine or surgery in a way cited in this section, or who uses the title "Doctor" or the letters "Dr." or the letters "M.D." in connection with that individual's name, contrary to this section, commits a Class E crime. Nothing contained in this section prevents an individual who has received the doctor's degree from a reputable college or university, other than the degree of "Doctor of Medicine" from prefixing the letters "Dr." to that individual's name, if that individual is not engaged, and does not engage, in the practice of medicine or surgery or the treatment of a disease or human ailment. Nothing contained in this section prevents an individual who has received the degree "Doctor of Medicine" from a reputable college or university but who is not engaged in the practice of medicine or surgery or the treatment of a disease or human ailment, from prefixing the letters "Dr." or appending the letters "M.D." to that individual's name, as long as that individual's license to practice has never been revoked by the board.

VIII. **Request for New Section entitled "Protection for Physicians who Decline to Participate"**

1. Rebekah Bernard *on behalf of* Physicians for Patient Protection
   Lisa Moreno, M.D. *on behalf of* American Academy of Emergency Medicine
   Matthew Davis, M.D. *on behalf of* Maine Association of Psychiatric Physicians
   Alyson Maloy, M.D. *on behalf of* Portland Cognitive and Behavioral Neurology

   WRITTEN COMMENTS: The commenters urge the boards to include a provision in the rule to protect physicians from retaliation in employment, medical staff status, and credentialing when they do not want to enter into collaborative agreements, practice agreements, or the correlate of these agreements presented by their health care system or physician group practices. The commenters further urge the boards to protect physicians who "disagree with the contractual rules by a health care system or physician group that require physicians to enter into such formal agreements with PAs."

   - BOARDS' RESPONSE: Comments not accepted. This request is beyond the rule making authority of the boards and is outside of the scope of the re-proposed changes to the rule.

Nothing in this chapter may be construed as to affect or prevent the practice of the religious tenets of a church in the ministration to the sick or suffering by mental or spiritual means.

Comments Received After Initial Proposal

MaineHealth

August 7, 2020

Via E-mail
dennis.e.smith@maine.gov
susan.e.strout@maine.gov

Dennis E. Smith
Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout
Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

RE: Proposed Amendments to Board Rule Chapter 2 Physician Assistants

Dear Mr. Smith and Ms. Strout:

Thank you for the opportunity to comment on the proposed amendments to Board Rule Chapter 2 Physician Assistants. This submission is by MaineHealth, Maine's largest integrated non-profit health care system. MaineHealth provides a continuum of health care services to the residents of eleven counties in Maine and one in New Hampshire through its eight acute care hospitals, physician practices, lab, home health care services, and an integrated continuum of inpatient and community-based behavioral health services.

With a growing health care workforce shortage, we truly appreciate the intent of the proposed amendments to Board Rule Chapter 2 Physician Assistants. We have concerns, however, and proposed suggested revisions, based primarily on the fact that, as drafted, the amendments do not, in some areas, provide the necessary flexibility to implement these changes within a large health care system like MaineHealth. Also, as drafted, the amendments in some instances place the burden on physician assistants to undertake actions that we, as their employer, are better equipped to undertake. The minor revisions we propose below do not take away the intent and/or goals of the proposed amendments, but rather are requested in order to add flexibility to some requirements of collaborative and practice agreements and to enable an employer, in addition to and/or instead of an individual physician assistant, to perform some of the mandated tasks.

Our requested changes to the proposed rule amendments are as follows:

Section 7 – Uniform Elements of Written Collaboration and Practice Agreements.

Subsection 1. (A): Requested Change: We request the language reflect Public Law, Chapter 627 and state as follows: "the tasks that the physician assistant may be delegating" instead of "will be delegating." This change will still allow for a collaborative agreement and practice agreement to itemize all of the tasks that a physician assistant (PA) may ask a medical assistant (MA) to do (all of which would still be in compliance with the remaining legal obligations and scope of relevant practices), but will not be so restrictive as to require a PA to always ask a MA to do a certain task (via the phrase of commitment "will be"). Flexibility in day-to-day practice is important, including if a PA determines that a particular MA (including a new MA, for example) is unable to do a particular task on a particular day and circumstances under which a PA determines in his/her judgment that it is best, for patient safety, to undertake the task himself/herself. The "will do" language does not afford for that flexibility, and any deviation from the collaborative agreement and/or practice agreement subjects the PA to potential discipline under the current rules as written.

Subsection 1 (D): Requested change: Allow a PA's employer, and not just a PA, to prepare, maintain and produce/have on file the required collaborative and practice agreements. The current proposed rule places the burden on the PA exclusively to prepare, maintain and keep on file the collaborative or practice agreements, and subjects the PA to penalties/potential discipline if he/she falls short in these regards. Within large and/or organized healthcare systems, which employ PAs and which also place accountabilities on PAs and physicians under credentialing and privileging processes, the burden may be better assumed by the employer to develop/prepare, maintain and produce the collaborative and practice agreements. Also, such employers are able to better track when changes are necessary to such agreements, including if and where changes may be needed due to transitions in employment of consulting/collaborating physicians. MaineHealth's request is to make the following change to the proposed rule under Section 7, Subsection (1)(D): "Physician assistants licensed to practice in accordance with these rules, and/or the employers of such physician assistants, must prepare and have on file in the main administrative office of the practice or practice location a written, dated collaborative or practice agreement ..." The requested change does not take away from the intent of the original proposed rule to ensure that required collaborative and practice agreements are prepared, filed and maintained, but rather affords healthcare systems some flexibility in where to place this burden including to ensure that such agreements are prepared, maintained, updated, and filed appropriately.

Section 8 – Uniform Notification Requirements for PAs

Subsections (1) & (2): Requested changes: First, allow the PA's employer (in addition to and/or instead of the PA) to make the required notifications of any changes to and/or terminations of collaborative or practice agreements, including by submitting revisions and notifications to the Board(s). This request is made in the same spirit as that set forth above under Subsection (1)(D) of Section 7 – specifically, the burden on these matters may better fall to a PA's employer within an organized

healthcare system including when the system has its own employment rules and its own credentialing and privileging requirements and processes.

The second change is to add some flexibility in the number of days to submit changes to collaborative and practice agreements in writing to the Board(s), due to the immense challenges and work burdens that PAs, physicians and healthcare systems are already facing in delivering and prioritizing patient care.

The requested changes are therefore to add the following language in the following areas:

Subsection (1) – Change of Collaborative Agreement or Practice Agreement

"A physician assistant licensed by the Board and/or the employer for such physician assistant shall notify the board in writing within thirty (30) calendar days of any change to a collaborative agreement or practice agreement to the Board for review and approval."

Subsection (2) – Termination of Collaborative or Practice Agreement

"A physician assistant licensed by the Board and/or the employer for such physician assistant shall notify the Board in writing within thirty (30) calendar days regarding the termination of any collaborative or practice agreement. Such notification shall include the reason for termination."

Subsection 4 – Death/Departure of Collaborating Physician

MaineHealth's requested changes to Section 8, Subsection 4 have both practical and legal considerations behind it. First – the primary requested change is to eliminate this subsection altogether, as the death or permanent/long term departure of a collaborating physician is already encompassed in a required change to a collaborative agreement under subsection (1) of Section 8. If a physician is no longer able to be a collaborating physician pursuant to death and/or permanent or long term departure, the PA is already required to notify the Board(s) of a change to the relevant collaborative or practice agreements (including for example by changing the agreement to reflect a new collaborative physician) under Section 8, Subsection (1). Moreover, PAs and Hospital systems may learn of death or disability resulting in permanent/long term departures of physicians through conversations, communications or events protected by HIPAA, state privacy laws and/or state or federal employment privacy laws, where further disclosure of such matters by such PAs and/or Hospital systems are legally prohibited. Subsection 4 is therefore not only arguably unnecessary in light of Subsection (1), but also legally complicating.

If Subsection 4 must and is legally able to be retained, then a separate requested change is, again, to enable the PA's employer to undertake the burden of

notifying the Board(s) of the death or permanent or long-term departure of a collaborating physician who is a signatory to either a collaborative or practice agreement. Also, we the request that the time limit for making such requested notification be extended to 30 days from the date that the death or disabling condition of the physician became known. MaineHealth therefore requests that Subsection 4 of Section 8 read as follows: "A physician assistant licensed by the Board, and/or the employer for such physician assistant, shall notify the Board in writing within thirty (30) calendar days upon learning of the death or permanent or long term departure of a collaborating physician who is a signatory to either a collaborative agreement or a practice agreement."

The reason behind the requested change(s) are that an employing entity, versus an individual PA, is much more likely (and in the case of MaineHealth, is likely always going to be) knowledgeable about whether and under what specific circumstances a collaborating physician may have a permanent or long term departure from employment. In this regard, typically a long term and/or permanent departure is caused by either a medically disabling condition, and/or termination of employment, which matters are deemed confidential by both federal and state law as well as by employer policy and practice. Employers are therefore precluded, and/or do not share by policy, this particular kind of information with individual employees, including PAs. It would be unfair to subject a PA to discipline under the new proposed rules for failure to provide information to the Board(s) if the nature of the information is not something that the PA himself/herself would be privy to, whether by law or by operation of employer policy. Further, the request for the extension of time to 30 days from date of notice to notify the Board(s) of the death or permanent/long term departure of a collaborating physician is to enable allowance for the natural period of time that passes in order for an employer to collect underlying information related to health conditions, leaves of absence and/or basis for employment separations as to such physicians (and other employees). For example, as related to permanent and/or long term departures occasioned by medical conditions, the process to obtain documentation of the underlying condition and/or the basis for any alleged period of time needed away from work typically takes numerous weeks, and often more than 10 days. The proposed 10 day notice requirement, therefore, may not be practicably met. MaineHealth would not want its PAs sanctioned or disciplined for events outside of their (as well as the employer's control).

In conclusion, MaineHealth thanks you for the opportunity to provide comments to the proposed amendments to Board Rule Chapter 2 Physician Assistants. We have put thoughtful consideration into our need and substance of response, and limited it only to what we feel is most warranted. We truly appreciate the intent of the proposed amendments, and respectfully ask only that the Board(s) consider and adopt the few changes above for the articulated reasons.

Thank you,

Sarah Calder
Director of Government Affairs, MaineHealth

AMERICAN
PSYCHIATRIC
ASSOCIATION

800 Maine Avenue, S.W.
Suite 900
Washington, D.C. 20024

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August 7, 2020

Maine Board of Licensure in Medicine
Maine Board of Osteopathic Licensure
161 Capitol Street
Augusta, Maine 04333-0143

Dear Board of Licensure in Medicine and Board of Osteopathic Licensure,

On behalf of the American Psychiatric Association, a national medical specialty society representing more than 38,800 psychiatric physicians, as well as their patients and families, we write with concern about "Proposed Amendments to Board Rule Chapter 2 Physician Assistants." The current draft regulations do not ensure patient safety, nor do they comport with the underlying language of LD 1660. We urge you to consider detailed rules that will clarify under what circumstances physician assistants should practice.

In LD 1660, "physician" is defined as "a person licensed as a physician under this chapter or chapter 48." "This chapter" refers to chapter 36, Osteopathic Physician licensure and chapter 48 is licensure provided by the Board of Licensure in Medicine. The proposed rule has a definition section but does not provide a definition for "physician." To retain the intent of the law; the definition for physician should be echoed in the regulation: "'physician' is a person licensed as a physician under chapter 36 or chapter 48."

In addition, we are concerned that the proposed rule would authorize a facility or the Board to determine the scope of practice for a physician assistant. This does not correspond with physician scope of practice; for instance, a psychiatrist cannot decide to suddenly become a dermatologist one day and have the facility or Board solely determine the physician's scope of practice. A physician's scope of practice is based on years of training, including Accreditation Council of Graduate Medical Education (ACGME)-approved residency programs and multiple exams proving the physician has the skills needed to be a medical specialist. Similarly, a facility or Board should not unilaterally determine a physician assistant's scope of practice without specific evidence that a physician assistant has completed additional education and training to be certified in that specialty.

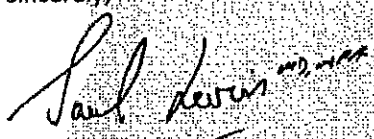
To address these concerns, we suggest including detailed regulatory language requiring certification in the specialty in which a physician assistant will be practicing **and** defining the specific education and training of each specialty for those physician assistant "specialties" that do not have certification programs.

This rule changes the terminology of the relationship between the physician and the physician assistant from "supervision" to "collaborative agreement" and "practice agreement." As a result, this rule authorizes physician assistants to practice far more freely, however it renders a physician no less liable for the actions of a physician assistant. This could be ameliorated by adding language indicating that physicians shall not be held liable in cases where physician assistants are the primary patient contact unless the collaborating physician was willfully negligent.

In 2013 and 2015, Governor LePage signed health care practitioner transparency legislation into law (24 M.R.S.A. § 2988), requiring a health care practitioner to disclose the license under which the health care practitioner is practicing. We recommend including similar language in this rule requiring physician assistants to identify the license under which they practice. We also strongly advise that physician assistants be required to say aloud that they are physician assistants, especially during the pandemic when telehealth patients will not be able to see practitioners' name badges. Patients should be provided this information in a clear manner so that they can make informed decisions about their medical care.

Thank you for the opportunity to share our concerns and suggestions. If you have any questions regarding this information, please contact Erin Philp, Director of State Government Relations, at ephilp@psych.org.

Sincerely,



Saul M. Levin, M.D., M.P.A., FRCP-E, FRCPsych
CEO and Medical Director
American Psychiatric Association

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

August 7, 2020

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137 State House Station
Augusta, ME 04333-0137
dennis.e.smith@maine.gov

Susan E. Strout
Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142
susan.e.strout@maine.gov

RE: Board of Licensure in Medicine and Board of Osteopathic Licensure Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Dennis E. Smith and Ms. Susan E. Strout,

The American Academy of Physical Medicine and Rehabilitation (AAPM&R) appreciates the opportunity to provide comments on the proposed amendments from the Maine Board of Licensure in Medicine and the Board of Osteopathic Licensure pertaining to the licensure and practice of physician assistants. AAPM&R is the national medical specialty organization representing nearly 100 physicians, residents, and medical students in Alabama who are specialists in physical medicine and rehabilitation (PM&R). PM&R physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability, and are experts in designing comprehensive, patient-centered treatment plans. Physiatrists utilize cutting-edge as well as time-tested treatments to maximize function and quality of life.

AAPM&R writes in opposition to the proposed amendments to remove the physician supervision requirements for physician assistants. Physiatrists work collaboratively with many allied and advanced practice health care providers, who are valued members of the rehabilitation team. However, we believe that physician-led, patient-centered, team-based care is the best approach to providing optimized care for patients. We have great concern that providers who have not gone through the extensive training and medical education that a physician has, would be allowed to practice independently of a physician to provide patient care. Physician assistants, while skilled, knowledgeable, and important to patient care, are not physicians. The role of physician assistants on the health care team is determined by many factors, including education and training level and individual experience and proficiency. Physician assistants should provide patient care to the extent of their education and training, subject to the oversight of a supervising physician.

There is a significant disparity in the education and training between a physician and physician assistant. Physicians spend over 11 years in medical training in order to ensure they are properly trained and educated to diagnose and treat patients. The skills, knowledge, and abilities of physician assistants and physicians are not equivalent, but instead are complementary. The most effective way to maximize the talents of the complementary skill

aaPM&R

American Academy of
Physical Medicine and Rehabilitation

sets of both professionals is to work as a team to care for patients in the physician-led, team-based approach.

Given the proposed amendment to remove the physician supervision requirements for physician assistants is maintained, a collaborative agreement between the physician and physician assistant must be upheld. Collaborative agreements may allow physician assistants to provide quality patient care to the extent of their education and training, as agreed upon by their health care team to ensure patient safety. A collaborative agreement may also allow the physician to provide more complex patient care and leadership duties suited to their level of expertise. AAPM&R believes that the consultation provision should be enforced to the fullest extent to ensure that physician assistants, based on the patient's condition, the education, competencies and experience of the physician assistant and the standards of care, consult with, collaborate with, or refer the patient to an appropriate physician or other health care professional. Furthermore, we firmly agree that a physician must be accessible to the physician assistant at all times for consultation and that a physician assistant, upon request of the Board, shall identify the physician who is currently available or was available for consultation with the physician assistant. To create a formal structure that would promote standardization of the process for establishing collaborative agreements, we believe that the both licensing boards should develop standard forms and review the appropriateness of collaborative and practice agreements in various clinical settings.

Thank you for your consideration of the provided comments. Please contact Brit Galvin, Health Policy and State Legislative Affairs Manager, Department of Health Policy and Practice Services via email at bgalvin@aapmr.org or via telephone at (847) 737-6004, should you have any additional questions or concerns.

Sincerely,

Stuart Glassman, MD, MBA
AAPM&R State Advocacy Committee, Chair

ALAN HULL & SUSAN KEPES
120 PHEASANT HILL DRIVE, PORTLAND, MAINE 04103

August 6, 2020

Dennis E. Smith, Executive Director; Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333- 0137

Susan E. Strout, Executive Secretary; Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333- 0142

Re: Chapter 2 revisions

Dear Ms. Strout, Mr. Smith, and Board Members,

With the impact of the coronavirus this year, and the necessity of changing the Boards' workflows as well as having additional work, it is particularly notable that the work Chapter 2 revision proceeded apace. The Boards, board staff, and all involved should be proud of their work.

The Chapter 2 revisions appear generally congruent with the statute changes. There are two areas that I would respectfully suggest need further work and revision.

PL 2020, c. 627 states:

> 6. Practice Agreement Requirements.
>
> A physician assistant who has more than 4,000 hours of clinical practice may be the principal clinical provider in a practice that does not include a physician partner as long as the physician assistant has a practice agreement with an active physician, and other health care professionals as necessary, that describes the physician assistant's scope of practice.

The proposed Chapter 2 revision states:

8. Criteria for Requiring Collaborative Agreements or Practice Agreements

B. **Practice Agreement.**

Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner **or who own and/or operate an independent practice** must have the following in order to render medical services under their Maine license:

(1) A Board-approved practice agreement with a Maine physician holding an active, unrestricted physician license.

The bolded addition to the proposed Chapter 2 revision describes a business situation of the PA. I feel that this addition is inappropriate as it is not mentioned in the statute, and if the legislators wished to designate a specific business model, they would have done so. It is also an inappropriate addition, as the Boards are charged with regulating the practice of medicine, not prescribing business situations or PAs.

*I respectfully ask that "**or who own and/or operate an independent practice**" be removed from the Chapter 2 revision.*

I understand the Boards' need to be able to request of a PA the identity of the "available consultant" in SECTION 6, UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS. This need flows from:

4. Consultation. A physician assistant shall, as indicated by a patient's condition, the education, competencies and experience of the physician assistant and the standards of care, consult with, collaborate with or refer the patient to an appropriate physician or other health care professional. The level of consultation required under this subsection is determined by the practice setting, including a physician employer, physician group practice or private practice, or by the system of credentialing and granting of privileges of a health care facility. **A physician must be accessible to the physician assistant at all times for consultation.** Consultation may occur electronically or through telecommunication and includes communication, task sharing and education among all members of a health care team.

Unfortunately, the proposed Chapter 2 revision

SECTION 63. UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS

3. **Consultation**

> Physician assistants shall, as indicated by a patient's condition, the education, competencies and experience of the physician assistant and the standards of care, consult with, collaborate with or refer the patient to an appropriate physician or other health care professional. The level of consultation required is determined by the practice setting, including a physician employer, physician group practice, or private practice, or by the system of credentialing and granting of privileges of a health care facility. A physician must be accessible to the physician assistant at all times for consultation. Consultation may occur electronically or through telecommunication and includes communication, task sharing and education among all members of a health care team. Upon request of the Board, a physician assistant shall identify the physician who is currently available **or was available for consultation** with the physician assistant.

includes the phrase "or was available for consultation" in the last sentence. This phrase is problematic as there is no addressed time frame as to how far in the past, the physician "available for consultation" will have to be identified. Will these records have to be maintained for 10 days, 10 weeks, 10 months, 10 years, or in perpetuity? Long-term maintenance of these records would be burdensome, and onerous. There should be a definitive timeframe for these records to be maintained.

With our current technology, medical records programs change relatively frequently, and unfortunately, importing all the data from the old system into the new system is expensive, extremely time-consuming, and frequently does not happen. Schedules whether electronic or hard copy, can be misplaced, or inadvertently discarded.

I would ask the physicians on the Boards to see if they can identify who the physician preceptor was on August 7 during the second year of their residency. Could they do so readily? Could they gain access to the records to identify that preceptor? If they were to name the residency director as a default preceptor, could they be assured that that physician would not have been on vacation or out ill that day? To expect a Maine PA to be able to identify the consultant available at five years, 10 years, or 20 years in the past is spurious.

I would respectfully suggest and hope that the phrase "or was available for consultation" can be modified to include a definitive timeframe in the past. One year seems to be reasonable duration of time for the maintenance of those records.

I hope that the boards will look favorably upon my suggestions. I would also like to give everyone involved with this revision my personal thanks for the open manner in which this was done.

I can be contacted at alanhull@maine.rr.com if anyone has any questions.

Sincerely,

Alan Hull, PA-C

Alan Hull, PA-C

M|H|A
Maine Hospital Association

MAINE'S LEADING
VOICE FOR HEALTHCARE

August 7, 2020

Dennis E. Smith, Executive Director
Maine Board of Licensure in Medicine
137 State House Station
Augusta, ME 04330

Director Smith,

Please accept this letter on behalf of the Maine Hospital Association (MHA). MHA supports the Chapter 2 Joint Rule Regarding Physician Assistants.

MHA participated in the legislative process in connection with the underlying bill.

Maine hospitals employ many physician assistants all across the state. A hospital will be considered a "health care facility" under the terms of the rule and will be impacted by the rule.

We believe the rule is consistent with the underlying law and addresses the issues the manner expected by the legislature.

We do agree with the PA Association that the provision in Section 6(3) may present challenges with respect to retrospective requests. A limit of some kind seems warranted.

I'm happy to speak with you on this issue at your convenience.

Thank you.

Yours,

Jeffrey Austin
VP of Governmental Affairs

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137
(tel) 287-3605 (fax) 287-6590
dennis.e.smith@maine.gov

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142
(tel) 287-2480 (fax) 536-5811
susan.e.strout@maine.gov

RE: Comment on proposed revisions to Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

My name is Angela Leclerc and I've been a PA in Maine for 15 years. Most of my career has been spent in inpatient acute care medicine with some moonlighting in outpatient medicine. I serve as a leader at my current institution, working very collaboratively with my physician colleagues in critical care. I also serve on multiple committees at our institution and nationally, as well as a clinical educator to advanced practice provider students, medical students and physician resident and fellows in neuro and surgical critical care. Finally, outside of my volunteer work with the Maine Association of Physician Assistants (MEAPA), my career involves clinical research with two recent publications in the Neurocritical Care journal. However, the most rewarding part of my practice is patient care. Our physician colleagues; neurosurgeons, neurologists and critical care attendings, will frequently share the importance of our presence in the neuro and surgical critical care programs at our institution. We are a consistent level of expertise in the unit that directly improve patient safety.

On behalf of the MEAPA, I would like to thank you all for your work during these very uncertain times, it is a challenge to keep moving forward as before the pandemic and your dedication to the revision of Chapter 2 is appreciated.

The proposed Chapter 2 rules really are reflective of current practice for PAs in Maine and will allow increased access as well as quality improvement and safety monitoring of the care provided by PAs in Maine. This will increase public safety.

That being said, there are a two changes I would like to respectfully suggest.

1. Request for addition of timeframe to identify available physician:
   MEAPA supports PAs being able to identify which physicians are available for consultation, however, requests that the language be adjusted to include a specific timeframe, and would suggest:

   [...] Upon request of the Board, a physician assistant shall identify the physician who is currently available **or was available for consultation** with the physician assistant ***up to one year from the date of care***.[...]

2. Deletion of any reference to a business relationship:

SECTION 63. UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS

[...]

8. Criteria for Requiring Collaborative Agreements or Practice Agreements

[...]

B. **Practice Agreement.** Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner **or who own and/or operate an independent practice** must have the following in order to render medical services under their Maine license:

[...]

The bolded language above references regulation of a structure of business rather than regulation of practice and appears to be inappropriate. It is not in the revised statute. In addition, using the term "independent" is confusing (when thinking of PA practice vs PA business). MEAPA recommends this language be deleted in its entirety, and the revised language read:

B. **Practice Agreement.** Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner must have the following in order to render medical services under their Maine license:

In closing, MEAPA would like to thank you again for your work and commitment to the safety of our patients and the professionalism of our practice. I believe in the high quality and safe patient care we have been providing and will continue to provide Maine.

Sincerely,
Angela Leclerc, MSPAS, PA-C
President MEAPA
207-233-9592
leclea@mmc.org

From: Andrew N.
To: Smith, Dennis E
Subject: Comments on Proposed Amendments to Board Rule Chapter 2 Physician Assistants
Date: Thursday, August 6, 2020 9:56:39 PM

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Dennis:

After reviewing the statute and the Maine Board of Licensure in Medicine's proposed rule, I have the following concerns.

1. There should be a public hearing. This is a substantial change in Physician Assistant licensing and oversight. Consider this a request for a public hearing

2. The impact statement on Maine small businesses is deficient. It states there is no new burden, but the rule creates collaboration and practice agreements. There are different criteria for each type of agreement and they may need to be constantly updated.

3. Maine physician is undefined. This implies a physician licensed and residing in Maine, but it is not defined. Given the movement to telehealth, and the practice of medicine across state lines, I think it is important that "Maine physician" be someone locally available and licensed.

4. The BOLIM must evaluate and approve each collaboration and practice agreement. I am not sure the Board has the capability to properly evaluate, oversee, update and enforce these agreements. This is critical to the safety of patients. Physicians move, change jobs, and retire. The scope of practice for independently practicing PA's may be on constant flux. It may be much harder to keep an updated collaboration or practice agreement tham anticipated by the proposed rule. I am afraid these agreements may just become a "check the box" document that is filed, but never updated or reviewed until after a problem occurs.

Andrew Nicholson, MD, JD

From: Strout, Susan E
To: Smith, Dennis E; Lathrop, Maureen S
Subject: FW: 2 Joint Rule Regarding Physician Assistants
Date: Thursday, August 6, 2020 8:38:17 AM

Sending this along in case she sent only to me for some reason. Thanks, Sue

---

From: CHRISTINE THOMAS <cladamsthomas@hotmail.com>
Sent: Thursday, August 06, 2020 7:38 AM
To: Strout, Susan E <Susan.E.Strout@maine.gov>
Subject: 2 Joint Rule Regarding Physician Assistants

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Ms. Strout

As a Physician Assistant who has practiced in Maine for 24 years, I would like to support the proposed **Joint Rule Regarding Physician Assistants**

I believe the changes to the current regulations will allow better access to health care for all Mainers by removing limitations. It will also put us on equal footing with other professionals who can work independently despite having less experience.

Thank you

Christine Thomas PA 608

From: Lathrop, Maureen S
To: Smith, Dennis E
Subject: FW: Comments Proposed Changes Rule 2 Physician Assistants
Date: Tuesday, August 4, 2020 7:16:03 AM

Chapter 2 comment

From: Strout, Susan E <Susan.E.Strout@maine.gov>
Sent: Sunday, August 2, 2020 4:40 PM
To: Lathrop, Maureen S <Maureen.S.Lathrop@maine.gov>
Subject: FW: Comments Proposed Changes Rule 2 Physician Assistants

Hi Maureen,

Please see this comment that doesn't appear to have been sent along to anyone but me.

Thanks, Sue

Susan E. Strout, Executive Secretary
Maine Board of Osteopathic Licensure
142 State House Station
Augusta ME 04333-0142
Tel: 207/287-2480 (currently, please call 207/446-4205 as I am teleworking)
Fax: 207/536-5811
Web: www.maine.gov/osteo

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From: Corey Cole <coreycoledo@gmail.com>
Sent: Saturday, August 01, 2020 11:34 PM
To: Strout, Susan E <Susan.E.Strout@maine.gov>
Subject: Comments Proposed Changes Rule 2 Physician Assistants

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.
Section 6 1.A) A physician assistant may provide any medical service for which the physician assistant has been prepared by education, training and experience and is competent to perform. The scope of

practice of a physician assistant is determined by the practice setting.

Would there be any procedures or scope of practice that they would be restricted from performing such as "major surgery", perimortem c-sections, endovascular procedures, etc? I realize that there is still a credentially process as outlined later in the statue but as it written it seems too broad.

Section 6.6) A physician assistant is legally liable for any medical service rendered by the physician assistant.

I feel that there should be a comment about the PA needing to have malpractice insurance whether it be provided by themselves or their employer.

Sincerely,

Corey Cole, DO

From: Lathrop, Maureen S
To: Smith, Dennis E; Strout, Susan E
Subject: FW: PA law rules
Date: Tuesday, August 4, 2020 8:11:03 AM

Dennis and Sue,

I received a comment on Chapter 2.

Maureen

-----Original Message-----
From: Maria Paone <rheapaone@me.com>
Sent: Tuesday, August 4, 2020 8:04 AM
To: Lathrop, Maureen S <Maureen.S.Lathrop@maine.gov>
Subject: PA law rules

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

I am highly concerned about the language of the new law allowing independent practice for PAs. It will set a dangerous precedent for other states.

PAs have only 2 years of graduate education and no residency training. This bill essentially permits them the same rights and privileges as a physician who went to school for 4 years and trained for another 3-7 years after.

This bill allows PAs to practice in any specialty of their choice. Even if their 4000 hours are spent in pediatrics, they can get a job in the ICU as an independent practitioner without a single hour of extra training. There should be language in the law mandating another training period before being allowed independent practice in another specialty.

The law allows PAs to "collaborate" with physicians and takes out all reference to "supervision" even when they first graduate. This is unsafe. At the very least, their initial post graduate period should be required to be "under direct supervision." How do they expect to learn medicine without guidance? The public should not be experimented on for the satisfaction of their ego and the greed of the corporations who want to hire them in place of physicians.

PAs and NPs like to say they want to practice to the "top of their license." In the case of a PA, their license is to practice as a Physician Assistant, not as a Physician. This law enables them to bypass 2 years of school and 3-7 years of training, board specialty exams and recertification and practice to the full extent of a Physician's license. More, actually, because, unlike a physician, they are permitted to switch specialities at will.

Either medical school and physician training has value or it doesn't. If a law permitting medical students the same rights as this law does PAs, there would be a public outcry that dangerously undereducated and poorly trained doctors were being licensed. And that would be correct. There should be no shortcuts to the practice of medicine.

Thank You,
Maria Paone, MD

Sent from my iPhone

From: CHRISTINE THOMAS
To: Smith, Dennis E
Subject: Joint Rule Regarding Physician Assistants
Date: Thursday, August 6, 2020 8:43:18 AM

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Mr Smith

As a Physician Assistant who has practiced in Maine for 24 years, I would like to support the proposed **Joint Rule Regarding Physician Assistants**

I believe the changes to the current regulations will allow better access to health care for all Mainers by removing limitations. It will also put us on equal footing with other professionals who can work independently despite having less experience.

Thank you

Christine Thomas PA 608

Date: August 7, 2020

To: Maine Board of Licensure in Medicine
Maine Board of Osteopathic Licensure

From: Maine Chapter American College of Emergency Physicians

Subject: Chapter 2 - Joint Rule Regarding Physician Assistants

Dear Board Members,

The Maine Neurological Society, a professional association of Maine neurologists and clinical neuroscience professionals, is concerned about the ramifications that LD 1660 would have on the patients of our great state. In providing care for our patients, we have always appreciated the importance of other types of medical practitioners participating on our health care teams as crucial participants. Nonetheless, we have concerns that the removal of requirements related to supervision potentially compromises patient safety in our practice setting.

The terms of Chapter 627 allow a physician assistant to essentially provide medical services independent of meaningful physician oversight if they wish to open a solo practice after 4,000 hours of clinical experience. We would urge the Board to give additional attention to defining "scope of practice" in these rules, particularly what constitutes appropriate education, training, and experience in order to provide a particular medical service. Clearly delineated requirements for detailed and meaningful collaborative agreements and practice agreements that take into consideration practice and clinical settings are essential to promote high quality care and patient safety.

All residents of Maine deserve access to high-quality patient care delivered by health care professionals with the appropriate level of education and training. Protect Maine's patients by ensuring that the PAs training and experience be practiced in the context of a health care teams that are organized to provide high quality care to our patients.

Thank you in advance for your willingness to hear our concerns. Please contact MNS Executive Director Cathryn Stratton at cstratton@mainemed.com with any questions.

Sincerely,

Maine Neurological Society

Megan Selvitelli, MD, President
Anthony Knox, MD, Vice-President
Jacques Reynolds, MD, Treasurer/Secretary
Cathryn Stratton, Executive Director

Maine Chapter
Advancing Emergency Care

American College of
Emergency Physicians

CHAPTER OFFICERS

PRESIDENT
Garreth Debiegun, MD, FACEP
garreth.biegun@gmail.com

PRESIDENT-ELECT
Nathan Donaldson, MD FACEP
natedon78@gmail.com

IMMEDIATE PAST-PRESIDENT
James Mullen, MD, MBA, FACEP
jmullen@bluewateremergency.com

TREASURER
David Stuchiner, MD, FACEP
dstuchiner@gwi.net

COUNCILLORS
Charles Pattavina, MD, FACEP
cpattavina@sjhhealth.com

Garreth Debiegun, MD, FACEP
garreth.biegun@gmail.com

Thomas Dancoes, DO, FACEP
tdancoes@bluewateremergency.com

CHAPTER ADMINISTRATION

EXECUTIVE DIRECTOR
Cathryn Stratton
Maine Chapter, ACEP
PO Box 190
Manchester, ME 04351
(p) 207-592-5725
(c) 207-446-1362

Date: August 7, 2020

To: Maine Board of Licensure in Medicine
Maine Board of Osteopathic Licensure

From: Maine Chapter American College of Emergency Physicians

Subject: Chapter 2 - Joint Rule Regarding Physician Assistants

Dear Board Members,

As the leading organization representing Maine's emergency physicians, the Maine Chapter of the American College of Emergency Physicians appreciates the opportunity to comment on the proposed rule regarding physician assistant licensure. As you know, the unique nature of emergency medicine requires preparation for an endless array of emergency injuries and illnesses that may require the attention of our departments on any given day. Having a reliable network with clear certification standards is particularly important to our members because of the frequency with which we receive and refer new patients in our practice and specialty.

The extensive training of our Board certified, residency trained physicians prepares our members to provide the highest quality care in that practice environment. In providing that care, we have always appreciated the importance of other types of medical practitioners participating on our health care teams as crucial participants in the provision of care. Nonetheless, we have concerns that the removal of requirements related to supervision potentially compromises patient safety in our practice setting. As such, we would urge the respective boards to exercise their full rulemaking authority in a manner that addresses the needs of patients under the recently enacted statute.

Patients experiencing an emergency medical condition typically want the assurance that comes with knowing the training and credentials of the health care professionals that are providing their care. The Maine legislature has recognized that patients have a right to this information, in 2013 enacting "An Act Establishing Health Care Practitioner Transparency Requirements." Among its provisions, the Act prohibited "deceptive or misleading advertising," as defined, regarding the practitioner's license and required that practitioners that have direct patient interactions display identification containing the practitioner's name, the type of license held, including the common term for the profession, and the practitioner's medical staff position.

Given the added confusion that patients may experience under new requirements as to the credentials of those providing treatment, we believe that it would be appropriate to confirm all of those requirements in the context of these rules.

In addition, we would urge the Board to give additional attention to the need to define "scope of practice." Properly defined, an emergency physician is one who has completed residency training and passed rigorous examinations in emergency medicine in order to become a specialist in the field. The requirements for practice in a specialty setting contemplated for independent physician assistants under the proposed rules contain far less rigor and, in fact, would allow for specialty practice largely based on self-reporting related to practice settings but largely independent of actual reportable accomplished training. We believe that this is not in the best interest of patients and that a more rigorous means for determining scope of practice would be appropriate.

We advise that the Board in its Rule Making should define what constitutes appropriate education, training and experience in order to provide a particular medical service. Medical training for physicians consists of medical education followed by postgraduate education, generally a minimum of three years or longer. This post graduate training is curriculum based and training programs are reviewed by the ACGME or the AOA for their ability to provide adequate training to ensure the public that graduates of these programs can provide safe specialty care.

Before closing, we should emphasize that we value the training and experience of physician assistants who are an important part of the emergency department environment. None of these comments are intended in any way to denigrate their training and experience. However, it is important that their training and experience be practiced in the context of a health care team that is organized to provide high quality care to our patients. As such, we would suggest that the rules for Chapter 2 should

a. describe the nature of the training that should occur during the 4000 hours of practice in which a physician assistant must have a collaborative agreement. The Rules should include the requirement that any Scope of Practice agreement should be based on evidence of curricula-based training.
b. specify that an additional 4000 hours of training should be necessary if the Physician Assistant elects to practice in a different medical specialty than the one in which the initial training occurred.

Thank you for your consideration of these comments. If you have questions, comments or would like clarification, please contact Cathy Stratton (cstratton@mainemed.com or call (207) 446-1362).

Sincerely,

Maine Chapter, American College of Emergency Physicians

Garreth Deblegun, MD, FACEP, President
Nathan Donaldson, DO, FACEP, President-Elect
James Mullen, MD, FACEP, Immediate Past President
David Stuchiner, MD, FACEP, Secretary/Treasurer
Charles Pattavina, MD FACEP, Councillor
Thomas Dancoes, DO, FACEP, Councillor

Northern Light Health

Northern Light Health
Government Relations
43 Whiting Hill Road
Brewer, Maine 04412

Office 207-861-3282
Fax 207-872-2030

Northern Light Health
Acadia Hospital
A.R. Gould Hospital
Beacon Health
Blue Hill Hospital
C.A. Dean Hospital
Eastern Maine Medical Center
Home Care & Hospice
Inland Hospital
Maine Coast Hospital
Mercy Hospital
Northern Light Health Foundation
Sebasticook Valley Hospital

August 6, 2020

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

Subject: Proposed Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

On behalf of Northern Light Health, our member organizations and clinicians we thank you for the opportunity to comment on proposed rule changes regarding physician assistants. Our comment focuses on two areas of policy in the proposed rule.

Section 6. 8. Criteria for Requiring Collaborative Agreements or Practice Agreements
The proposed rule refers to agreement requirements for physician assistants with more than or less than 4,000 hours of documented clinical practice. We request that the final rule provide more detail on what qualifies as documented clinical practice. Is the standard as basic as the number of hours generally employed as a physician assistant or it is more complex relating to the number of hours performing clinical tasks as a licensed physician assistant.

Section 7. Uniform Elements of Written Collaborative and Practice Agreements
We ask that the respective boards develop standardized collaborative and practice agreement templates for optional use by physician assistants.

Sincerely,

Lisa Harvey-McPherson RN, MBA, MPPM
Vice President Government Relations

From: Dana Green
To: Smith, Dennis E
Subject: physician assistant chapter 2 changes
Date: Friday, August 7, 2020 4:45:10 PM

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Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137
(tel) 287-3605 (fax) 287-6590
dennis.smith@maine.gov

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142
(tel) 287-2480 (fax) 536-5811
susan.e.strout@maine.gov

RE: Comment on proposed revisions to Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

My name is Mr. Dana Green and I've been a PA in Maine for 25 years. I am the very first physician assistant from the state of Maine to complete a formal physician assistant residency in psychiatry and obtain a CAQ (certificate of advanced qualifications in psychiatry). I am now 66 years old and work as a weekend and holidays provider at VA Maine inpatient psychiatry unit at Togus.

I would like to thank you for all your professional work during such challenging and uncertain times. I am also thankful for the proposed revisions to the physician assistant medical practice rules of the newly approved Chapter 2. This will provide expansion of physician assistant services in the coming years for Maine's medical communities.

Overall I find the new Chapter 2 rules are well thought out. I do see that the statement about being able to provide information surrounding prior medical providers and provider working relationships as leading to potential problems. Time will tell.

Continue your leadership on behalf of the residents of Maine.

Sincerely,
Dana

Dana L. Green
PAC, CAQ Psychiatry
VA Maine Healthcare System
home address: 29 Moosehorn Drive

Bucksport 04416
Phone 207-469-3150
Email dgreen30422@gmail.com

Sent from my iPad

Sent from my iPad

Portland Cognitive and
Behavioral Neurology

Maine Board of Licensure in Medicine
137 State House Station
161 Capital Street
Augusta, ME 04333-0143

Thursday, August 6th, 2020

Dear Board members,

As professional organizations representing different specialties in medicine, we are writing to submit comments on the amendment draft to Board Rule Chapter 2. We appreciate the invitation for comments.

As the Maine Board of Licensure in Medicine (BOLIM) may agree, there are numerous concerning aspects of this law, which was passed at the onset of a pandemic without consideration of viewpoints expressed in years past when this bill was previously considered. However, now that it is in the rule-making process, we have a need to protect the public. Four areas of concern we would like to address as opportunities in this rule-making process are: scope of practice, truth in advertising, collaboration, and pay parity.

Scope of Practice

Point (8) on page 6 of the BOLIM draft under "Uniform Requirements for Full License" requires for licensure that a physician assistant (PA) "demonstrates current clinical competence as required by this law." (This requirement is also found on page 11 under license reinstatement.) Clinical competence is not explicitly defined under the law, per se, but on page 15, under Uniform Scope of Practice for Physician Assistants, PAs are granted the authority to provide "any medical service for which they physician assistant has been prepared by education, training, and experience and is competent to perform. The scope of practice of a physician assistant is determined by the practice setting."

The scope of practice of physicians is determined by completion of a Liaison Committee on Medical Education (LCME)-accredited medical school, followed by highly competitive acceptance into and completion of an Accreditation Council of Graduate Medical Education (ACGME)-approved residency program. This nearly-decades-long process to become a physician is most often followed by passing multi-day specialty exams to earn "board-certification." Certification in one's American Board of Medical Subspecialties (ABMS) specialty is determined by a 3 to 7 year-long residency, some with an additional 1 to 3-year long fellowship. This process ensures rigorous standardization of skills and includes multiple overlapping determinants of competence.

No similar oversight in PA training exists. The draft appears to show that the BOLIM has opted to forego the need for this rigorous determination of safe scope of practice and opt instead to allow PAs to claim expertise based on practice location or whatever training and education the PA decides is sufficient. Under this system, a PA could legally claim to be a "specialist" in dermatology after working for a few weeks in a dermatology practice, while a physician with many years more training in dermatology is legally barred from such claims. The confusion created by this double standard communicates to patients that the training of a PA "specialist" exceeds that of a physician, and yet this deception is legal on a state level. Likewise, a PA could decide he/she is competent to perform a thoracentesis after watching one in the emergency department. This PA with no

449 Forest Avenue #214 | Portland, ME 04101 | p: 207-222-3021 | f: 207-536-0334 | pcbnpsych.com | info@pcbnpsych.com

formal training in this procedure could decide to perform this procedure on a patient, who has no idea of the lack of training of this clinician and the associated risk. No true informed-consent is possible, as the risks of the procedure being performed by an untrained individual are additive to the inherent risks of the procedure. Relying on the employer to ensure and/or provide the training and oversight for PAs' scope of practice places the responsibility on to employers, who practice in a business model, not in an altruistic one of educator or supervisor.

The BOLIM does not determine scope of practice for physicians through the licensing process because there is already a rigid system in place that determines physician scope of practice. However, since a similar system is not in place for PAs, how is the BOLIM going to protect public safety by ensuring PAs are competent to perform in the scope of practice they self-declare? If there is no answer, perhaps this needs to be carefully established as part of the rule-making process. The speed of the law-making seems to demand more from the medical system than currently exists to determine scope of practice of PAs in a manner commensurate with public safety.

In the absence of an existing system to determine the bounds of PA scope of practice, two options are:

1. to disallow PA claims of specialization based on practice location; see also "Truth in Advertising" below

2. to require consultation with physicians that occurs in person, on-site while practicing, to determine and approve scope of practice. Due to their rigorous standardization of education, physicians *are* in a position to determine safe scope of practice by PAs on a case-by-case basis. This suggestion is different than the on-paper approval provided by BOLIM staff, who are removed from observing the actual provision of care, that is being proposed in the current draft. Furthermore, this suggestion is *different* from "collaboration" (which suggest equal but complementary expertise between a physician and a PA) or "supervision" (which is not permitted by the statute). The PA would be legally liable for his or her own work, but would be required by the BOLIM to document external validation of safety to function safely within a defined scope of practice. We understand that the BOLIM has attempted to achieve this via collaboration agreements, which we believe does not accomplish one of the stated goals of LD1660 of removing physician liability from PAs' practice. We address this specific issue in greater detail in the section "Collaboration" below.

Truth in Advertising

As discussed above, the draft proposal as written allows PAs to define their own scope of practice. This option not only lacks safeguards for patient safety, but also allows misleading self-promotion on specialization. The AMA performed a longitudinal Truth in Advertising survey that found that 61% of patients thought that PAs with a doctorate of medicine science were physicians (https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/arc/tia-survey_0.pdf). We believe as regulators of both physician and PA practice, the BOLIM is in a unique position and indeed obligated to clear up the confusion and thereby empower them to make autonomous, educated decisions about healthcare purchasing. In the Truth in Advertising campaign stated above, 91% of respondents said that a physician's years of medical education and training are vital to optimal patient care. PAs should not be allowed to claim to be a "dermatology specialist" simply because they work in a dermatology office, which implies to patients that they have more experience in dermatology than the patient's primary care physician. Additionally, a PA with a medical science doctorate who passed the National Commission on Certification of Physician Assistants (NCCPA) certification program should not be allowed to claim she is a "board-certified family medicine doctor." These claims are misleading and

dangerous. We propose that the rule-making process include truth in advertising language that includes, but is not limited to, requirements for disclosure of licensure title to every patient, as well as require PAs to explicitly correct patients who refer to them as "doctor."

Collaboration

The term collaboration is used when discussing work between nurses and physicians because they belong to different professions. In contrast, physicians and physician assistants both belong to the profession of medicine. Because both physicians and PAs are now being allowed to practice medicine independently, but PAs complete significantly less training than physicians, physicians will continue to be held liable unless they are working in a consultation capacity. When a physician and a PA work together, the physician is either supervising (e.g. the physician shares responsibility for the patient) or the physician is consulting (e.g. not primarily responsible for the patient). When a physician "collaborates" with a PA on a case, the physician will be held liable. Therefore, we propose the term consultation agreement be used instead of collaboration agreements to more clearly define the roles and responsibilities of each party. Simply stating in the amendment that PAs are liable for their own mistakes will not make it so. Changes in language as proposed here, as well as other changes not relevant here (such as holding equal malpractice insurance) will be necessary.

In addition to the above discussion of language, we would like to comment on the omission of a consultation agreement (collaborative agreement, as per the draft) requirement for PAs hired by facilities that credential them. We believe this is a dangerous oversight in patient safety that assumes employers provide physician staff to meaningfully review their work, which is widely known to not occur. Furthermore, it continues to make physicians liable for the work done by PAs at those institutions. We do not see any justifiable reason to exclude inexperienced PAs hired by facilities from the consultation/collaborative agreement proposed by the Board. This is an issue of ensuring ongoing supervision to ensure safety in licensure and we do not believe oversight of that can safely be left to employers whose goal is maximum productivity of employees.

Pay Parity

We based our comments on the BOLIM draft, but do want to say that a paragraph in the osteopathic version appears to require pay parity for PAs. We do not see a similar statement in the BOLIM version.

Various interests have promoted the false narrative that a generic "health care provider" provides uniform medical services independent of the training of the "provider." This falsity is actualized by an insurance industry coding system that distinguishes the care of other specialties, such as occupational therapists, social workers, audiologists, chiropractors, and nutritionists, but makes no similar distinction between the nature of the service provided by physicians, nurse practitioners, and PAs, other than by a slight *percentage* reduction for non-physician providers (NPPs).

Pay parity laws gloss over the fact that physicians, NPs, and PAs, actually provide different medical services based on their expertise. The only public agencies that truly understand the differences in training and thus can protect the public from a false belief in equivalency are the medical boards. For the osteopathic medical board to promote pay parity is to equate the training and education of PAs with that of physicians. The downstream consequences of this false equivalency in the business-of-medicine model would be devastating to patient safety as lower-cost PAs are hired to provide "the same" medical care as physicians, when in fact the care is not the same. Furthermore, patients lose the right to see a physician when HMOs fill their panels with PAs and

insist that rather than see a family practice physician as a PCP, the patient MUST see a PA who works in family practice because they provide "the same" medical service.

Our concern with the draft as it stands is that rather than permit a specific type of clinician to work independently, it functionally gives PAs a license to practice medicine in the same capacity as physicians, without them actually completing the education and training necessary to achieve that level of competence. The practice of medicine would thus be largely performed by people without medical degrees, while the public continues to be lost in confusion about the actual training and oversight of these clinicians, which they understandably assume others (the employers, the BOLIM) are doing.

In closing, thank you very much for taking the time to read these comments.

Sincerely,

Maine Neurological Society
Megan Selvitelli, MD, President
Anthony Knox, MD, Vice President
Jacques Reynolds, DO, Treasurer/Secretary
Cathy Stratton, Executive Director

American Academy of Emergency Medicine
Lisa A. Moreno, MD MS MSCR FAAEM FIFEM, President
Evie Marcolini, MD, FAAEM, FACEP, FCCM, Chair, EM Workforce Committee

Physicians for Patient Protection
Purvi Parikh, MD, FACP, FACAAI

Portland Cognitive and Behavioral Neurology
Alyson Maloy, MD, FAPA, FABIHM

Maine Osteopathic Association | Maine Medical Association | Spectrum Healthcare Partners

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To: Board of Licensure in Medicine
Board of Osteopathic Licensure

From: Maine Medical Association
Maine Osteopathic Association
Spectrum Healthcare Partners

Date: August 7, 2020

Subject: CHAPTER 2- Joint Rule Regarding Physician Assistants

We appreciate the opportunity to submit the following comments on the proposed amendments to the proposed joint rule pertaining to the licensure and practice of physician assistants in response to Public Law 2019, Chapter 627.

Maine needs physician assistants. They are a vital part of our physician-led health care teams. However, it is critical for the public to understand that physician assistants and physicians are *NOT* essentially interchangeable, and that the two professions *DO NOT* have a body of knowledge and clinical skills that are equivalent. Each member of a physician-led health care team has an important role to play, working together to provide the best outcomes for patients while also driving improvements in patient care. While there is no question about the level of service and professionalism physician assistants bring to a health care team, they are not physicians. Any other characterization underestimates the clinical complexity that often accompanies a medical determination and plan of care.

Nevertheless, the terms of Chapter 627 allow a physician assistant to essentially provide medical services independent of meaningful physician oversight if they wish to open a solo practice after 4,000 hours of clinical experience. While we continue to have strong reservations about aspects of the legislation, we support the provision outlining that, for all physician assistants, in every clinical setting, "*a physician must be accessible to the physician assistant at all times for consultation*," and that upon request of the Board, "*a physician assistant shall identify the physician who is currently available or was available for consultation with the physician assistant*." We also support the requirement that, "*a physician assistant is legally liable for any medical service rendered by the physician assistant.*"

One of our principal criticisms of the legislation was its delegation of overly broad authority to the licensing boards and its failure to specifically enumerate standards for determination of scope of practice and other important parameters for medical services provided by physician assistants. We believe that detailed and meaningful collaborative agreements and practice agreements with clearly defined protocols and elements are essential to promote high quality care and patient safety in most clinical situations, while also taking into consideration the different practice and clinical settings in which physician assistants function.

Chapter 627, and these and subsequent regulations, could have far-reaching implications for patient care. Therefore, under any construct of collaborative or practice agreements, we propose the following amendments to the joint rule:

Amend Section 6 (Uniform Scope of Practice for Physician Assistants), in subsection 1 (General) , by establishing a joint subcommittee of physician and physician assistants by the Boards of Licensure in Medicine and Osteopathic Licensure to lead the development of standard agreements and appropriate regulatory oversight. Because physician assistant services until enactment of Chapter 627 were technically medical services under the delegation and supervision of a person licensed to practice medicine, the boards should also develop standard forms and review the appropriateness of certain collaborative and practice agreements in various clinical settings. Such an approach would create a more formal structure and process and promote better communication, coordination, and expectations between the physician and physician assistant communities, and between the two licensing boards. In addition to potentially reviewing individual agreements prior to forwarding them for board review, joint committee members could first establish the proposal of basic standards and criteria that would be applicable to a given type of physician assistant practice setting.

- A requirement that each physician assistant and physician shall jointly review the authorization for collaborative or practice agreements annually,
- Each authorization for collaborative or practice agreements shall include a cover page containing the date of the annual review by the physician assistant and physician and an acknowledgement and signature of the same,
- Each authorization for collaborative or practice agreement shall be maintained in either hard copy or electronic format at the physician's and physician assistants' principal place of practice, and
- Medical services performed by a physician assistant under a collaborative or practice agreement must be appropriate to the skills and practice area of the physician as well as the physician assistant's level of competence, as determined by the physician, to ensure that accepted standards of medical practice are followed.

We also respectfully request amending Section 10 of the joint rule under Identification Requirements to include:

- Physician assistants licensed under these rules shall keep their license available for inspection at the location where they render medical services and shall, when rendering medical services, wear a name tag identifying themselves as a physician assistant. Physician assistants shall also verbally identify themselves as a physician assistant to each new patient.

Despite the enactment of Public Law 2019, Chapter 627, state law still clearly defines physicians as engaging in the "practice of medicine or surgery", while describing physician assistants as rendering "medical services." Studies have increasingly shown patients are confused about the qualifications of different health care professionals. Many non-physicians earn advanced degrees, and some degree programs now confer the title "doctor." As a result, patients often mistakenly believe they are meeting with physicians (medical doctors or doctors of osteopathic medicine) when they are not. As non-physicians increasingly seek to expand their scope of practice, there should come the added responsibility of visually, and verbally, disclosing their education, qualifications, and training. The latter also is necessary for the visually impaired.

Maine can leverage the knowledge and skills of physician assistants, and the increased availability of convenient settings for care delivery, to meaningfully expand access to services, while maintaining a clear

focus on patient safety and quality in care coordination and integration. Developing clear parameters and uniform expectations for allowing physician assistants to practice at the highest level of their knowledge and clinical training, while recognizing the important role physicians play in a physician-led care team, is the right path to take.

Thank you for considering these comments in your deliberations on these proposed amendments to Joint Rule Chapter 2.

The Maine Medical Association, Maine Osteopathic Association, and Spectrum Healthcare Partners are joined in our comments by the following:

- Maine Society of Eye Physicians and Surgeons (MSEPS),
- Maine Chapter of the American College of Emergency Physicians (MEACEP), and the
- Maine Neurological Society (MNS)

Any questions, comments, or requests for clarification can be answered by one, or all, of the following:

Dan Morin
Director of Communications & Government Affairs, Maine Medical Association
dmorin@mainemed.com
(207) 838-8613

Amanda Richards
Executive Director, Maine Osteopathic Association
arichards@mainedo.org
207-623-1101

Ann Robinson, Esq.
Partner, Pierce Atwood LLP for Spectrum Healthcare Partners
arobinson@PierceAtwood.com
207.791.1186

From: Robert Grover MD
To: noreply@maine.gov; Lathrop, Maureen S; Strout, Susan E
Subject: Re: Important Licensure Information
Date: Wednesday, July 8, 2020 4:23:08 PM

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If PAs don't need to be supervised, then surely physicains who had 2 years clinical training in medical or osteopathic school shouldn't need to do a residency to practice either.

Sent from my iPhone

On Jul 8, 2020, at 08:57, Maine Board of Licensure in Medicine <noreply@maine.gov> wrote:

July 8, 2020

The Board of Licensure in Medicine and the Board of Osteopathic Licensure propose amendments to a joint rule pertaining to the licensure and practice of physician assistants. The proposed amendments would:

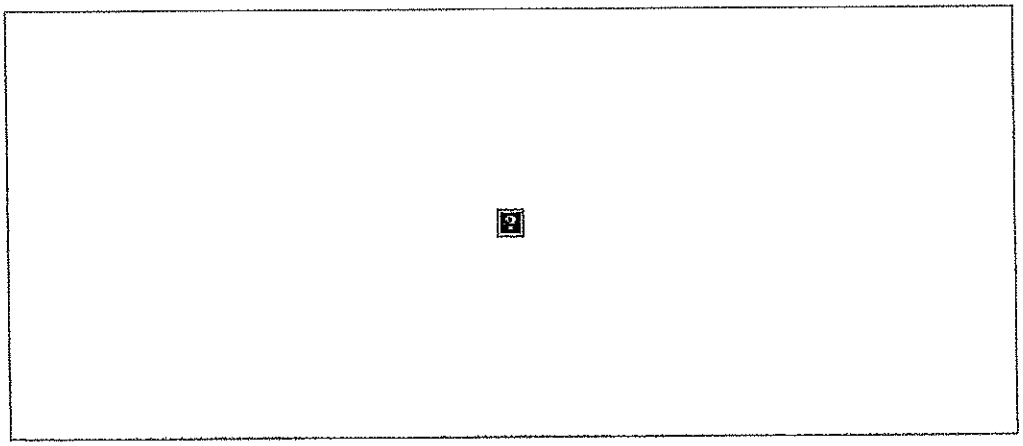
- Amend the definition of certain terms to eliminate registration and supervision
- Add definitions for certain terms, including "Health Care Facility," "Health Care Team," "Inactive Status License," and "Physician Group Practice";
- Eliminate registration and supervision requirements;
- Establish criteria for "Inactive Status Licenses";
- Establish uniform continuing clinical competency requirements;
- Amend the uniform fees;
- Establish criteria for collaborative agreements and practice agreements;

- Amend the uniform notification requirements to include legal change of name;
- Amend the continuing medical education (CME) requirements, including 3 hours of CME every 2 years regarding opioid prescribing.

Legal Requirement for Adopting: 32 M.R.S. §§ 2562 and 2594-E(5); §§ 32 M.R.S. 3269(7) and 3270-E(5); 10 M.R.S. § 8003(5)(C)(4).

Please click here for full details.

Comments are due by Friday, August 7, 2020 at 4:30 p.m.



Maine's Frontline Warmline is a free, confidential resource to support Maine's front-line clinician's and first responders during state and national emergencies such as COVID-19.

BOLIM E-NEWS Editor-in-Chief David Nyberg, Ph.D. • Graphic Design Ann Casady

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From: Strout, Susan E
To: Lathrop, Maureen S
Subject: FW: Comment on proposed revisions to Chapter 2 Joint Rule Regarding Physician Assistants
Date: Tuesday, August 11, 2020 7:10:41 AM

From: Scott Ellis <scepa207@gmail.com>
Sent: Friday, August 07, 2020 4:05 PM
To: Smith, Dennis <Dennis.Smith@maine.gov>; Strout, Susan E <Susan.E.Strout@maine.gov>
Cc: Ellis Scott <scellis@roadrunner.com>
Subject: Comment on proposed revisions to Chapter 2 Joint Rule Regarding Physician Assistants

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Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137
(tel) 287-3605 (fax) 287-6590
dennis.smith@maine.gov

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142
(tel) 287-2480 (fax) 536-5811
susan.e.strout@maine.gov

RE: Comment on proposed revisions to Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

My name is Scott Ellis, and I have been a practicing Physician Assistant (PA #619) in Emergency Medicine in Maine for over 20 years. I am honored to have been one of the original 17 graduates of the UNE Physician Assistant Charter Class of 1998, which was established to address the significant shortage of healthcare providers in Maine, especially in underserved areas of the state. In every healthcare practice that I have encountered from my clinical rotations in 1999 through my current position as Emergency Medicine Physician Assistant at Southern Maine Health Care, I have developed trusting and respected relationships with physician colleagues and consultants.

Providing healthcare to Emergency Department patients as a member of a healthcare team has been rewarding for me and hugely beneficial for our patient population. I still remember the day not long after I was hired as the first Emergency Department PA at Goodall Hospital in Sanford in 2003, when the attending physician assessed one of my patients after I sutured a laceration on their face, and praised me in front of the patient on the quality of my work. Over the years, even physicians I've encountered who have been skeptical about the role of a Physician Assistant in the world of Emergency Medicine have realized the benefits of the PA in the healthcare team.

With the growing demands for healthcare services in Maine and around the country, the role of the Physician Assistant as a member of the healthcare provider team has never been more necessary. That

is why LD1660 has been such an important step forward in Maine to insure that patients, especially in underserved parts of our state with significant physician shortages, have access to quality healthcare. Thank you for all your hard work during this Covid-19 Pandemic to craft these accurate, clear and thoughtful proposed revisions to Chapter 2.

The revisions to Chapter 2 Joint Rule Regarding Physician Assistants addresses the growing needs for healthcare providers in Maine by removing the physician supervisory requirements for PAs and establishing collaborative and practice agreements with physicians and other healthcare professionals. Overall, the Rules reflect the intent of LD1660 by eliminating language that implies physician liability for PA care, and allows the PA scope of practice to be determined at the practice level based on the PA's individual education, training, and experience.

However, there are two changes that I, and many of my PA colleagues with whom I've spoken, would like to see made to the present draft:

- In section 6, UNIFORM SCOPE OF PRACTICE FOR PHYSICIAN ASSISTANTS, subsection 3, "Consultation," the last sentence reads: "Upon request of the Board, a physician assistant shall identify the physician who is currently available ***or was available*** for consultation with the physician assistant." I would ask that "or was available" be modified to read: "or was available within 1 year of the request from the Board." As written, the rule presents an unlimited time frame. The proposed 1 year time frame allows PAs and administrators an appropriate length of time to keep records of available working and on-call physicians in tact.

- In section 8. Criteria for Requiring Collaborative Agreements or Practice Agreements, B. Practice Agreement, the rule reads: "Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner **or who own and/or operate an independent practice** must have the following in order to render medical services under their Maine license:"... I ask that the phrase "or who own and/or operate an independent practice" be deleted. This phrase is not appropriate as it identifies a business relationship and doesn't pertain to the regulation of the practice of medicine.

Thank you again for your work on these Chapter 2 Joint Rule revisions and your commitment to the safety of our patients and the professionalism of our practice.

Sincerely,

Scott C. Ellis, MS, PA-C, PA619
9 Westwoods Road
Kennebunk, Maine 04043
scellis@roadrunner.com

Comments Received After Re-Proposal

AAPA

October 30, 2020

Dennis E. Smith, Executive Director; Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333- 0137

Susan E. Strout, Executive Secretary; Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333- 0142

Re: Chapter 2 Reproposal

Dear Mr. Smith and Ms. Strout,

On behalf of the American Academy of PAs (AAPA) and the more than 1,000 PAs licensed in Maine, thank you for this opportunity to comment on the reproposed changes to Chapter 2 published on Sept. 30, 2020, that seek to implement the changes made to PA practice in Maine by LD 1660. AAPA is the national professional organization for all PAs (physician assistants) that advocates and educates on behalf of the profession. AAPA represents a profession of more than 140,000 PAs across all medical and surgical specialties and has extensive experience with state regulation of PA practice.

AAPA has serious concerns with the reproposed revisions to the PA regulations as they inaccurately capture the intent of LD 1660, the title of which was "An Act to Improve Access to Physician Assistant Care." In fact, the regulations as reproposed may do just the opposite and restrict access to PA care. ***These concerns are all related to the provisions regarding collaborative and practice agreements.***

Combining Collaborative Agreements and Practice Agreements

The law makes it clear that collaborative agreements and practice agreements are intended for differently situated PAs. Combining them as though the providers are the same is inappropriate and could lead to consequences unintended by LD 1660.

AAPA recommends separating collaborative agreements and practice agreements into distinct sections.

As written, the reproposed regulation would not draw the appropriate distinctions between collaborative agreements and practice agreements. Simply put, collaborative agreements are for PAs with less than 4,000 hours of practice and practice agreements are for PAs with more than 4,000 of practice who are the primary provider in a practice without a physician partner.

The two are not the same, and should not, in any section, be treated as such.

Requirements of Collaborative/Practice Agreements

The below requirements, which did not appear in the originally proposed revisions, have the potential to greatly restrict PA practice in Maine and limit access to PA-provided care. While the Board may use its discretion in requesting these items, many of the items listed or proposed are not broadly appropriate, not broadly applicable, unnecessarily onerous, or prohibit a PA from practicing.

9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements

A. In reviewing a proposed scope of practice delineated in a collaborative agreement or a practice agreement, the Board may request any of the following from the physician assistant:

(1) Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;

(2) Copies of previous plans of supervision, together with physician reviews;

(3) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

(4) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

(5) Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA or its successor organization;

(6) Preparation of a plan for rendering medical services for a period of time under the supervision of a physician;

(7) Successful completion of an educational and/or training program approved by the Board.

AAPA recommends deletion of this entire section.

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Many of these requirements would pose significant challenges and run counter to the intent of the new law. Examples include:

REQUIREMENT: Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;

CONCERN: This requirement would prohibit new PAs from practicing in Maine. PAs with less than 4,000 hours are required to submit a collaborative agreement for approval; for these PAs, many of whom are recent graduates and entering the workforce for the first time, providing this documentation is impossible.

An additional concern is requiring a PA to provide specific documentation of practice within a specified specialty, as it does not take into account the inherent flexibility of the PA profession. PAs, unlike physicians, are able to practice in multiple specialties and are not pigeonholed to just one. A PA may have extensive education and training in a particular specialty; without documentation or recent practice under an agreement, will the Board deny the PA the ability to practice? Many fields, such as mental health and primary care, are in need of qualified providers to provide care to patients; this arbitrary requirement may stifle care.

REQUIREMENT: Copies of previous plans of supervision, together with physician reviews

CONCERN: This requirement, like the first, presents issues for recent graduates. Recent graduates will not have previous plans of supervision. Further, PAs may not have kept previous plans of supervision, let alone documentation of the physician reviews of said plans. This would eventually be inapplicable in general – as plans of supervision have been eliminated entirely by LD 1660.

REQUIREMENT: Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

CONCERN: This requirement is unclear in whether it means current or previous agreements. Because of the general lack of specificity in this requirement, it could also be incredibly onerous on the PA to compile this information from an employer who may or may not still be in practice.

REQUIREMENT: Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

CONCERN: This incredibly broad requirement would significantly delay PAs ability to practice, thus harming consumers. Tracking down one letter from one physician is potentially onerous and time consuming; requesting multiple letters from multiple physicians would inevitably delay a PA's ability to practice in Maine.

Further, a physician may not be in the best position to attest to the competency of a PA, depending on their experience, the practice relationship, and specialty. This requirement presupposes that a physician would be in the best position to attest to a PA's competency on a particular subject, and does not consider the way modern care is delivered as part of a diverse team of providers.

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REQUIREMENT: Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the National Commission On Certification Of Physician Assistants (NCCPA) or its successor organization.

CONCERN: By the NCCPA's own definition, a CAQ "is a voluntary credential that Certified PAs can earn in seven specialties."[1] Three major concerns here are that the Boards may very well be requiring an additional certification that is voluntary, is only available in seven specialties (only a fraction of the total number of specialties and subspecialties), and a PA can only receive a CAQ after a certain number years of practice in that specialty.

REQUIREMENT: Preparation of a plan for rendering medical services for a period of time under the supervision of a physician.

CONCERN: LD 1660 eliminated supervision of PAs from statute. The Boards, here, appear to require PAs submitting either a collaborative or practice agreement to include a plan for supervision. **This is in direct conflict with LD 1660, and would be a major step in unnecessarily limiting patients' access to PAs.**

REQUIREMENT: Successful completion of an educational and/or training program approved by the Board.

CONCERN: This requirement is redundant and unnecessary. PAs are already required to graduate from a PA program approved by the board as a first condition of licensure.[2]

When Agreements are Required

The language in the below excerpt from the reproposed rules is of concern, as it appears to define those PAs who do not require either a collaborative agreement or a practice agreement. However, if read as such, it is an incomplete definition and has the potential to cause misinterpretation and confusion. The language does not include PAs who work in a solo physician practice and who have more than 4,000 hours of collaborative practice. These PAs would also be exempt from either a collaborative agreement or a practice agreement.

> 8. ***Criteria for Requiring Collaborative Agreements or Practice Agreements***
>
> *[...]*
>
> *C. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and are employed with a health care facility or physician group practice as defined by this rule under a system of credentialing and granting of privileges and scope of practice agreement are not required to have either a collaborative agreement or a practice agreement.*

[1] National Commission on Certification of Physician Assistants, "About Specialty Certifications of Added Qualifications (CAQs)," https://www.nccpa.net/specialty-caqs.
[2] ME. REV. STAT. tit. 32, § 3270-E(2)

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Another point of concern from the excerpt is that the statute simply requires the submission of documentation of 4,000 hours of clinical practice. However, the reproposed regulations state, *"Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board."* This would imply that the Board has the discretion to make this determination – an implication not founded in statute. The Academy recommends the following version be inserted for clarity:

C. Physician assistants with more than 4,000 hours of documented clinical practice submitted to the Board, and who are not the primary caregiver in a solo practice are not required to have either a collaborative agreement or a practice agreement.

The Academy once again thanks the Boards for their leadership in this process and consideration of these concerns. However, it is clear from the above concerns, that the Boards are overreaching their statutory authority, and proposing requirements not grounded in concern for public safety of patients. The Academy believes these concerns must be addressed or else access to PA-provided care, especially in areas of great need, will be greatly impacted and the profession will face a competitive disadvantage in the state.

Best regards,

Tillie Fowler

Tillie Fowler, JD
Senior Vice President, Advocacy and Government Relations
American Academy of PAs

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From: Pamela
To: Smith, Dennis E; Strout, Susan E
Subject: LD 1660
Date: Thursday, October 22, 2020 9:22:04 PM

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Dennis E. Smith, Executive Director

Board of Licensure in Medicine

137 State House Station

Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary

Board of Osteopathic Licensure

142 State House Station

Augusta, ME 04333-0142

DATE 10/22/2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

I am a practicing Physician Assistant in the State of Maine for the past 16 years and I would like to thank you for the opportunity to comment on the recently proposed changes to Chapter 2 Joint Rule Regarding Physician Assistants. LD1660 is essential in increasing care to underserved rural areas in Maine while recognizing the critical role the Physician Assistant profession plays in cost effective, patient centered health care. I am concerned that the proposed rules do not align with the laws as written or intended by our legislature. My fear lies within the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements". The law was written with thoughtful consideration with different contexts for each of these agreements with one for new graduates (the collaborative agreement) and the other for where experienced PAs are seeking to practice in areas of Maine not covered by a health care system or a physician group practice (practice agreements). Each scenario requires unique regulation and should not be combined. The proposed wording may possibly be a result of misunderstanding of these two very different agreements, however, ultimately would be detrimental to our most vulnerable underserved population in Maine for which healthcare is often limited.

I am also concerned and disheartened at the proposed wording section of the rule making that Physician Assistants must wear a name tag that correctly identifies one as a Physician Assistant, Physician Assistants must verbally introduce oneself as a Physician Assistant and correct the patient each and every time they may incorrectly call a Physician Assistant a Physician. I would hope that the BOLM and our medical colleagues acknowledge that Physician Assistants are ethical and professional medical care providers who are proud of their profession and would not intentionally mislead a patient as belonging to another profession.

I thank you in advance for your time and consideration of my comments. I urge the BOLM to continue with LD 1660 as intended by law which will allow increased and affordable access to health care.

Sincerely,

Pamela Barter-Chessman, PA-C

Portland Cognitive and
Behavioral Neurology

Dennis E Smith, Executive Director
via email: dennis.e.smith@maine.gov
Maine Board of Licensure in Medicine
137 State House Station
161 Capital Street
Augusta, ME 04333-0143

Susan E Strout, Executive Secretary
via email: susan.e.strout@maine.gov
Maine Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

Friday, October 30, 2020

Dear Allopathic and Osteopathic Medical Board members,

Thank you for reviewing our comments to the Chapter 2 reproposal. As physicians representing various medical specialties, and an organization representing 12,000 physicians, residents, medical students, and assistant physicians interested in patient safety in scope of practice matters, we are grateful to have the opportunity to submit comments.

These comments focus on two areas: (1) requirements for scope of practice agreements and (2) protection from retaliation for physicians who decline to enter into collaborative agreements, practice agreements, or similar agreements presented by their health care system or physician group practice with credentialing and granting of privileges exempt from a Board-approved collaborative or practice agreement.

Requirements for Scope of Practice Determinations

In section 7, subsection 9, paragraph A, the rules state, "In reviewing a proposed scope of practice delineated in a collaborative agreement or in a practice agreement, The Board may request any of the following from the physician assistant:". We suggest "may request" be changed to "shall be required" to create more baseline uniformity in scope of practice agreement determinations.

Similarly, we suggest the documentation of clinical practice in section 6, subsection 8, paragraph D, be standardized. We suggest that the section read "Acceptable documentation of clinical practice includes, but is not limited to, all of the following:" The current language ("Acceptable documentation of clinical practice includes, but is not limited to the following") does not specify

whether all - or how many - of the five items are required for acceptable documentation of clinical practice.

The reasons that scope of practice determinations in the Chapter 2 rules is so extraordinarily important is that the current scope of practice for physicians is determined prior to licensure by completion of four years of medical education accredited by the Liaison Committee of Medical Education (LCME) or the American Osteopathic Association Commission on Osteopathic College Accreditation (COCA) and a three- to seven-year residency program that is accredited by the Accreditation Council of Graduate Medical Education. As written, Chapter 2 effectively permits PAs to become licensed to provide many of the same medical services as licensed physicians without a similarly intensive and extensive academic and supervised clinical training. Although scope of practice is not determined at the Maine state licensure level, in the case of physicians an exhaustive process exists prior to physicians' applying for a state medical licensure that establishes physicians' competency to practice in a given area. The same process to determine safe scope of practice for PAs prior to state licensure does not exist. Thus the need for standardization at the Maine Medical Board level assumes infinitely more gravity for assuring the safety of the public.

Protection from Retaliation for Physicians who Decline to Participate

The practice of medicine by physicians includes ethical and legal considerations. We urge rulemaking to include a provision to protect physicians from retaliation in employment, medical staff status, and credentialing when they do not want to enter into collaboration agreements, practice agreements, or the correlate of these agreements presented by their health care system or physician group practice that has a system of credentialing and granting of privileges. We urge the Boards to protect physicians who disagree with the contractual rules by a health care system or physician group that require physicians to enter into such formal agreements with PAs. Physicians must not be compelled to participate in a process if they deem it undesirable or unsafe to patients. Maine is a conscience clause state and a physician's right to conscientiously refrain or object from various medical practices is an established right.

We propose the following language be added to section 6, subsection 8, as a new subparagraph E:

> E. Relief From Retaliatory Actions.—
> (1) No hospital or physician shall be permitted to retaliate against a physician who declines to participate in a collaborative agreement or practice agreement with a physician assistant.
>
> (2) A physician shall be entitled to all relief necessary to make that physician whole, if that physician is terminated, demoted, limited, restricted, suspended, revoked, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment, medical staff membership, or hospital/practice credentialing because of the physician's declining or refusing to enter into a collaborative agreement or practice agreement with any physician assistant.

Despite the statement in section 6, subsection 6 that, "A physician assistant is legally liable for any medical service rendered by the physician assistant," in considering whether to enter into a practice agreement or collaborative agreement with a PA, a physician may determine there is still substantial legal exposure. This exposure includes not only malpractice exposure, but also licensure exposure and potential exposure to claims made by the federal government or other payors for certifying services not permitted by them to be provided solely by PAs despite that Chapter 2 permits the services to be provided by PAs. This added liability is a practical consequence of these agreements and further justifies the need to protect the right of physicians to decline to participate in such arrangements without retaliation by health care systems and employer group practices.

We thank you for taking the time to read our comments and for your hard work on this difficult task of rule-making.

Sincerely,

Physicians for Patient Protection
Rebekah Bernard, President

American Academy of Emergency Medicine
Lisa A. Moreno, MD, MS, MSCR, FAAEM, FIFEM, President
Evie Marcolini, MD, FFAAEM, FACEP, FCCM, Chair, EM Workforce Committee

Maine Association of Psychiatric Physicians
Matthew Davis, MD, President
Edward Pontius, MD, Legislative Affairs Representative

Portland Cognitive and Behavioral Neurology
Alyson Maloy, MD, FAPA, FABIHM, President

From: Dionne, Andrew
To: Smith, Dennis E; Strout, Susan E
Subject: Comment on Chapter 2 Joint Rule
Date: Wednesday, October 14, 2020 1:25:08 PM

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Mr. Smith and Ms. Strout,

I would like to send along a brief comment on the updated amendments to the Chapter 2 Joint Rule Regarding Physician Assistants. As the CMO for MaineGeneral Medical Center, I have watched closely the progression of these changes over the past year, and I am generally supportive of what has been proposed and passed. At MaineGeneral, we are undertaking changes in our Medical Staff Bylaws in response to the new rule, as I suspect many other hospital systems in Maine are doing.

When reviewing the most recent updates to the Rule, I was a bit surprised to see the changes in Section 12, as follows:

1. Physician assistants licensed under this rule shall:
    A. Keep their licenses available for inspection at the location where they render medical services;
    B. When rendering medical services, wear a name tag identifying themselves as physician assistants; and
    C. Verbally identify themselves as physician assistants whenever greeting patients during initial patient encounters and whenever patients incorrectly refer to them as "doctors."

I read the three published comments that advocated for the change in this section, but I would like to request reconsideration of part 1-C, notably to remove the section stating ***"and whenever patients incorrectly refer to them as "doctors.""***

Having worked with PA colleagues for more than 2 decades, and also having the privilege for the past ten years to have involvement with the National Commission on Certification of Physician Assistants (NCCPA), I have found that PAs are very proud of their certification and make a strong effort to identify themselves based on their credentials, as well as to correct patients when they mistakenly refer to them as "doctor". In my experience, this correction has always been made clearly, but in a manner so as not to seem to denigrate the patient or harm the relationship they are forming with the PA. In contrast to the comments previously advocating for the change in Section 12, I think the examples they provide suggest those who are deliberately trying to mislead patients.

Maine already has strong laws about who can refer to themselves as a "Doctor" as well as laws against false advertising or fraudulent proffering of one's credentials. To me, those laws are clear, with obvious statement of the penalty for transgression. In my opinion, the addition in this Rule requiring PAs to correct a patient each and every time they hear themselves referred to as "doctor" is unnecessary and potentially harmful to the patient-practitioner relationship. We are all aware of patients who may incorrectly refer to every medical staff member as "doc" based on their

appearance and manner, and frequent corrections, especially if done based on concern for breaking the law, seems excessive and unnecessary. In addition, this section is not clear on what the penalties for not correcting this situation would be, and it may lead to PAs feeling the need to document the correction often to protect themselves from backlash.

I believe that leaving Section 12 as written, with the removal of the last phrase, will have the same effect that proponents have asked for, which is clear & consistent communication on the PA credentials.

Thank you for your time and consideration.

Andrew J. Dionne, MD
Chief Medical Officer, MaineGeneral Medical Center
Office Phone: (207) 626-1976
Admin Support: (207) 621-9305
Fax: (207) 626-1049
Email: andrew.dionne@mainegeneral.org

MaineGeneral Medical Center

KOZAK & GAYER, P.A.

MAINE OFFICE
157 CAPITOL STREET, SUITE 1
AUGUSTA, MAINE 04330
TEL: (207) 621-4390
FAX: (207) 621-4394

COLORADO OFFICE
134 F STREET, SUITE 207
SALIDA, COLORADO 81201
TEL: (719) 207-4440
FAX: (719) 207-4466

WWW.KOZAKGAYER.COM

Michael A. Burian
Admitted in Maine and Massachusetts
Charles F. Dingman
Admitted in Maine
Taylor D. Fawns
Admitted in Maine
Steven L. Johnson
Admitted in Colorado, Maine, New Hampshire, and Vermont (Inactive)
Joseph M. Kozak
Admitted in Maine, New Hampshire, New York, and Vermont
Benjamin P. Townsend
Admitted in Maine, New Hampshire, and Vermont
Michael D. Seitzinger (Of Counsel)
Admitted in Maine
Gordon K. Gayer (Of Counsel)
Admitted in Maine

October 30, 2020

VIA E-MAIL

Dennis E. Smith, Executive Director
dennis.e.smith@maine.gov
Board of Licensure in Medicine
137 State House Station, Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
susan.e.strout@maine.gov
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

Re: Re-Proposed Amendments to Chapter 2, Joint Rule Regarding Physician Assistants

Dear Executive Director Smith and Executive Secretary Strout:

This firm represents, and hereby files comments of behalf of, the Maine Primary Care Association ("MPCA"), seeking modification of the Re-Proposed Joint Rule of the Boards of Licensure in Medicine and Osteopathic Licensure regarding Physician Assistants ("PAs"). MPCA is a membership organization that represents the collective voices of Maine's twenty Federally Qualified Health Centers ("FQHCs"), also referred to as "community health centers" or "CHCs". Collectively these health centers serve more than 210,000 patients in over 70 rural and underserved Maine communities, delivering high quality, primary and preventive medical, behavioral health, and dental services. CHCs are not-for-profit, community-based organizations governed by local boards and staffed by professionals who are subject to federally mandated systems of credentialing and granting of privileges. CHCs are the backbone of the safety net health care system; they are required by law and regulation – and driven by their charitable

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missions – to provide access to high-quality, affordable health care regardless of a person's ability to pay.

In summary, these comments request one simple but crucial change in the proposed rule. As currently drafted, the rule would – we suspect inadvertently and, we submit, inconsistently with Legislative intent – omit Maine's community health centers from the provisions applicable to "health care facilities", even though CHCs have in place the very safeguards that the Boards and the Legislature recognized as a basis for treating practice within a health care facility differently from independent practice.

The Board's joint rule implements a major change in the oversight of physician assistant practices, enacted this spring by PL 2019, Chapter 627, "An Act To Improve Access to Physician Assistant Care". In providing a more independent licensing structure for physician assistants, the statute recognizes that the scope of a physician assistant's practice will vary depending on the setting of that practice, and it also recognizes that the degree of oversight by the Boards will differ accordingly.

As the Boards have recognized throughout their preparation and proposal of rules implementing this change, the statute identifies one of the practice settings calling for a different level of oversight as a "health care facility," within which the scope of a PA's practice would be determined by the facility's "system of credentialing and granting of privileges." See 32 MRS §§ 2594-F(2) and 3270-G(2), as enacted by §§ B-13 and B-17 of the Act, respectively. Similarly, the new law requires consultation with other health care professionals essentially when called for by the circumstances, adding that the "level" of consultation is determined in appropriate instances "by the system of credentialing and granting of privileges of a health care facility." Id. §§ 2594-F(4) and 3270-G(4). Carrying forward this theme that a distinguishing feature of the "facility" practice setting is the system of privileges, the statute requires a "collaborative agreement" for less experienced PAs but makes an exception for a PA "working in a physician group practice setting or a health care facility setting under a system of credentialing and granting of privileges and scope of practice agreement," providing that in such cases the PA "may use that system . . . and agreement in lieu of a collaborative agreement." Id. §§ 2594-F(5) and 3270-G(5).

In their original joint rulemaking proceeding, the Boards repeatedly noted and reflected in their drafting of the rule an important distinction between independently practicing physician assistants and those practicing in a health care facility or group practice that has a credentialing and privileging system. The Boards correctly rejected certain comments urging greater regulatory oversight with regard to facility and group practice settings, noting that such settings provided an important "safety net" because the PAs were working alongside other professionals, and the facilities or group practices had organizational responsibility for the quality and effectiveness of care provided by all such professionals credentialed and privileged to serve their patients. See, e.g., the Boards' *Draft Basis Statement and Response to Comments* at pp. 15-16, 18, 19-20 (September 30, 2020).

While the rule was thoughtfully crafted with this distinction in mind, the newly proposed § 6(9), brings into sharp relief what appears to be an oversight in the Boards' drafting of its proposed rule, an omission that operates to exclude federally qualified health centers from statutory provisions that, in context, logically include them. Proposed paragraph 6(9)(B) states

that "[p]hysician assistants who work *outside of a health care facility or physician group practice* may not render medical services *until their scope of practice is reviewed and approved by the Board.*" As currently drafted, this provision read in conjunction with the definitions of group practice and facility would require Board review of the scope of practice for PAs currently practicing in Maine's CHCs, even though those professionals are subject to detailed systems of credentialling and granting of privileges.

Neither "health care facility" nor "scope of practice agreement" are defined in Chapter 627, nor elsewhere in Title 32. The Boards, however, did choose to define "health care facility" in their proposed rules, and they did so in a manner that excludes community health centers, even though such health centers maintain credentialing and privileging systems. Pursuant to program requirements established under federal law by the Health Resources and Services Administration ("HRSA") every FQHC is required to have a system of credentialing and granting of privileges in place for all clinical staff members including physician assistants. See the HRSA Health Center Compliance Manual, Ch. 5: Clinical Staffing, a copy of which is attached to the email message transmitting these comments today.

The exclusion in the proposed rule arises because the Boards selected a definition for "health care facility" that required the entities to be "licensed pursuant to State law." Proposed rule at § 1(11). Because federally qualified health centers are authorized and overseen by federal authorities rather than state licensing law, they fall outside the definition used in the proposed joint rule, even though they maintain, and are required by law to maintain, systems of credentialing and privileging.

There is no reason to believe that the Legislature intended to exclude community health centers from its references to health care facilities in the licensing statutes. Nothing about the language of subsections 2,4, and 5 of the amended §§ 2594-F and 3270-G suggests a limitation to licensed entities, because the references to reliance on credentialing and privileging systems encompass both health care facilities and physician group practices, the latter being a category of health care enterprise that clearly is not subject to Maine licensure. Moreover, there is ample precedent in Maine law for including non-licensed entities in this definition. The term "health care facility" is found in various places in Maine law. While it is sometimes limited to licensed entities, there is no reason to believe that the Legislature had such a narrow definition in mind in crafting Chapter 627, which focuses on the existence of privileging and credentialing mechanisms as the reason for treating PAs practicing in these settings differently. In at least two contexts outside of Title 32, the Legislature has used the term "health care facility" to explicitly encompass non-State-licensed community health centers. See 22 MRS § 2053(3-A), in the enabling statute for the Health Care Facilities Authority, and 22 MRS § 8702(4), in the enabling

statute for the Maine Health Data Organization. The former[1] refers to "community health centers" among other unlicensed entities, while the latter[2] includes "a federally qualified health center certified by the United States Department of Health and Human Services, Health Resources and Services Administration." In context, there is no reason to believe that facilities authorized by federal law and required by that law to maintain credentialing and privileging systems would have fallen outside of the Legislature's intended scope for the term as used here, when the purpose was to adjust the oversight of PAs depending upon the setting in which they are practicing.

It is possible that many CHCs could argue in the alternative that they are included in the definition of "physician group practice" in the proposed joint rule at § 1(18). This definition, however, refers to an entity that is "composed" of at least two physicians. CHCs, as nonprofit corporations, do not have physicians as "members" or "owners." Therefore, the Boards would have to construe the term "composed" loosely in order to embrace CHCs here rather than in the health care facility definition. Moreover, a small CHC might have only one physician on its staff at a given time along with several other health care professionals, all subject to a system of credentialing and privileging and the other "safety net" characteristics that the Boards have recognized in their fashioning of these rules, yet it would be excluded from the exceptions to collaborative and practice agreements and direct Board review of PA scope if the only applicable definition were the "physician group practice." Relying on a broad construction of this definition would introduce regulatory uncertainty and at a minimum would discriminate arbitrarily against a small CHC with only one physician.

The current version of the rule, if read to exclude CHCs, or some of them, from the definitions of physician group practice and health care facility, would unduly burden CHCs, which have the system of credentialing and privileging envisioned by both the Legislature and the Boards, by requiring them to participate with their PAs in some additional level of scope of practice oversight. For less experienced PAs, this would mean developing and obtaining Board approval for collaborative agreements; for more experienced PAs, the requirements are not as clear, since the "practice agreements" required for independent PAs would not apply, but

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[1] This subsection reads in its entirety (emphasis added):
3-A. Health care facility. "Health care facility" means a nursing home that is, or will be upon completion, licensed under chapter 405; a residential care facility that is, or will be upon completion, licensed under chapter 1663; a continuing care retirement community that is, or will be upon completion, licensed under Title 24-A, chapter 73; an assisted living facility that is, or will be upon completion, licensed under chapter 1664; a hospital; a community mental health facility; a scene response air ambulance licensed under Title 32, chapter 2-B and the rules adopted thereunder; a facility of a hospice program that is, or will be upon completion, licensed under chapter 1681; a nonprofit statewide health information network incorporated in the State for the purpose of exchanging health care information among licensed health care providers in the State; *or a community health center*.

[2] This subsection reads in its entirety (emphasis added):
4. Health care facility. "Health care facility" means a public or private, proprietary or not-for-profit entity or institution providing health services, including, but not limited to, a radiological facility licensed under chapter 160, a health care facility licensed under chapter 405, an independent radiological service center, *a federally qualified health center certified* by the United States Department of Health and Human Services, Health Resources and Services Administration, a rural health clinic or rehabilitation agency certified or otherwise approved by the Division of Licensing and Regulatory Services within the Department of Health and Human Services, a home health care provider licensed under chapter 419, an assisted living program or a residential care facility licensed under chapter 1663, a hospice provider licensed under chapter 1681, a state institution as defined under Title 34-B, chapter 1 and a mental health facility licensed under Title 34-B, chapter 1. For the purposes of this chapter, "health care facility" does not include retail pharmacies.

proposed section 6(9)(B) seems to mandate prior Board review and approval of each such PA's scope of practice unless they are practicing in a group practice or health care facility setting.

Accordingly, MPCA respectfully submits that the Boards' joint rule should be revised to explicitly include community health centers with credentialing and privileging systems in its definition of health care facility. This could be accomplished by revising subsection 1(11) to read as follows:

> 11. "Health care facility" means a facility, institution or entity licensed pursuant to State law or certified by the United States Department of Health and Human Services, Health Resources and Services Administration that offers healthcare to persons in this State, including hospitals ~~and,~~ any clinics or offices affiliated with hospitals, and any community health center that ~~have~~ has a system of credentialing and granting of privileges to perform health care services and that follows a written professional competence review process.

Such a change would be consistent with the way in which the term "health care facility" is used throughout the rule as proposed and would avoid the irrational exclusion of CHCs from the scope of those provisions and exceptions, including newly proposed subsection 6(9). The change would address the concerns raised in these comments and would not be "substantially different" from the re-proposed rule: it would simply clarify and assure consistency between the rule and the intention of the enabling statute. Thus, the Board is authorized to make this change under 5 M.R.S. § 8052(5)(B).

Thank you for considering these comments on behalf of Maine's community health centers. The MPCA and the undersigned would be pleased to respond to any questions that you may have or to work with the Boards to refine the changes suggested above to the extent you have questions or concerns about the suggested language.

Sincerely,

Charles F. Dingman

cc: Darcy Shargo, CEO, Maine Primary Care Association

Maine Osteopathic Association | Maine Medical Association | Spectrum Healthcare Partners

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To: Board of Licensure in Medicine
Board of Osteopathic Licensure

From: Maine Medical Association
Maine Osteopathic Association
Spectrum Healthcare Partners

Date: October 30, 2020

Subject: CHAPTER 2- Joint Rule Regarding Physician Assistants, 2020-P138, P139 (2nd publication)

Thank you for this opportunity to comment on the proposed amendments to the joint rule pertaining to the licensure and practice of physician assistants from the Board of Licensure in Medicine and the Board of Osteopathic Licensure. We appreciate the Boards' meaningful effort to address some of the concerns that we expressed in our comments on the original rule. As we stated in those comments, we recognize that there are inherent problems created by the authorizing legislation that are beyond the ability of the Boards to fully remedy. But we view the amended draft of the proposed rule as one which establishes the conditions and limitations that the Boards have determined to be both necessary, and permitted by the authorizing legislation, to protect the public health and safety of patients.

As mentioned in our previous comments, dated August 7, 2020, one of our principal criticisms of the legislation was its delegation of overly broad authority to the licensing boards and its failure to specifically enumerate standards for determination of scope of practice and other important parameters for potential future medical services provided by physician assistants with more than 4,000 hours of documented clinical experience working independently and outside of health care facilities or physician group practices . We appreciate each board's willingness to better establish basic standards and criteria under a new paragraph to Section 6(8) entitled "Criteria for Requiring Collaborative Agreements or Practice Agreements," that would be applicable to collaborative or practice agreements for those practice settings and confirming that those agreements need to be within the physician's competence, and lawful practice.

Despite the statutory prohibition for the boards to review or approve privileging and scope of practice agreements of physician assistants rendering medical services within a health care facility or physician group practice, we were encouraged to read your comment in the draft basis statement and responses to comments that either board may request them when conducting a specific investigation for licensees working within health care facilities or physician group practices. It is an important regulatory reminder that simply because certain licensed physician assistants may eventually be allowed to practice independently, it does not entitle them to perform the same spectrum of services as other Board licensees, such as physicians, without first consulting with an appropriate physician.

We feel it is very important to note the current landscape of health care during this once in a lifetime pandemic. Despite certain licensing and regulatory practice restrictions being relaxed through emergency declarations to ensure capacity to handle potential patient surges, and the passage of PL 2020 c. 627, the convergence, and clinical uncertainty, of the coronavirus with the oncoming flu season could lead to diagnostic errors. The complexity of diagnosing something that has very similar symptoms to

another medical condition, in this case the flu, raises a lot of concerns in the medical community, as do delayed medical exams that can lead to undiagnosed or worsening medical conditions. In addition, COVID-19 may induce and/or obscure other illnesses. Therefore, it is imperative to promote the highest quality care and patient safety in all clinical situations, at all times, while recognizing the importance of a physician-led care team to provide the best care possible.

Thank you again for your willingness to consider our previous comments and for the time you are now taking to review these.

Any questions, comments, or requests for clarification can be answered by one, or all, of the following:

Dan Morin
Director of Communications & Government Affairs, Maine Medical Association
dmorin@mainemed.com
(207) 838-8613

Amanda Richards
Executive Director, Maine Osteopathic Association
arichards@mainedo.org
207-623-1101

Ann Robinson, Esq.
Partner, Pierce Atwood LLP for Spectrum Healthcare Partners
arobinson@PierceAtwood.com
207.791.1186

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

10/28/2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants. MEAPA appreciates both boards for their excellent work thus far; we are impressed by your dedication to ensuring the proposed rules support the intent of the law. I refer to the following section of Public Law Chapter 627:

> *7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.*

MEAPA feels that this section of the law provides an excellent summary of the intent and goals the legislature had in mind when passing the bill earlier this year. With this as our guidepost, we've compiled the following comments.

COMMENT 1:

After careful review of the proposed rules, MEAPA's first concern is regarding the new proposed section, **"9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements"** found at the bottom of page 12 and continuing on page 13. The intents of the Collaborative Agreements and Practice Agreements are distinctly different; the combining of these criteria is confusing and does not align with the distinctly different practice environments of the PAs in each distinct group.

-Collaborative Agreements are intended for new graduate PAs with <4000 hours of clinical practice who are practicing in an institution or practice that does NOT have a credentialing process in place.

-Practice agreements are for PAs with >4000 hours of clinical practice who are the sole medical provider at a practice or own their practice, where there is NO credentialing process in place.

Therefore, one is for a new graduate who MUST collaborate with a physician in the setting of no credentialing and the other is for a PA who is *not a new graduate* and is an agreement with a physician that is submitted to the board, where the latter PA may be required to produce increased proof of competency in the area of practice as there is no credentialing in place.

MEAPA recommends separating the two agreements' scope of practice criteria. The rules must promote public safety while aligning with the law and allowing for increased access to PA healthcare services. New graduate will be better supported with their own section on scope of practice criteria. Furthermore, the PA with the practice agreement will be more easily able to work with the Board to develop their appropriate scope of practice to address the needs of Mainers, with their own section relating to scope of practice criteria. Separating the criteria will help avoid confusion on the part of the PA and their physician collaborators and partners. It is paramount that the rule support access to affordable, high-quality healthcare services especially in rural areas where access is desperately needed.

COMMENT 2:
In addition, the following criteria listed under above referenced Section 9, *excludes* new graduates in the collaborative agreement, exactly who this provision was made for.

> *Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;*

A new graduate *cannot* document previous hours of practice, hence the collaborative agreement. For this reason and those stated above MEAPA recommends separating the collaborative and practice agreement criteria.

COMMENT 3:
This leads to an additional concern in the rules around the different categories of PA practice environments:

a. The PA has under 4000 hours of experience and must have either a collaboration agreement OR work in a healthcare setting which has a credentialing/privileging system which allows the PA to work under that system in lieu of a written collaboration agreement
b. The PA has over 4000 hours and is acting as the principal clinical provider OR is the owner of a clinic pursuant to a Practice Agreement approved by the board.
c. The PA has over 4000 hours and is working in ANY healthcare system that has a physician OR physicians where the PA is NOT the principal provider and is not the owner of the practice. The law as written does not require PAs in this situation to have a collaboration OR a practice agreement.

After carefully considering the above, please refer to Section 8. C. below in bold:

8. Criteria for Requiring Collaborative Agreements or Practice Agreements

A. Collaborative Agreement. Physician assistants with less than 4,000 hours of documented clinical practice must have one (1) of the following in order to render medical services under their Maine license:

(1) A Board-approved collaborative practice agreement with a Maine physician holding an active, unrestricted physician license; or

(2) A scope of practice agreement through employment with a health care system or physician group practice as defined by this rule that has a system of credentialing and granting of privileges.

B. Practice Agreement. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner or who own and/or operate an independent practice must have the following in order to render medical services under their Maine license:

(1) A Board-approved practice agreement with a Maine physician holding an active, unrestricted physician license.

C. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and are employed with a health care facility or physician group practice as defined by this rule under a system of credentialing and granting of privileges and scope of practice agreement are not required to have either a collaborative agreement or a practice agreement.

Section 8. has accounted for: **1.** the PA that is a new graduate (collaborative agreement or healthcare system/practice with credentialing) **2.** the PA that is the principal clinical provider without a physician or who is the owner/operator for an independent practice (practice agreement with a Maine physician holding an active, unrestricted license). Section 8. C. is intended to outline those PAs that *do not need* a collaborative or practice agreement. However, the entire section failed to include the last and final category of PA practice environment: **3.** the PA who has >4000 hours of clinical time and works at a physician owned practice or group that lacks a credentialing system. This third PA is left out of Section 8. C. and we urge the Board to revise this section to include this PA practice environment as excluding them would be out of alignment with the laws intent, to increase access to PA care.

COMMENT 4:

Finally, regarding **Physician Assistant Identification**, the proposed rule states:

> the physician assistant will "verbally identify themselves as a physician assistant whenever greeting patients during initial patient encounters *and whenever the patients incorrectly refer to them as "doctors".*

While MEAPA understands the intent of this proposed rule, the law states that we must identify ourselves as physician assistants. This is accomplished through verbal identification at the time of introduction, name tags that clearly state credentials and other clarifications as necessary. The PA, like all other healthcare professionals, has an ethical duty to not misrepresent themselves, their credential or their role. Physician Assistants add value to our health system and proudly represent themselves as such.

More concerning is the effect this has on patient care. After the verbal and name badge identification, an attempt to correct and educate, further repeated correction of patients actually detracts from their care. To correct a patient with PTSD, dementia, acute encephalopathy or a retired veteran who served our country at a time where Army Medics and Navy Corpsmen were referred to as "Doc" derails conversations and trust, impeding patient care.

Patients and families who are receiving a difficult diagnosis (i.e. cancer, neurodegenerative condition, notification of a catastrophic health occurrence , the impending death or death of a loved one) *hear only 10% of what a healthcare provider* is saying to them. It may be that the PA appropriately introduced themselves, wore a name badge clearly identifying that they are a PA and corrected the patient or family member who inappropriately referred to them as "doctor", and this patient or family member will only remember that they were told they have cancer or that their loved one was near the end of their life and would pass soon. They won't remember that they saw a physician assistant which could lead to a PA being cited for misrepresenting themselves, when, in fact, the patient and/or family did not remember.

In closing, thank you for your consideration of our comments. The outcome of these new regulations shouldn't create barriers for young people entering the healthcare workforce. Nor should these rules hinder comprehensive healthcare access for Mainers in the far corners of the State. Nor should repeated PA identification get in the way of building trust and communication between a PA and their patient.

Sincerely,

Angela Leclerc, MSPA, PA-C

President, MEAPA

From:	Cynthia
To:	Strout, Susan E; Smith, Dennis E
Subject:	Chapter 2 rules re: physician assistants - comments
Date:	Friday, October 30, 2020 4:02:28 PM

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Dennis E. Smith, Executive Director

Board of Licensure in Medicine

137 State House Station

Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary

Board of Osteopathic Licensure

142 State House Station

Augusta, ME 04333-0142

10/30/2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for the opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule re: Physician Assistants. I was lucky to be present at one of the committee sessions regarding the legislation, and I am glad to see the proposed rules

largely align with the legislative intent of the new law. I refer to this section of Public Law Chapter 627, regarding intent of the law:

7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.

I would like to draw attention to the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements" at the bottom of page 12 onto page 13. I am concerned that grouping the Collaborative Agreements together with the Practice Agreements may cause confusion. Collaborative Agreements are meant primarily for PAs new to practicing medicine, while Practice Agreements are meant for PAs who plan to practice in rural areas of Maine not covered by a health care system or a physician group practice. They were designed to address different scenarios and require unique regulation to ensure the safety of the public without unduly limiting PA scope of practice. Collaborative Agreements and Practice Agreements should not be lumped together simply for administrative convenience.

For instance, while criteria like the one below are appropriate for Practice Agreements, it would have been impossible for me to meet the criteria when I was a new graduate almost 10 years ago. It is not realistic to include this in criteria for a Collaborative Agreement:

Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement.

I was also struck by the requirement to repeatedly correct a patient who refers to you as "doctor." This legislation was enacted in part to recognize the professionalism of PAs, who undergo years of training, licensure, and usually credentialing processes. Professionalism automatically includes correct identification. I have tweaked my self-introduction to avoid mis-categorization as a nurse or as a physician, pausing after introducing myself by name to slowly and clearly say, "I am a physician assistant." I have a large name badge that says "Physician Assistant." I write "Cynthia Davies, PA" on the white boards in my patient's

rooms. Educating patients about the PA role is part of my daily routine. However, the requirement under the proposed rules to repeatedly correct a patient who refers to you as "doctor" has nothing to do with patient care.

Patients do occasionally mis-identify me as a doctor or more often, as a nurse. They may excuse themselves on the phone when I enter by saying, "The nurse is here, I have to go." They may answer my question about why they waited so long to present for care by saying they "don't like doctors." When and where appropriate, I correct them. Do I stop to correct every single person who asks the "nurse" for a ginger ale? Or when, as I'm walking out the door, the patient with dementia says, "thanks, doc"? That depends. The patient cares less about who I am than about whether I can get them the ginger ale. Spelling out in the law a requirement for repeated correction implies that physician assistants will only avoid overstepping their boundaries if they have such explicit rules. It implies that we want to represent ourselves as doctors. I am proud to be a physician assistant and am very clear with patients about my role. It is not necessary to beat them over the head with it.

Thank you for considering my comments. I hope the new rules will follow the intent of the law as closely as possible, allowing easier access to comprehensive healthcare for all Mainers.

Sincerely,
Cynthia Davies, PA

From: Allen, PA-C, Lisa
To: Smith, Dennis E
Subject: LD 1660
Date: Friday, October 30, 2020 1:39:36 PM

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Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

10/30/2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants. I am so excited to see the laws expand and provide patients with better access to medical care. I also greatly appreciate your commitment to ensuring the proposed rules align not only with law as written, but also the legislative intent as reflected in the law. I refer to the following section of Public Law Chapter 627:

> *7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.*

It is with this in mind that I express concern regarding the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements" found at the bottom of page 12 and continuing on page 13. I understand the boards' wish to be efficient with their rules, forms, and processes. However, I think that many PAs and their collaborating or partner physicians could be confused by the grouping of these criteria together. There are specific criteria that it would be nearly impossible for a PA with less than 4,000 hours to provide. This section comes to mind right away:

> *Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;*

I urge the boards to create a separate list of criteria for reviewing scope of practice for PAs in collaborative agreements from the list for those in practice agreements. The collaborative agreement is meant for new graduates whereas practice agreements are meant for those rare instances where PAs are seeking to practice in areas of Maine not covered by a health care system or a physician group practice. Each scenario requires unique regulation to ensure the safety of the public.

I will also note that I have concerns regarding the section discussing self-identification and clarification from other roles in the institution. In addition to keeping a license at your workplace, wearing a name badge that correctly identifies you as a "physician assistant" AND introducing yourself as a physician assistant, the proposed rule states: the physician assistant will "verbally identify themselves as a physician assistant whenever greeting patients during initial patient encounters *and whenever the patients incorrectly refer to them as "doctors".* Although a single correction is appropriate, further corrections would be onerous and detract from patient centered care. I understand the intent of this rule is to ensure that PAs are not misrepresenting themselves as something other than Physician Assistants. However, there are no other healthcare providers in Maine with a rule that creates a *duty to repeatedly verbally correct* a patient. Most importantly, many of our PAs, regardless of their practice setting, are caring for vulnerable populations (i.e. PTSD, dementia, delirium etc.) where repeatedly correcting them would lead to further harm and confusion and would undermine their care while focusing on something that is out of the control of the PA. For instance, I spent over 10 years working in pediatrics and this directive would cause undue confusion with children. Although I always identified myself as a Physician Assistant to the parent and child, most young children do not understand the various roles of the multiple individuals in the medical field. Therefore, they would refer to me as "doctor" and my medical assistant as "nurse". To continuously correct them would simply cause significant frustration (on both sides), use up meaningful time, decrease rapport between provider and patient, and minimize the true focus of the visit.

In closing, thank you for your consideration of my comments. The outcome of these new regulations should not hinder comprehensive healthcare access for Mainers but rather expand access and good quality medical care.

Sincerely,

Lisa Allen PA-C
Physician Assistant, Clincal Director
Northern Light Walk In Care
32 Resort Way
Ellsworth ME 04605

From: Coton, Angela
To: Smith, Dennis E; Strout, Susan E
Subject: Act to Increase Access to Physician Assistant Care
Date: Monday, October 26, 2020 2:20:19 PM

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Good day,

My name is Angela Coton and I am a full-time practicing Physician Assistant since 2010. I would like to offer my feedback on Section 9A.

1. Section 9A combines collaborative and practice agreements. These are two separate types of agreement and are treated as such in the law. Subsequently, the subsections that follow should be rewritten. The law was written with great care and deliberation on the different contexts for each of these agreements. In the most blunt terms - one is meant for new graduates (the collaborative agreement) and the other is meant for those rare instances where PAs are seeking to practice in areas of Maine where they would be the principle clinician or are the owner of a clinic (practice agreements.)

-*Collaborative agreements* are for PAs working directly WITH physician colleagues and with less than 4000 hours of clinical practice in settings without credentialing.

-*Practice Agreements* are for PAs with more than 4000 hours of clinical practice who own (or are the principal medical licensee) within a practice

1. In addition to keeping a license at your workplace, wearing a name badge that correctly identifies you as a "physician assistant" AND introducing yourself as a physician assistant, the proposed rule states: the physician assistant will "verbally identify themselves as a physician assistant whenever greeting patients during initial patient encounters *and whenever the patients incorrectly refer to them as "doctors".*

This is onerous and detracts for patient centered care. While I understand the intent of this rule (ensuring that PAs are not misrepresenting themselves as something other than Physician Assistants), there are no other healthcare providers in ME with a rule that creates a duty to repeatedly verbally correct a patient. Most importantly, many PAs, regardless of their practice setting, are caring for vulnerable populations (i.e. PTSD, dementia, delirium etc.) where repeatedly correcting a patient would lead to further harm and confusion. In addition, it could undermine patient care as we would be focusing on something that is out

of the control of the PA.

Sincerely,

Angela Coton, Physician Assistant, MPAS
Ear, Nose, & Throat
MaineGeneral Health
angela.coton@mainegeneral.org

Scott C. Ellis, MS, PA-C
9 Westwoods Road
Kennebunk, Maine 04043
207-251-2032
scellis@roadrunner.com

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

October 27, 2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you to both Boards for your work on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants. I appreciate your commitment to assuring that the proposed new rules reflect the legislative intent of LD1660, as defined in Public Law Chapter 627:

> *7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.*

I am concerned about the new proposed Section 6. Uniform Scope of Practice for Physician Assistants, subsection 9: "Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements"

While it is understandable that the Boards wish to be efficient with regards to rules, forms, and processes, the grouping of the rules for Collaborative Agreements and Practice Agreements may be confusing to both PAs and their collaborating or partnering physicians. LD1660 separately defines Collaborative and Practice Agreements and the unique requirements of each. To reduce confusion, it would seem more in line with the intent of LD1660 and provide more clarity to PAs and physicians to create a separate list of criteria for scope of practice for Collaborative Agreements and Practice Agreements. Each addresses a specific level of clinical experience of the PA and should not be grouped together.

As a PA in Maine for over 22 years, I have always clearly identified myself as a Physician Assistant, worn a nametag that identifies me as a Physician Assistant, and corrected patients who refer to me as a doctor. Despite these actions, there are still some patients who refer to all providers as "doctor" no matter how many times they are corrected. In these instances, it is impractical to require a PA to continue to correct the patient, once it has been clearly stated and repeated that one is a physician assistant. I request that **Section 12, paragraph 1C** be changed from, "Verbally identify themselves as physician assistants whenever greeting patients during initial patient encounters and whenever patients incorrectly refer to them as "doctors." to **"Verbally identify themselves as physician assistants when greeting and interacting with patients."**

Thank you for thank you for your consideration of my comments. Access to comprehensive healthcare in Maine is dependent on making certain that the new Chapter 2 Joint Rule Regarding Physician Assistants clearly differentiates the Collaborative and Practice Agreement rules as intended and defined in LD1660.

Sincerely,

Scott C. Ellis, MS, PA-C

From: David Duchin
To: Strout, Susan E; Smith, Dennis E
Subject: Chapter 2
Date: Friday, October 23, 2020 7:39:42 PM

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October 23, 2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you very much for giving me this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants and for all your hard working in making this possible for myself and the PA profession.

I have small concern regarding the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements" found at the bottom of page 12 and continuing onto page 13. I feel that many PAs and their collaborating physicians can be confused with grouping these criteria together.

> *Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;*

Would the board please consider creating a separate list of criteria for reviewing scope of practice for PAs in collaborative agreements from the list for those in practice agreements. I've been told about a few PAs that are wanting to practice in very rural areas of Maine that are not covered by a health care system and would be extremely difficult to provide documentation for this and may dissuade them working in underserved areas.

Regards,
David Duchin PA-C

From:	kisa 112
To:	Smith, Dennis E; Strout, Susan E
Subject:	Section 12
Date:	Thursday, October 29, 2020 7:29:47 PM

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Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

October 29, 2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you very much for giving me this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants and for all your hard work in making this possible for myself and the PA profession.

I have a small concern regarding the new proposed section 12. Identification Requirements. I understand the intent of the rule- not to misrepresent ourselves as something other than Physician Assistants.

I work with many patients who have PTSD, Dementia, TBI as well as other conditions where repeatedly correcting them can lead to further harm and confusion and may undermine their care focusing on something that is out of my control. Many PA's already have their PhD or doctorates in a different field, and there are currently many doctoral PA programs and I can see how this may cause further confusion.

Would the board please consider removing this requirement or change it to say when asked about their job title - we must say we are Physician Assistants.

Regards,
David Duchin PA-C

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

October 26, 2020.

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistant practice in Maine.

1.) As a practicing PA, I am concerned with the proposed new section re: **Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements** found at the bottom of page 12 and continuing on page 13. While I understand the intent, the grouping of these two distinct and separate types of agreements undermines their purpose. "Collaboration Agreements", by definition, assume that there is physician presence and oversight of a particular clinic or healthcare setting. Conversely, a "Practice Agreement" is a setting in which the PA is the principal clinical provider OR owner of a practice. This would potentially require a more thorough vetting by the Board of a particular PA's education/experience.

   There are several examples of how combining these criteria could contribute to hiring and staffing difficulties in Maine (contrary to the intent of the law). One in particular is this requirement:

   > *Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;*

   While an argument can be made that the above could be reasonable for a Practice Agreement, if this requirement is necessary for a collaboration agreement, under the rules proposed, the Board would essentially preclude ANY new grad Physician Assistant from working in any healthcare system or clinic EXCEPT those that have a credentialing/privileging system. There are many clinics (rural and otherwise) that are run, owned, or staffed by physicians that do not have a credentialing/privileging system.

   For this reason, I urge the Board to make *separate and distinct* criteria for reviewing scope of practice for PAs in collaborative agreements vs those in practice agreements. The law was written with great care and deliberation on the different contexts for each of these agreements. One is meant for new graduates (the collaborative agreement) and the other is meant for those rare instances where PAs are seeking to practice in a setting where they own the practice or are the principal clinical provider (practice

agreements.) Each scenario requires unique regulation to ensure the safety of the public. Without this separation, PAs may be put at a disadvantage both in hiring and from practicing to the full scope of their education and training simply because they can't provide all the documentation included in the proposed list.

2.) As the board explained in a previous memo, the law essentially creates 3 categories of PA practice environments:
   a. The PA has under 4000 hours of experience and must have either a collaboration agreement OR work in a healthcare setting which has a credentialing/privileging system which allows the PA to work under that system in lieu of a written collaboration agreement
   b. The PA has over 4000 hours and is acting as the principal clinical provider OR is the owner of a clinic pursuant to a Practice Agreement approved by the board.
   c. The PA has over 4000 hours and is working in ANY healthcare system that has a physician OR physicians where the PA is NOT the principal provider and is not the owner of the practice. The law as written does not require PAs in this situation to have a collaboration OR a practice agreement.

However, the board has not made clear that PAs with >4000 hours of clinical practice AND working in a healthcare facility/physician practice *regardless of credentialing/privileging system* are able to practice in that environment without a collaboration OR practice agreement. This is outlined in the Boards proposed rule (8. C), below:

> 8. Criteria for Requiring Collaborative Agreements or Practice Agreements
>
> A. Collaborative Agreement. Physician assistants with less than 4,000 hours of documented clinical practice must have one (1) of the following in order to render medical services under their Maine license:
>
> (1) A Board-approved collaborative practice agreement with a Maine physician holding an active, unrestricted physician license; or
>
> (2) A scope of practice agreement through employment with a health care system or physician group practice as defined by this rule that has a system of credentialing and granting of privileges.
>
> B. Practice Agreement. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and who are the principal clinical provider without a physician partner or who own and/or operate an independent practice must have the following in order to render medical services under their Maine license:
>
> (1) A Board-approved practice agreement with a Maine physician holding an active, unrestricted physician license.
>
> **C. Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and are employed with a health care facility or physician group practice as defined by this rule under a system of credentialing and granting of privileges and scope of practice agreement are not required to have either a collaborative agreement or a practice agreement.**

Section 8C as written excludes a number of PA/physician partnerships that are not "a health care system or physician group practice as defined by this rule that has a system of credentialing and granting of privileges" – In order to have the rule follow the law, Section 8C should be rewritten to include these types of practices (i.e. single physician

practice, multi physician practice that does not have credentialing/privileging system, etc...).

3.) Physician Assistant Identification -- the proposed rule states: "the physician assistant will "verbally identify themselves as a physician assistant whenever greeting patients during initial patient encounters *and whenever the patients incorrectly refer to them as "doctors"*

While the intent of this rule is clear, the application of it becomes difficult and may detract from patient care. PAs, like all licensed health care providers have an ethical responsibility to properly identify themselves to patients. This is accomplished through proper initial introductions, a nametag, and other clarifications *as necessary*. To codify in rule the requirement to repeatedly correct a patient using the term "doctor" creates a situation where the licensed professional is deprived of their discretion in determining if repeated correction is in the best interest of the patient. There may be exigent circumstances, patient mental capacity issues, and/or logistical constraints that may prohibit or suggest against repeated correction of a patient using an erroneous appellation. This rule makes no such exception. Further, there is no rule requiring other healthcare providers governed by the Board to make similar and repeated corrections to patients if they are misaddressed. For these reasons, this particular requirement should be removed.

Thank you for your consideration of my comments.

Sincerely,

Jed Jankowski, PA-C
Portland, ME

From: Amy Hoffman
To: Smith, Dennis E; Strout, Susan E
Subject: LD 1660
Date: Tuesday, October 20, 2020 1:00:09 PM

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Dennis E. Smith, Executive Director

Board of Licensure in Medicine

137 State House Station

Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary

Board of Osteopathic Licensure

142 State House Station

Augusta, ME 04333-0142

October 20, 2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants.

I want to start by commending both boards for their excellent work thus far. I have been impressed by your commitment to ensuring the proposed rules align not only with law as written, but also the legislative intent as reflected in the law. I refer to the following section of Public Law Chapter 627:

> *7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.*

It is with this in mind that I express much concern regarding the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements" found at the bottom of page 12 and continuing on page 13.

I understand the boards' wish to be efficient with their rules, forms, and processes. However, I think that many PAs and their collaborating or partnering physicians could be confused by the grouping of these

criteria together. There are specific criteria that it would be nearly impossible for a PA with less than 4,000 hours to provide. As an example, this section comes to mind right away:

> *Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;*

I urge the boards to create a separate list of criteria for reviewing scope of practice for PAs in "Collaborative agreements" from the list for those in "Practice agreements".

The law was written with great care and deliberation on the different contexts for each of these agreements. In the most blunt terms - one is meant for new graduates (the collaborative agreement) and the other is meant for those rare instances where PAs are seeking to practice in areas of Maine not covered by a health care system or a physician group practice (practice agreements.) Each scenario requires unique regulation to ensure the safety of the public.

Compiling these two types of Agreements into a single list will discourage PAs from staying in Maine and/or moving to Maine as he/she will not be able to practice the full scope of his/her education and training. This would all be simply because said PA would not be able to or may have great difficulty providing all the documentation included in the proposed list.

I am one of those experienced PAs that would be directly affected by such a global approach to the above legal language. I am a specialist PA and have been for over a decade. I have been working in health care for over 25 years. Should the language become more restrictive, I would certainly have to consider whether or not to bring my practice to the great state of Maine. I, like so many of my health care provider colleagues, have much to offer Mainers. It would be a shame to further barriers to health care in your great state.

In addition, the proposed legal language requiring a PA to not only wear a name badge with proper identification but also verbally correct a patient each and every time he/she incorrectly identifies the PA as a physician is an undue burden to the PA/patient relationship. We are all trained professionals. We wear our IDs, we verbally introduce ourselves appropriately and do correct patient's when they incorrectly identify us. To repeat that over and over again undermines the care at hand. We are all professionals and have professional integrity. We do not need a law to remind us to be this way. We've sworn an oath just as our physician colleagues have done.

In closing, thank you for your consideration of my comments. The outcome of these new regulations should NOT create barriers for trained PAs entering the healthcare workforce nor hinder comprehensive healthcare access for Mainers.

Sincerely,

<!--[if !supportLineBreakNewLine]-->
<!--[endif]-->
Amy Hoffman, PA-C, MMS

ALAN HULL, PA-C

120 PHEASANT HILL DRIVE, PORTLAND, MAINE 04103

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

October 29, 2020

Re: Proposed Chapter 2 Revisions

Dear Ms. Strout and Mr. Smith,

I would like to thank you, the Boards, and all of the Boards' staff for the good work you do each day. I continue to be amazed at the continuation of the Boards' work in this difficult time, as well as working on the completion of the Chapter 2 revision.

My apologies on the length of this letter, but it is my understanding that it is unlikely that I will have an opportunity to comment further. Some of the comments may not apply depending on the answer to previous comments.

Concerning:
Section 6. 8. C
"Physician assistants with more than 4,000 hours of documented clinical practice as determined by the Board and are employed with a health care facility or physician group practice as defined by this rule under a system of credentialing and granting of privileges and scope of practice agreement are not required to have either a collaborative agreement or a practice agreement."

Comment: This subsection dealing with PAs with more than 4,000 hours of clinical practice documented to the Board, does not appear entirely consistent with PL 627 and is also confusing.

It also lumps into this sub-section "Practice Agreement" of which the requirements for needing a "Practice Agreement" are clearly defined in Section 6. 8. B.

From PL 627

"5. Collaborative agreement requirements.

A physician assistant with less than 4,000 hours of clinical practice documented to the board *shall work in accordance with a collaborative agreement with an active physician that describes the physician assistant's scope of practice, except that a physician assistant working in a physician group practice setting or a health care facility setting under a system of credentialing and granting of privileges and scope of practice agreement may use that system of credentialing and granting of privileges and scope of practice agreement in lieu of a collaborative agreement.*

A physician assistant is legally responsible and assumes legal liability for any medical service provided by the physician assistant in accordance with the physician assistant's scope of practice under subsection 2 and a collaborative agreement under this subsection.

Under a collaborative agreement, collaboration may occur through electronic means and does not require the physical presence of the physician at the time or place that the medical services are provided.

A physician assistant shall submit the collaborative agreement, or, if appropriate, the scope of practice agreement, to the board for approval and the agreement must be kept on file at the main location of the place of practice and be made available to the board or the board's representative upon request.

Upon submission to the board of documentation of 4,000 hours of clinical practice, a physician assistant is no longer subject to the requirements of this subsection."
(Sentences separated for clarity)

When separated out, the first through fourth sentences are requirements for "Collaborative Agreements" that apply to PAs with less than 4,000 hours of clinical practice that has not been documented to the Board.

The last sentence clearly states that "Upon submission to the board of documentation of 4,000 hours of clinical practice" the first four paragraphs in the sub-section of PL 627 no longer apply."

In effect, once the PA has documented 4,000 hours of clinical practice to the Board, the PA is no longer required to have a "Collaboration Agreement."

Suggest that Section 6. 8. C be modified to clearly state that per PL 627 PAs who have documented 4,000 hours of clinical practice to the Board are no longer subject to a requirement for a collaboration agreement.

In addition, recommend that the reference to "Practice Agreement" in 6. 8. C be removed as need for "Practice Agreements" is adequately described in Section 6. 8. B.

Concerning:
*"Section 6. **Uniform Scope of Practice for Physician Assistants**:*

8.

D. Acceptable documentation of clinical practice includes, but is not limited to the following:

(1) Copies of previous plans of supervision, together with physician reviews;

(2) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;

(3) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;

(4) Attestation of completion of 4,000 hours of clinical practice, together with an employment history;

~~(1)~~(5) Verification of active licensure in the State of Maine or another jurisdiction for 24 months or longer."

Comment: While this addition to the proposed rule provides some welcome guidance as to documenting 4,000 hours of clinical practice, the wording suggests an overly complex, burdensome, and lengthy process. It is also unclear if ALL of the "acceptable documentation" in numbers 1-5 is required. Specific comments to the sub-section are below:

Please clarify if all or some of the items in sub-section D are required.

D. "Acceptable documentation of clinical practice includes, but is not limited to the following:"

Recommend inserting the words "4,000 hours" between "of" and "clinical" for clarity. Please also consider altering the sentence to read something similar to "Acceptable documentation of clinical practice may include, but is not limited to the following:"

(1) "Copies of previous plans of supervision, together with physician reviews;

(2) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;"

Comment: Consider combining the first and second items. Item 1 appears to be a required component of the documentation, and as plans of supervision are no longer required, it would be impossible to accomplish item 1 for PAs who became licensed after the passage of PL 627.

Suggest wording such as: "Copies of previous plans of supervision, credentialing and privileging documents, collaboration agreements, and practice agreements, as applicable, together with practice or physician reviews sufficient to document 4,000 hours of clinical practice."

(3) "Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;"

From the Draft BSRC dated Sept 30, 2020: "It should be noted that the documentation of 4,000 hours of clinical practice is a separate and distinct issue from "scope of practice." Physician assistants with more than 4,000 hours of documented clinical practice who render medical services outside of a health care facility or physician group practice still must have their scope of practice delineated in a written "practice agreement" and reviewed and approved by the boards."

Comment: This requirement seems to assume a change in practice setting or scope of practice. It also implies that the PAs scope of practice is at issue, which the Boards, in the above quote state is untrue. Many PAs upon accomplishing the 4000 hours of practice will, and should, document that milestone even they do not anticipate any change is practice setting or scope of practice. As scope of practice is addressed in other sections of Chapter 2 having the physician attesting to "medical services proposed" is duplicative and redundant.

I would suggest wording such as: "Letter (s) from a physician(s) attesting to the PA's competency to render medical services."

(4) "Attestation of completion of 4,000 hours of clinical practice, together with an employment history;"

Comment: This item would be clearer if the words "by the physician assistant" were included.

Also, requiring an employment history in addition to items 1 and 2 above is redundant and burdensome as this is essentially the information requested in items 1 and 2.

Suggest addition of "by the PA" after the word "Attestation ". Also suggest removing the requirement for an employment history.

~~(1)~~(5) "Verification of active licensure in the State of Maine or another jurisdiction for 24 months or longer."

Comment: The statute allows PAs with 4,000 hours of clinical practice to document their time in practice to the Board, and thusly be able to practice without a collaboration agreement. A PA who works in clinical practice 50 hours a week could verify 4,000 hours of practice in as little as

80 weeks (20 months). To avoid confusion, suggest that statutory language (4,000 hours) be maintained.

Consider wording such as: "Verification of active licensure in the State of Maine or another jurisdiction for a sufficient time to document 4,000 hours of clinical practice."

Concerning:
"9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements

A. In reviewing a proposed scope of practice delineated in a collaborative agreement or a practice agreement, the Board may request any of the following from the physician assistant:

1. *Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement.*
2. *Copies of previous plans of supervision, together with physician reviews;*
3. *Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;*
4. *Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;*
5. *Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA;*
6. *Preparation of a plan for rending medical services for a period of time under the supervision of a physician;*
7. *Successful completion of an educational and/or training program approved by the Board.*

B. Physician assistants who work outside of a health care facility or physician group practice may not render medical services until their scope of practice is reviewed and approved by the Board."

Comment: In Section 6. 9. A The words "*In reviewing a proposed scope of practice...the Board may request*" seem to indicate that the entire section 9 is information that is not a required element of an application for a Collaborative Agreement or Practice Agreement, but is information the Board could request only if needed.

Please clarify if the list in Section 6. 9. A is only to be used if the Board needs additional information, of if including one or more of the items is a requirement?

Comment: If the items in section 9 are a required element of the application, and not by Board request only, then the new sub-section 9. is unclear as to whether SOME OR ALL of the items listed are required in an application for a Collaboration Agreement or Practice Agreement.

Please clarify if the items are a requirement in an initial application, whether some or all of the items are requirements? If some, how would they be specified?

Comment: The addition of this new sub-section 9 that combines "Collaborative Agreement" and "Practice Agreement" engenders confusion and makes it difficult to appreciate the nuanced difference between a "Collaborative agreement," and a "Practice Agreement" as it applies to scope of practice.

Draft BSCR Chapter 2 dated 9/30/2020, states: 'The boards do, however, agree that the rule should include some minimum criteria for reviewing the proposed scope of practice of physician assistants who render medical services in settings other than health care facilities or physician group practices (e.g. independent practice) pursuant to a "collaborative agreement" or "practice agreement."'

The use of the term "independent practice" is confusing. As seen below, the term is utilized in PL 627, but, is unclear.

From PL 627 ***2. Scope of practice.*** *"A physician assistant may provide any medical service for which the physician assistant has been prepared by education, training and experience and is competent to perform. The scope of practice of a physician assistant is determined by practice setting, including, but not limited to, a physician employer setting, physician group practice setting or independent private practice setting, or, in a health care facility setting, by a system of credentialing and granting of privileges."*

Does "independent practice" in the sub-section mean a PA who is practicing with one physician outside of a group practice or organized health care system, or does it refer to a PA as "the principal clinical provider in a practice that does not include a physician partner?" If "independent practice" refers only the latter, then the combining of the "Collaboration Agreement" and "Practice Agreement" is inappropriate in sub-section 9 as PAs in a Collaboration Agreement are not "the principal clinical provider in a practice that does not include a physician partner" and should not be under the same level of scrutiny in the approval process. If "independent practice" refers to both types of practice, it should be clearly defined.

As "independent practice" could refer to either type of practice, it should be clearly defined.

> *Definition from PL 627 '"Collaborative agreement" means a document agreed to by a physician assistant and a physician that describes the scope of practice for the physician assistant as determined by practice setting and describes the decision-making process for a health care team, including communication and consultation among health care team members.'*
>
> *Definition from PL 627 '"Practice agreement" means a document agreed to by a physician assistant who is the principal clinical provider in a practice and a physician that states the physician will be available to the physician assistant for collaboration or consultation.'*

For a PA to practice under an "practice agreement" the PA would have to have at least 4,000 hours of experience which has been documented to the boards and be the "the principal clinical provider in a practice." While PAs functioning under "collaborative agreement" may be "employed in healthcare system or group practice with a system of credentialing and privileging," most PAs working under the "collaborative agreement" will likely be in small practices with only a few collaborating physicians. The requirements enumerated under the new section 9 will make it difficult or impossible for recent PA graduates to function in small independent physician owned practices and may impact the stated goal of PL 627 to "address the need for affordable and high-quality health care service throughout the state".

Highly suggest that the proposed Section 6. 9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements, be divided into two sub-sections separating the criteria for "Collaborative Agreements" and "Practice Agreements."

Comment: The next group of comments will address specific items under section 9 that are directed to the "Collaborative Agreement". (Comments specific to Practice Agreements will be addressed later)

1. "Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement."

- This item is duplicative and unnecessary as "SECTION 4. UNIFORM CONTINUING CLINICAL COMPETENCY REQUIREMENTS, 1. Requirements" states the criteria for demonstrating current competency in this rule.
- This requirement assumes that PAs practice in a specialty. PAs are trained in a generalist model, and requiring documentation of a specialty would preclude many PAs from fulfilling this requirement.
- This requirement would preclude new or recent graduates from fulfilling this requirement and could limit the ability of PAs to render needed health care services.
- It would also impair mobility of the PA profession to respond to changing medical workforce needs.
- Members of a medical practice should ideally have varying skill sets. Having the PA being locked into a *"particular medical specialty"* reduces the teams' ability to utilize complimentary training and experience to enhance patient care.
- The requirement is contrary to the intent of PL 627.

This requirement should be eliminated in its entirety for Collaborative Agreements but if retained, the words "within a particular medical specialty" should be removed.

2. "Copies of previous plans of supervision, together with physician reviews;"
    - This would be impossible for new PA graduates.
    - This may be difficult for PAs who have worked in an organized healthcare system that has merged or has ceased to operate, or has worked with a collaborating physician who is no longer available to provide this information.

This requirement should be eliminated in its entirety for collaborative agreements.

3. "Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;"

    - This would be difficult for recent graduates and impossible for new graduates.
    - This is largely redundant to the information that would be provided in the form for Collaboration Agreements
    - It may be difficult for a PA to obtain these items from a previous employer.
    - If the PA is transitioning to employment in a different specialty, the documents listed may not apply to the current practice setting.

It should clearly be stated that the information would only be requested due to a need to clarify a submission for a Collaborative Agreement. If item 2 above is retained, then suggest combining items 2 and 3 above to read similar to: "Copies of previous plans of supervision, credentialing and privileging documents, collaboration agreements, and practice agreements, as applicable, together with practice or physician reviews."

4. "Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;"
    - This would be impossible for new PA graduates.
    - This is de facto an additional licensing requirement in addition to the qualification requirements in PL 627.
    - The requirement for a written attestation in addition to the requirements for a collaboration agreement in PL 627 is redundant and burdensome.

This requirement should be eliminated in its entirety for collaborative agreements.

5. "Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA;"

FROM THE NCCPA WEBSITE: "The CAQ is a voluntary credential that Certified PAs can earn in seven specialties: Cardiovascular &Thoracic Surgery, Emergency Medicine, Hospital Medicine, Nephrology, Orthopaedic Surgery, Pediatrics and Psychiatry."

- The only primary care CAQ is in pediatrics. This may alter dynamics in the medical workforce preventing PAs from attempting to work in primary care.
- It reduces the ability for PAs to respond to changing medical workforce needs.
- To be able to apply for CAQ status, a PA must have worked in that specialty for 2000-4000 hours precluding recent PA graduates from being able to complete this requirement.
- The CAQ is a recognition of expertise in a specialty, but the PA must continue to be certified by the NCCPA in general medicine and therefore is not an accurate reflection of the PAs knowledge base.
- The CAQ may not apply to the PAs current practice setting.
- This requirement is contrary to PL 627.

This requirement should be eliminated in its entirety for collaborative agreements.

6. "Preparation of a plan for rendering medical services for a period of time under the supervision of a physician;"
    - Public Law 627 eliminates the supervision requirement for PAs and has been replaced by "collaboration agreements".
    - Per PL 627 a Collaboration Agreement *"describes the decision-making process for a health care team, including communication and consultation among health care team members."* This is done at the practice level and is an ongoing process. This item is not needed as the statute requires a description of the decision making process in a Collaboration Agreement.
    - This appears to be time limited and ignores the ongoing process of collaboration.
    - The practice can develop a plan for physician oversight if necessary.

This requirement should be eliminated in its entirety for collaborative agreements.

7. "Successful completion of an educational and/or training program approved by the Board."
    - This requirement is difficult for new and recent graduates, and would decrease the availability of "affordable, high-quality health care services throughout the State" which was a stated purpose of PL 627.
    - It is unclear whether this is in addition to the requirements for PA licensure.
    - Does this apply to clinical and non-clinical education and training?
    - While there are some "post-graduate" PA training programs, most PAs do not go into these programs, so such a requirement is counter to PL 627.
    - Unless the PA is practicing outside the usual and customary role of a PA, to require PAs in a "Collaborative Agreement" have additional training beyond the rigorous ARC-PA standards would impair the PAs ability, especially recent graduates, to fulfill the needs of Maine citizens.

This requirement should be modified to make it clear that additional training is not required for PAs unless they are practicing in an unusual role.

B. "Physician assistants who work outside of a health care facility or physician group practice may not render medical services until their scope of practice is reviewed and approved by the Board."

Comment: The way this is written, a single unclear or controversial item on a proposed Scope of Practice, could delay approval of the Collaboration Agreement for a considerable amount of time. This section could cause hardship for an underserved community and/or the practice and PA if the process is delayed.

Please consider modifying this sentence to provide for a partial approval of a Scope of Practice until such time as the items of debate could be addressed.

Comment: The next group of comments will address specific items under section 9 that are directed to the "Practice Agreement". (Comments specific to Collaborative Agreements are above)

9. "Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements"

A. "In reviewing a proposed scope of practice delineated in a collaborative agreement or a practice agreement, the Board may request any of the following from the physician assistant:"

1. "Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement."

- This item should not be required in a primary care setting.
- This item is duplicative and unnecessary as "SECTION 4. UNIFORM CONTINUING CLINICAL COMPETENCY REQUIREMENTS, 1. Requirements" states the criteria for demonstrating current competency in this rule.
- This requirement assumes that PAs practice in a specialty. PAs are trained in a generalist model, and requiring documentation of a specialty would preclude many PAs from fulfilling this requirement.
- Documentation of experience "in a particular specialty" would also impair mobility of the PA profession to respond to changing needs of the medical workforce.

The words "in a particular medical specialty" should be eliminated.

2. "Copies of previous plans of supervision, together with physician reviews;"

- This may be difficult for PAs who have worked in an organized healthcare system that has merged or has ceased to operate, or has worked with a collaborating physician who is no longer available to provide this information.
- Over time as more PAs are functioning under PL 627 which eliminates the Plan of Supervision requirement, this request will become increasingly difficult and eventually impossible to fulfill.

- This is redundant and duplicative as items in Section 6. 8. D. are required to be documented for the PA to be recognized for having achieved 4,000 hours of clinical practice.

This item should be eliminated for Practice Agreements.

3. "Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;"

- This is redundant and duplicative as items in Section 6. 8. D. are required to be documented for the PA to be recognized as having achieved 4,000 hours of clinical practice.

This item should be eliminated for Practice Agreements. If it and number 2 above are not eliminated, then the two items should be combined with wording such as: "Copies of previous plans of supervision, credentialing and privileging documents, collaboration agreements, and practice agreements, as applicable, together with practice or physician reviews."

4. "Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;"

5. "Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA;"

FROM THE NCCPA WEBSITE: "The CAQ is a voluntary credential that Certified PAs can earn in seven specialties: Cardiovascular &Thoracic Surgery, Emergency Medicine, Hospital Medicine, Nephrology, Orthopaedic Surgery, Pediatrics and Psychiatry."

- The only primary care CAQ is in pediatrics. This may alter dynamics in the medical workforce preventing PAs from attempting to work in primary care.
- It reduces abilities for PAs to respond to changing medical workforce needs.
- To be able to apply for CAQ status, a PA must have worked in that specialty for 2000-4000 hours precluding recent PA graduates from being able to complete this requirement.

- The CAQ is a recognition of expertise in a specialty, but the PA must continue to be certified by the NCCPA in general medicine and therefore is not an accurate reflection of the PAs knowledge base.
- The CAQ may not apply to the PAs current practice setting.
- The requirement ignores other certification or other specialized training such as Certified Diabetes Care and Education Specialist.
- It ignores other rigorous training that does not lead to a "certification."

This requirement should be eliminated for Practice agreements, but if retained, reworded to something similar to: "Documentation of other meritorious certification or other acceptable educational experiences" eliminating the reference to a CAQ.

6. "Preparation of a plan for rending medical services for a period of time under the supervision of a physician;"

- Public Law 627 eliminates the supervision requirement for PAs and utilization of the term "supervision" is confusing.
- The collaborating physician and PA can develop a plan for physician oversight if necessary.

Suggest that the term supervision be eliminated and clarify that oversight can be utilized if needed.

7. "Successful completion of an educational and/or training program approved by the Board."

- It is unclear whether this is in addition to the requirements for PA licensure.
- Does this apply to clinical and non-clinical education and training?
- While there are some "post-graduate" PA training programs, most PAs do not go into these programs so such a requirement is counter to PL 627.
- Unless the PA is practicing outside the usual and customary role of a PA, to require PAs in a "Practice Agreement" have additional training beyond the rigorous ARC-PA standards would impair the PAs ability, especially recent graduates, to fulfill the needs of Maine citizens.

Please clarify that this item is needed only if the PA is practicing outside of the usual and customary role of a PA.

B. "Physician assistants who work outside of a health care facility or physician group practice may not render medical services until their scope of practice is reviewed and approved by the Board."

Comment: This is written as a prohibition on rendering any medical service until the scope of practice is reviewed and approved by the Board. A single controversial or unclear item on a proposed scope of practice could delay approval of the Practice Agreement for several months, even if there are only one or two items that need clarification. This section could cause a hardship for an underserved community and/or the PA if the process is delayed.

Please consider modifying this sentence to provide for a partial approval of a Scope of Practice until such time as the items of debate could be clarified, reviewed, and approved.

Concerning: *"Section 12*

1. 'Physician assistants licensed under this rule shall:

A. Keep their licenses available for inspection at the location where they render medical services;

B. When rendering medical services, wear a name tag identifying themselves as physician assistants; and

C. Verbally identify themselves as physician assistants whenever greeting patients during initial patient encounters and whenever patients incorrectly refer to them as "doctors."'

Comment: PAs frequently have professional relationships with patients that spans years and decades. Once the patient has been informed of, and understands the role of the PA in their care, having to correct the patient who refers to a PA as "doctor" or "Doc" at each occurrence, could be viewed by the patient as rude and disrespectful, disrupt the flow of clinical information, and harm the PA-patient relationship. Repeated correction could also confuse a patient with altered mental acuity, such as a dementia victim.

Individuals who have been in the military services, frequently refer to all medical professionals as "Doc". It is a term of respect, and it is difficult to extinguish the career-long habit. It may be as difficult as having a Marine not address an individual as "Sir" or "Ma'am" which can be almost impossible. Again, repeated correction of a patient could be rude and disrespectful.

The phrase '... and whenever patients incorrectly refer to them as "doctors."' in C should be eliminated. A compromise could be to add a phrase such as: "PAs should not represent themselves professionally as anything but a physician assistant."

I thank everyone involved for their hard work and diligence. I am confident that we can get to a revised Chapter 2 that will serve the citizens of Maine well.

Sincerely,

Alan Hull, PA-C

From: Morse, Erwin
To: Smith, Dennis E; Strout, Susan E
Subject: State of Maine PA Law LD 1660
Date: Friday, October 30, 2020 1:48:22 PM

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Good afternoon. It appears there is an attempt to combine collaborative agreements (less than 4000 hours of practice would need this) and a practice agreement (if a PA has their own practice) which the law intended to be very different.

Erwin "Earl" Morse, PA-C, MPAS
Primary Care Provider
Gold Team, Bangor VA Clinic
Bangor Maine

From: Kristi Kalajian
To: Smith, Dennis E
Subject: Comments on LD 1660
Date: Wednesday, October 28, 2020 7:32:36 PM

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Dennis E. Smith, Executive Director

Board of Licensure in Medicine

137 State House Station

Augusta, ME 04333-0137

10/28/20

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith,

I am the Lead Physician Assistant for a team of PAs who provide acute care to severely mentally ill persons in the care of the State of Maine and I am writing to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants. Thank you to both boards for their excellent work thus far; I have been impressed by your commitment to ensuring the proposed rules align not only with law as written, but also the legislative intent as reflected in the law. I refer to the following section of Public Law Chapter 627:

> *7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.*

I have a concern regarding the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements" found at the bottom of page 12 and continuing on page 13. I think that many PAs and their collaborating or partner physicians could be confused by the grouping of these criteria together. There are specific criteria that would be nearly impossible for a PA with less than 4,000 hours to provide. This section comes to mind right away:

Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or

practice agreement;

I urge the boards to create a separate list of criteria and rewrite this subsection. The scope of practice for PAs in collaborative agreements should be separate from those in practice agreements. The law was written with great care and deliberation on the different contexts for each of these agreements. In the most blunt terms - one is meant for new graduates (the collaborative agreement) and the other is meant for those rare instances where PAs are seeking to practice in areas of Maine not covered by a health care system or a physician group practice (practice agreements.) Each scenario requires unique regulation to ensure the safety of the public. I fear that, by mixing the two, PAs may be discouraged from practicing to the full scope of their education and training simply because they can't provide all the documentation included in the proposed list.

In addition, the requirement of the PA to "verbally identify themselves as a physician assistant whenever greeting patients during initial patient encounters *and whenever the patients incorrectly refer to them as "doctors",* is understood in its intent to avoid misrepresentation, but in practice this rule for constant correction would be onerous and in some cases could derail a discussion into a semantic one and possibly undermine patient care. We do it of course, regularly, because we are professionals, but honestly I don't see how it could be enforced and I propose it be stricken.

In closing, thank you for your consideration of my comments. The outcome of these new regulations shouldn't create barriers for young people entering the healthcare workforce. Nor should these rules hinder comprehensive healthcare access for Mainers in the far corners of the State.

Sincerely,

Kristin Kalajian PA-C

From: Morrow, Gretchen L.
To: Smith, Dennis E; Strout, Susan E
Subject: Chapter 2
Date: Wednesday, October 28, 2020 3:45:40 PM

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Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

DATE 10/28/2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants. I want to start by commending both boards for their excellent work thus far; I have been impressed by your commitment to ensuring the proposed rules align not only with law as written, but also the legislative intent as reflected in the law. I refer to the following section of Public Law Chapter 627:

> 7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.

It is with this in mind that I express concern regarding the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements" found at the bottom of page 12 and continuing on page 13. I understand the boards' wish to be efficient with their rules, forms, and processes. However, I think that many PAs and their collaborating or partner physicians could be confused by the grouping of these criteria together. There are specific criteria that it would be nearly impossible for a PA with less than 4,000 hours to provide. This section comes to mind right away:

> Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of
> the collaborative agreement or practice agreement;

I urge the boards to create a separate list of criteria for reviewing scope of practice for PAs in collaborative agreements from the list for those in practice agreements. The law was written with great care and deliberation on the different contexts for each of these agreements. In the most blunt terms - one is meant for new graduates (the collaborative agreement) and the other is meant for those rare instances where PAs are seeking to practice in areas of Maine not covered by a health care system or a physician group practice (practice agreements.) Each scenario requires unique regulation to ensure the safety of the public. I fear by mixing the two PAs may be discouraged from practicing to the full scope of their education and training simply because they can't provide all the documentation included in the proposed list.

I would also like to comment on how I identify myself. Daily as I introduce myself to my patients I introduce myself as such, "Hello, my name is Gretchen Morrow and I am a Physician Assistant and I will be your primary care provider". I can tell you that often this is met with a return of "its nice to meet you doc" or "so what should I call you"? I then reply that I am a PA and that they can call me Gretchen. Often even this is met with "Ok Doc". One could speculate that this may be reflective of the population I care for, our country's veterans. They were used to calling any medic in the field "doc". However I found this within civilian based practice as well. I work in the Emergency room where I am often referred to as the nurse and even asked when the provider will see them. In all of these instance I correct my patients and remind them that I am a PA and I will be providing their care. I do not become offended if I am called the nurse, I simply correct and move on, often to be referred to as the nurse again. I am so very proud of my profession, my degree, my training and my experience. I am happy to tell people that I am a PA and I prefer to be called by my first name. I sit in an office where my degree and licensure is hung on my wall next to my desk. They bring a lot of attention because I attended a Massachusetts school so often patients believe I am from Mass and they begin to tease!. I remind them proudly that I am from Maine. A clear example of how I visually display my degree.
Also I would note that the other day on the phone a patient called me Megan, despite introducing myself, stating my name and title. I corrected him once then let him go on. Despite my efforts, corrections and proper introductions sometimes patients insist on calling me the wrong name, the wrong title, even calling me an unkind name for which we often refer to those fine folks from Massachusetts. I feel that we are proud of our profession and placing the wording of identification into this document felt demeaning. We clearly do our best. Constantly reminding and correcting a patient or caregiver can create barriers to care with our message or treatment getting lost in constant corrections and interruptions. Correcting the patient each time they misidentify me creates a breakdown in our therapeutic relationship, hence why I let my patient call me Megan during our phone conversation – He knew I was his primary care provider, he understood the treatment, he misspoke my name. I think that I was effective but would have been less
In closing, thank you for your consideration of my comments. The outcome of these new regulations shouldn't create barriers for young people entering the healthcare workforce. Nor should these rules hinder comprehensive healthcare access for Mainers in the far corners of the State.

Sincerely,
Gretchen Morrow PA-C

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

10/30/2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for the opportunity to provide feedback on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants. I want to start by commending both boards for their excellent work thus far; I have been impressed by your commitment to ensuring the proposed rules align not only with law as written, but also the legislative intent as reflected in the law. I refer to the following section of Public Law Chapter 627:

> *7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.*

It is with this commitment to rulings aligning with our roles as PA's, that I am expressing my concern regarding the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements" found at the bottom of page 12 and continuing on page 13. I understand the boards' wish to be efficient with their rules, forms, and processes; however, I think that many PAs and their collaborating or partner physicians could be confused by the grouping of these criteria together. There are specific criteria that would make it nearly impossible for a PA with less than 4,000 hours to provide care. This section comes to mind right away:

> *Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;*

I strongly urge the boards to create separate lists of criteria for reviewing scope of practice for PAs in collaborative agreements and for those in practice agreements. The law was written with great care and deliberation pertaining to the different contexts for each of these agreements. In the most blunt terms - one is meant for new graduates (the collaborative agreement) and the other is meant for those rare instances where PAs are seeking to practice in areas of Maine not

covered by a health care system or a physician group practice (the practice agreement.) Each scenario requires unique regulations to ensure the safety of the public. My fear is that by mixing the two, PAs may be discouraged from practicing to the full scope of their education and training, simply because they can't provide all the documentation included in the proposed list.

My current role as a Physician Assistant is in a Neuro-critical Care unit, as well as Medical and Surgical Critical Care. I have been practicing medicine in this specialty for over 6 years. If the legislation, as currently proposed, had been in effect when I was a new graduate and beginning my career in Neurocritical Care, it would have created significant barriers to my professional development. It was because of my ability to begin my career without having accumulated 24 months of clinical practice prior, that I was able to become the PA that I currently am today.

In addition, I would like to comment on the proposed legislation pertaining to PA identification. We, as Physician Assistants, pride ourselves on prioritizing the safety and wellbeing of our patients. We dedicate time to educating the community and our patients on our role in the medical field. As with any other accredited medical profession, we as PA's represent ourselves with dignity and good intention and identify ourselves by name/profession and with badge ID's. I am concerned about the proposed legislation, as stated below:

> *'the physician assistant will "verbally identify themselves as a physician assistant whenever greeting patients during initial patient encounters and whenever the patients incorrectly refer to them as "doctors".'*

To enforce that a PA must correct a patient every time they misspeak our professional title would create distrust, frustration, and undo years of rapport that citizens of our state have developed with their PA's. The focus of any patient-provider interaction should be on developing trust and creating an opportunity for patient's to confide in their provider in a judgment free and non-stressful environment, in order to develop the best plan of care. While we understand the intent of this rule (ensuring that PAs are not misrepresenting themselves as something other than Physician Assistants), there are no other healthcare providers in ME with a rule that creates a duty to repeatedly verbally correct a patient. Most importantly, many of our PAs, regardless of their practice setting, are caring for vulnerable populations (i.e. PTSD, dementia, delirium, etc.) where repeatedly correcting them would lead to further harm and confusion and would undermine the patient care, due to focusing the interaction on something that is out of the PA's control.

In closing, thank you for your consideration of my comments. The outcome of these new regulations should not create barriers for young people entering the healthcare workforce, which I fear they will, if not amended. These rules should also not hinder access to comprehensive healthcare for Mainers in the far corners of the State, which is paramount to the mission of many Physician Assistant's in this beautiful state.

Sincerely,

Erin L. Muthig, PA-C
Department of Critical Care Medicine
Maine Medical Center
Portland ME, 04102

From:	Ryan Trosper
To:	Smith, Dennis E; Strout, Susan E
Subject:	Chapter 2 ruling regarding physician assistants
Date:	Thursday, October 29, 2020 2:16:44 PM

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Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137

Susan E. Strout, Executive Secretary
Board of Osteopathic Licensure
142 State House Station
Augusta, ME 04333-0142

October 29, 2020

RE: Chapter 2 Joint Rule Regarding Physician Assistants

Dear Mr. Smith and Ms. Strout,

Thank you for this opportunity to comment on the recently proposed changes to the Chapter 2 Joint Rule Regarding Physician Assistants. I have been impressed by your commitment to ensuring the proposed rules align not only with law as written, but also the legislative intent as reflected in the law. I refer to the following section of Public Law Chapter 627:

> *7. Construction. To address the need for affordable, high-quality health care services throughout the State and to expand, in a safe and responsible manner, access to health care providers such as physician assistants, this section must be liberally construed to authorize physician assistants to provide health care services to the full extent of their education, training and experience in accordance with their scopes of practice as determined by their practice settings.*

It is with this in mind that I express concern regarding the new proposed section, "9. Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements. I understand the boards' wish to be efficient with their rules, forms, and processes. However, many PAs and their collaborating or partner physicians could be

confused by the grouping of these criteria together. There are specific criteria that it would be nearly impossible for a PA with less than 4,000 hours to provide. This section comes to mind right away:

Documentation of at least 24 months of clinical practice within a particular
medical specialty during the 48 months immediately preceding the date of
the collaborative agreement or practice agreement;

I urge the boards to create a separate list of criteria for reviewing scope of practice for PAs in collaborative agreements from the list for those in practice agreements. The law was written with great care and deliberation on the different contexts for each of these agreements. In the most blunt terms - one is meant for new graduates (the collaborative agreement) and the other is meant for those rare instances where PAs are seeking to practice in areas of Maine not covered by a health care system or a physician group practice (practice agreements.) Each scenario requires unique regulation to ensure the safety of the public. By mixing the two, PAs may be discouraged from practicing to the full scope of their education and training simply because they can't provide all the documentation included in the proposed list.

Currently, I provide healthcare to Mainers at a Federally Qualified Health Center, providing care to some of Maine's most vulnerable population. My employers require my PA license be displayed in the waiting room, that I wear a name badge identifying myself as a physician assistant. As a healthcare professional, I, as do other PAs, identify ourselves by our profession when meeting with patients. A law that requires I point out patient errors and correct patients every time they make an error during the patient/provider visit does not promote a patient centered approach to healthcare. This is even more destructive to a patient/provider relationship when working with vulnerable populations such as PTSD, dementia, delirium, patients whom do not speak English or speak English as a secondary language. Repeated corrections would lead to confusion, undermine their care, help to remove them from feeling that they are a valued member of their care (patient centered approach).

Thank you for this opportunity to share my concerns. The outcome of these new regulations shouldn't create barriers for people entering the healthcare workforce. Nor should these rules hinder comprehensive healthcare access for Mainers in the far corners of the State.

Sincerely,

Ryan J Trosper PA-C

Sent from my iPhone

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning

October 28, 2020

Dennis E. Smith, Executive Director
Board of Licensure in Medicine
137 State House Station
Augusta, ME 04333-0137
dennis.smith@maine.gov

Dear Mr. Smith, and Members of the Board of Licensure:

The Federal Trade Commission ("FTC" or "Commission") Office of Policy Planning appreciates the opportunity to comment on the proposed Chapter 2 Joint Rule Regarding Physician Assistants ("Proposed Rule").

We understand that comments are due Friday, October 30, 2020. Under present time constraints, FTC staff cannot conduct a specific analysis of the various provisions of the Proposed Rule, or of their likely impact on competition and health care consumers in Maine's health care markets. We hope, however, that prior FTC staff analyses of physician assistant ("PA") and related scope of practice regulations will be helpful to you and your colleagues. Two such FTC staff documents are attached to this letter.[1]

First, in December 2016, FTC staff submitted comments on proposed PA regulations to the Professional Licensure Division of the Iowa Department of Public Health.[2] There, staff noted that "patients would likely benefit if physician assistants . . . can practice with as few restrictions as possible, consistent with their education, training, skills, and experience."[3] Correspondingly, the staff explained that additional regulatory requirements should not be imposed "unless there is substantiated health and safety evidence supporting such requirements," as such regulations "could decrease access to care and potentially increase health care costs for … consumers, as well as to physicians and health care institutions that employ PAs."[4]

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[1] The attached documents express the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. They do not necessarily represent the views of the FTC or any individual Commissioner. The Commission did, however, vote to authorize staff to issue each of these documents.

[2] FTC Staff Comment to the Professional Licensure Div., Iowa Dep't Public Health, Regarding Proposed New Rules of the Iowa Board of Physician Assistants (2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-professional-licensure-division-iowa-department-public-health-regarding-proposed/v170002_ftc_staff_comment_to_iowa_dept_of_public_health_12-21-16.pdf.

[3] *Id.* at 1.

[4] *Id.* at 9.

Second, in March 2014, the Commission authorized the staff to issue a report, *Policy Perspectives: Competition and the Regulation of Advanced Practice Registered Nurses* ("Report").[5] The Report describes a general framework for analyzing the costs and benefits of restrictions on the scope of practice of health care professionals,[6] and applies that framework and available evidence to issues analogous to some of those raised in the Proposed Rule and Maine LD 1660. That framework recommended consideration of the following:

- Are there any significant and non-speculative consumer health and safety needs that particular regulatory restrictions, extant or proposed, are supposed to meet?
- Do those particular regulations actually provide the intended benefits – such as improvements in health care outcomes or a reduced risk of harm from poor-quality services – or are there good grounds to think they are likely to provide those benefits?
- Are there other demonstrated or reasonably likely consumer benefits associated with the proposed regulation (e.g., reduced information or transaction costs for consumers who are choosing among providers, reduced consumer confusion in distinguishing among different types of providers, etc.)?
- When consumer benefits are slight, insubstantial, or highly speculative, a regulation that imposes non-trivial impediments to competition is not justified.
- If pertinent consumer harms have occurred, or risks are found to be substantial, is the proposed regulation likely to redress those harms or risks?
- Are the regulations narrowly tailored to serve the state's policy priorities? When particular regulatory restrictions address well-founded consumer protection concerns but – at the same time – appear likely to harm competition, consider whether the regulations are narrowly tailored to address those concerns without undue harm to competition, or whether less restrictive alternatives are available.[7]

We hope these documents will be helpful as you consider changes to licensure and scope of practice regulations for PAs in Maine. Please feel free to contact us if you have any questions about the attached materials or if further issues arise at your hearing. You may reach me directly at the address above or bsayyed@ftc.gov, or you may contact my colleague, Daniel Gilman, at (202) 326-3136 or dgilman@ftc.gov.

Respectfully submitted,

Bilal Sayyed, Director

CC The Hon. Linda Sanborn, Maine Senate
The Hon. Heather Sanborn, Maine Senate

---

[5] FED. TRADE COMM'N STAFF, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES (2014), https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf.

[6] *Id.* at 12-13.

[7] *Id.* at 17.

Policy Perspectives

Competition and the Regulation of Advanced Practice Nurses

Federal Trade Commission | March 2014

FEDERAL TRADE COMMISSION

March 2014

Edith Ramirez	Chairwoman
Julie Brill	Commissioner
Maureen K. Ohlhausen	Commissioner
Joshua D. Wright	Commissioner

This policy paper represents the views of the FTC staff and does not necessarily represent the views of the Commission or any individual Commissioner. The Commission, however, has voted to authorize the staff to issue this policy paper.

Policy Perspectives

Competition and the Regulation of Advanced Practice Nurses

Andrew I. Gavil, Director, Office of Policy Planning

Principal Authors

Daniel J. Gilman, Attorney Advisor, Office of Policy Planning

Tara Isa Koslov, Deputy Director, Office of Policy Planning

Contributors

Deborah L. Feinstein, Director, Bureau of Competition

Martin Gaynor, Director, Bureau of Economics

Michael J. Bloom, Bureau of Competition

Mark N. Hertzendorf, Bureau of Economics

Elizabeth R. Hilder, Bureau of Competition

David R. Schmidt, Bureau of Economics

Patricia Schultheiss, Office of Policy Planning

Inquiries concerning this policy paper should be directed to Daniel J. Gilman, Office of Policy Planning, at (202) 326-3136 or dgilman@ftc.gov.

Cover design and layout by Carrie Gelula, Division of Consumer and Business Education, Bureau of Consumer Protection.

This report is available online at
www.ftc.gov/policy/reports/policy-reports/commission-and-staff-reports
The online version of this report contains live hyperlinks.

CONTENTS

EXECUTIVE SUMMARY

The Federal Trade Commission (FTC or Commission) vigorously promotes competition in the health care industry through enforcement, study, and advocacy. Competition in health care markets benefits consumers by helping to control costs and prices, improve quality of care, promote innovative products, services, and service delivery models, and expand access to health care services and goods. While state legislators and policymakers addressing health care issues are rightly concerned with patient health and safety, an important goal of competition law and policy is to foster quality competition, which also furthers health and safety objectives. Likewise, to ignore competitive concerns in health policy can impede quality competition, raise prices, or diminish access to health care – all of which carry their own health and safety risks.

We are not suggesting that unfettered competition in health care services always leads to the best outcome for consumers. Actual or likely market failure, among other factors, may justify health and safety regulations. However, even well intentioned laws and regulations may impose unnecessary, unintended, or overbroad restrictions on competition, thereby depriving health care consumers of the benefits of vigorous competition. We thus urge policymakers to view competition and consumer safety as complementary objectives, and to integrate consideration of competition into their deliberations.[1]

This policy paper builds on FTC staff competition advocacy comments that focus on proposed state-level changes to statutes and rules governing the "scope of practice" of Advanced Practice Registered Nurses (APRNs). Scope of practice rules determine the range of health care procedures and services that various health care professionals are licensed to provide under state law. In the case of APRNs, these rules establish both the range of services APRNs may deliver and the extent to which they are permitted to practice independently, or without direct physician supervision.[2] Because APRNs and other practitioners, including physicians, may be trained and licensed to provide many of the same health care services, scope of practice restrictions can limit the supply of those primary health care services, as well as competition between different types of practitioners.

FTC staff competition advocacy comments have addressed various physician supervision requirements imposed on APRNs. Physician supervision requirements may raise competition

1. *See* Section II.B., *infra.*
2. For a general review of APRN scope of practice restrictions, and their variation across the states, *see, e.g.,* INST. OF MED., NAT'L ACAD. OF SCIENCES, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH 98-103, 157-61 annex 3-1 (2011) [hereinafter IOM FUTURE OF NURSING REPORT].

concerns because they effectively give one group of health care professionals the ability to restrict access to the market by another, competing group of health care professionals, thereby denying health care consumers the benefits of greater competition.[3] In addition, APRNs play a critical role in alleviating provider shortages and expanding access to health care services for medically underserved populations.[4] For these reasons, the FTC staff has consistently urged state legislators to avoid imposing restrictions on APRN scope of practice unless those restrictions are necessary to address well-founded patient safety concerns.[5] Based on substantial evidence and experience, expert bodies have concluded that ARPNs are safe and effective as independent providers of many health care services within the scope of their training, licensure, certification, and current practice.[6] Therefore, new or extended layers of mandatory physician supervision may not be justified.

Moreover, additional supervision requirements may not be tailored to accommodate the myriad relationships – collaborative, consulting, or referral-based – among APRNs, primary care doctors, specialty physicians, and other health care professionals, and may impair the abilities of health care professionals and provider institutions to develop new models of health care delivery in response to consumer preferences, health care needs, and new technologies. Under traditional as well as emerging models, all of these providers can contribute to safe, efficient, and coordinated patient care, consistent with each professional's education, licensure, and

3. Particular types of physician supervision or "collaborative practice" requirements, and the ways they can empower physicians to impede APRN entry into health services markets, are discussed *infra*, text accompanying notes 37-47.

4. APRNs already provide a disproportionately high share of primary care services in medically underserved areas and for medically underserved populations, and they may be better able to meet increasing demand in such contexts when they can work independent of undue supervision requirements. *See generally* NAT'L GOVERNORS ASS'N, NGA PAPER: THE ROLE OF NURSE PRACTITIONERS IN MEETING INCREASING DEMAND FOR PRIMARY CARE (2012), http://www.nga.org/files/live/sites/NGA/files/pdf/1212NursePractitionersPaper.pdf [hereinafter NGA PRIMARY CARE PAPER].

5. FTC and staff advocacy comments, testimony, and letters are detailed in Section III of this paper, below, and these and related comments are listed in Appendix 1 of this policy paper, and available on the FTC policy web page at http://www.ftc.gov/policy/advocacy/advocacy-filings.

6. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98-99; NGA PRIMARY CARE PAPER, *supra* note 4, at 7-8 (study funded by U.S. Dep't Health & Human Servs., reviewing literature pertinent to NP safety and concluding "None of the studies in the NGA's literature review raise concerns about the quality of care offered by NPs. Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures."); CHRISTINE E. EIBNER ET AL., RAND HEALTH REPORT SUBMITTED TO THE COMMONWEALTH OF MASSACHUSETTS, CONTROLLING HEALTH CARE SPENDING IN MASSACHUSETTS: AN ANALYSIS OF OPTIONS 99 (2009), http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR733.pdf [hereinafter "EIBNER ET AL., MASSACHUSETTS REPORT"] ("studies have shown that they provide care similar to that provided by physicians.") Some of the primary research underlying these assessments is cited *infra* note 137.

capabilities. Effective collaboration between APRNs and physicians does not necessarily require any physician supervision, much less any particular model of physician supervision.

The competition concerns voiced in FTC staff's scope of practice advocacy comments are consistent with the policy analysis of a 2011 Institute of Medicine (IOM) report, *The Future of Nursing: Leading Change, Advancing Health.*[7] The *Future of Nursing* report provides expert advice based on "[e]vidence suggest[ing] that access to quality care can be greatly expanded by increasing the use of . . . APRNs in primary, chronic, and transitional care,"[8] and expresses concern that scope of practice restrictions "have undermined the nursing profession's ability to provide and improve both general and advanced care."[9] The report found that APRNs' scope of practice varies widely "for reasons that are related not to their ability, education or training, or safety concerns, but to the political decisions of the state in which they work."[10] The report recognizes FTC competition advocacy in this area and specifically exhorts the FTC and the Antitrust Division of the U.S. Department of Justice to pay continued attention to the competition issues raised by scope of practice regulations.

The FTC has looked to the findings of the IOM and other expert bodies – analyses based on decades of research and experience – on issues of APRN safety, effectiveness, and efficiency.[11] Based on those expert analyses and findings, as well as our own reviews of pertinent literature and stakeholder views, the FTC staff has urged state legislators and policymakers to consider the following principles when evaluating proposed changes to APRN scope of practice.

- Consumer access to safe and effective health care is of critical importance.
- Licensure and scope of practice regulations can help to ensure that health care consumers (patients) receive treatment from properly trained professionals. APRN certification and

7. IOM FUTURE OF NURSING REPORT, *supra* note 2. The IOM was established in 1970 as the health arm of the National Academy of Sciences. *Id.* at iv. The IOM web page, with links to general descriptions of the IOM, IOM reports, and other IOM activities, is at http://www.iom.edu/.
8. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27; *see also id.* at 88 ("Given current concerns about a shortage of primary care health professionals, the committee paid particular attention to the role of nurses, especially APRNs, in this area."). The extent to which APRNs and other professionals might augment the primary care workforce has been of policy interest for some time. *See, e.g.*, OFFICE OF TECH. ASSESSMENT, U.S. CONG., HEALTH TECH. CASE STUDY 37, NURSE PRACTITIONERS, PHYSICIAN ASSISTANTS, AND CERTIFIED NURSE-MIDWIVES: A POLICY ANALYSIS, 39 (1986) [hereinafter OTA HEALTH TECH. CASE STUDY] ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].").
9. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 4.
10. *Id.* at 5.
11. *See supra* note 6.

state licensure requirements should reflect the types of services that APRNs can safely and effectively provide, based on their education, training, and experience.

- Health care quality itself can be a locus of competition, and a lack of competition – not just regulatory failures – can have serious health and safety consequences. More generally, competition among health care providers yields important consumer benefits, as it tends to reduce costs, improve quality, and promote innovation and access to care.
- Potential competitive effects can be especially striking where there are primary care shortages, as in medically underserved areas or with medically underserved populations. When APRNs are free from undue supervision requirements and other undue practice restrictions, they can more efficiently fulfill unmet health care needs.
- APRNs typically collaborate with other health care practitioners. Effective collaboration between APRNs and physicians can come in many forms. It does not always require direct physician supervision of APRNs or some particular, fixed model of team-based care.
- APRN scope of practice limitations should be narrowly tailored to address well-founded health and safety concerns, and should not be more restrictive than patient protection requires. Otherwise, such limits can deny health care consumers the benefits of competition, without providing significant countervailing benefits.
- To promote competition in health care markets, it may be important to scrutinize relevant safety and quality evidence to determine whether or where legitimate safety concerns exist and, if so, whether physician supervision requirements or other regulatory interventions are likely to address them. That type of scrutiny can be applied not just to the general question whether the State requires physician supervision or collaborative practice agreements, but to the particular terms of those requirements as they are sometimes applied to, for example, APRN diagnosis of patient illnesses or other health conditions, APRN ordering of diagnostic tests or procedures, and APRN prescribing of medicines.

I. INTEREST AND EXPERIENCE OF THE FTC

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[12] Competition is at the core of America's economy,[13] and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, and greater innovation. Innovation may include new and varied service delivery models that respond to the changing needs of the marketplace.

Health care is a major U.S. industry, and health care competition is crucial to the economy and consumer welfare. For these reasons, anticompetitive conduct in health care markets has long been a key focus of FTC law enforcement,[14] research,[15] and advocacy.[16] As a result, the FTC has developed significant expertise regarding competition issues affecting the health care industry.

12. Federal Trade Commission Act, 15 U.S.C. § 45.

13. Standard Oil Co. v. FTC, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

14. *See, e.g.*, HEALTH CARE DIV., FED. TRADE COMM'N, AN OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2013), *available at* http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf (covering all actions through March 2013). For information regarding all FTC health care matters, see http://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.

15. For example, in 2003, the FTC and the DOJ Antitrust Division held 27 days of hearings on health care and competition law and policy. *Competition in the Health Care Marketplace*, FED. TRADE COMM'N, http://www.ftc.gov/news-events/events-calendar/2003/02/health-care-competition-law-policy-hearings (last updated Apr. 10, 2013) (links to transcripts and other hearing materials); *see also Innovations in Health Care Delivery*, FED. TRADE COMM'N, http://www.ftc.gov/news-events/events-calendar/2008/04/innovations-health-care-delivery (last visited Feb. 28, 2014); *Emerging Health Care Competition and Consumer Issues*, FED. TRADE COMM'N, http://www.ftc.gov/news-events/events-calendar/2008/11/emerging-health-care-competition-and-consumer-issues (last visited Feb. 28, 2014); FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005), http://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report. A more comprehensive listing of FTC conferences and workshops is available at http://www.ftc.gov/news-events/events-calendar/all. Links to more FTC reports are available at http://www.ftc.gov/policy/reports.

16. FTC advocacy takes many forms, including letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, and amicus briefs. *See, e.g.*, Letter from FTC Staff to the Hon. Timothy Burns, La. House of Representatives (May 1, 2009), http://www.ftc.gov/os/2009/05/V090009louisianadentistry.pdf (regarding proposed restrictions on mobile dentistry); Written Testimony from the Fed. Trade Comm'n and U.S. Dep't of Justice to the Ill. Task Force on Health Planning Reform (Sept. 15, 2008), http://www.ftc.gov/os/2008/09/V080018illconlaws.pdf; Brief of the Fed. Trade Comm'n as Amicus Curiae in Actelion Pharmaceuticals Ltd. v. Apotex Inc., No. 1:12-cv-05743 (D.N.J. Mar. 11, 2013), *available at* http://www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf.

Competition research and advocacy are an important part of the FTC's statutory mission.[17] While Section 6 of the FTC Act[18] gives the Commission the authority to conduct investigations that might lead to enforcement actions, it also grants more general authority to investigate and report on market developments in the public interest, including authority to make legislative recommendations based on those investigations.[19]

The FTC has frequently utilized this unique authority to explore competition dynamics in the health care industry. For example, in 2003 the Commission and the Antitrust Division of the U.S. Department of Justice jointly conducted extensive hearings on health care competition issues.[20] Based on those hearings, along with an FTC-sponsored workshop and independent staff research, the two agencies in 2004 jointly released a comprehensive report on health care competition.[21] Among other topics, the hearings and report addressed potential competition concerns associated with professional regulations in the health care sector, including licensure and scope of practice

17. For a general discussion of the FTC's "policy research and development" mission and the role of the advocacy program, see, e.g., WILLIAM E. KOVACIC, THE FEDERAL TRADE COMMISSION AT 100: INTO OUR 2ND CENTURY (2009), http://www.ftc.gov/ftc/workshops/ftc100/docs/ftc100rpt.pdf (regarding "policy R&D" see pp. 92-109; regarding advocacy see pp. 121-24); *see also* James C. Cooper, Paul A. Pautler, & Todd J. Zywicki, *Theory and Practice of Competition Advocacy at the FTC*, 72 ANTITRUST L.J. 1091 (2005); Maureen K. Ohlhausen, *Identifying Challenging, and Assigning Political Responsibility for State Regulation Restricting Competition*, 2 COMPETITION POL'Y INT'L 151, 156-7 (2006) (competition advocacy "beyond enforcement" of the antitrust laws); William E. Kovacic, *Measuring What Matters: The Federal Trade Commission and Investments in Competition Policy Research and Development*, 72 ANTITRUST L.J. 861 (2005); Timothy J. Muris, Chairman, Fed. Trade Comm'n, Remarks at the International Competition Network Panel on Competition Advocacy and Antitrust Authorities, Creating a Culture of Competition: The Essential Role of Competition Advocacy (Sept. 28, 2002), http://www.ftc.gov/public-statements/2002/09/creating-culture-competition-essential-role-competition-advocacy; Arnold C. Celnicker, *The Federal Trade Commission's Competition and Consumer Advocacy Program*, 33 ST. LOUIS U. L.J. 379 (1989); Maurice E. Stucke, *Better Competition Advocacy*, 82 ST. JOHN'S L. REV. 951 (2008). For a recent overview, see Tara Isa Koslov, *Competition Advocacy at the Federal Trade Commission: Recent Developments Build on Past Success*, 8 CPI ANTITRUST CHRON. 1 (2012).

18. 15 U.S.C. § 46.

19. *Id.* at § 46(a), (b), (f).

20. *See Competition in the Health Care Marketplace*, *supra* note 15.

21. FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf [hereinafter FTC & DOJ, A DOSE OF COMPETITION].

regulations.[22] Related professional regulation issues also were the subject of prior FTC research[23] and competition advocacy.[24]

II. BACKGROUND ON APRNS AND SCOPE OF PRACTICE ISSUES

II.A. Advanced Practice Registered Nurses

Most state practice laws recognize APRNs as a distinct category of nursing professional.[25] An APRN is a nurse practitioner with a graduate nursing degree, in addition to undergraduate nursing education and practice experience, who has been trained to provide a broad range of services, including the diagnosis and treatment of acute and chronic illnesses.[26] Nationally, "[m]ore than a quarter of a million nurses are APRNs . . . who hold master's or doctoral degrees and pass national certification exams."[27] In addition, APRNs generally attend nationally accredited education and training programs, and receive certification from nationally accredited certifying

22. *See, e.g., id.* at ch. 2, pp. 25-28, 30-33 ("Through licensure requirements, states may restrict market entry by physicians and allied health professionals . . . and further limit the scope of authorized practice." *Id.* at 25.).

23. *See, e.g.*, CAROLYN COX & SUSAN FOSTER, BUREAU OF ECON., FED. TRADE COMM'N, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION (1990), http://www.ramblemuse.com/articles/cox_foster.pdf.

24. Comments of the Bureaus of Competition, Consumer Protection, and Economics of the Fed. Trade Comm'n to the Council of D.C. on Proposed Bill 6-317 to Create Specific Licensing Requirements for Expanded Role Nurses (Nov. 22, 1985); Brief of the Fed. Trade Comm'n as Amicus Curiae on Appeal from United States District Court, Nurse Midwifery Associates v. Hibbett, 918 F.2d 605 (6th Cir. 1990), *appealing* 689 F. Supp. 799 (M.D. Tenn. 1988). Based on analogous issues, the Commission also has enforced the antitrust laws in credentialing matters. *See* In the Matter of Med. Staff of Mem. Med. Ctr., 110 F.T.C. 541 (1988) (Complaint) (alleging anticompetitive combination or conspiracy to deny credentials to nurse midwife). For a general discussion of these advocacies and underlying competition issues, see Daniel J. Gilman & Julie Fairman, *Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice, 24* HEALTH MATRIX (forthcoming 2014).

25. Professional titles and nomenclature (e.g., "APRN," "ARNP," "nurse practitioner," etc.), as well as APRN licensure criteria and scope of practice rules, have been converging nationally, although they still vary across the states. IOM FUTURE OF NURSING REPORT, *supra* note 2, app. D (regarding APRN Consensus Model and Final Report of the APRN Consensus Work Group and the National Council of State Boards of Nursing APRN Advisory Committee). The National Council of State Boards of Nursing posts updated maps of, e.g., states that recognize "APRN" as a professional title, states that permit independent APRN practice, and states that permit independent APRN prescribing. *APRN Maps*, NAT'L COUNCIL OF STATE BDS. OF NURSING, https://www.ncsbn.org/2567.htm (last updated Feb. 2014). As implemented in one state's statutes and regulations, see, e.g., La. Rev. Stat. Ann. § 37:913(3)(a)(b) (2012); *see also* La. Admin. Code tit. 46, pt. XLVII, § 4505 (2012) (Louisiana State Board of Nursing regulations regarding APRNs).

26. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 23, 26.

27. *Id.* at 23. For an overview of APRN requirements generally, see *id.* at 26, table 1-1 (types of APRN practice) and 38-45.

boards.[28] There are four types of APRNs: nurse practitioners (NPs); nurse midwives (NMWs); certified registered nurse anesthetists (CRNAs); and clinical nurse specialists (CNSs).[29] Despite this range of available specialties, most APRNs are engaged in primary care,[30] and most APRNs are trained and licensed to provide a broad range of primary care services.[31] This policy paper synthesizes FTC staff advocacy comments regarding regulations applicable to APRNs and NPs generally, rather than regulations focused on specialized APRNs such as CRNAs or NMWs.[32]

APRNs, like other health care professionals, are subject to various categories of state regulation. In all states and the District of Columbia, APRNs face licensure requirements that determine who may enter the profession.[33] Related scope of practice rules further define the types of services APRNs are authorized to provide and the extent to which they are permitted to practice

28. *See id.* at 23, 41-42.

29. *See id.*

30. *See, e.g.*, CATHERINE DOWER & EDWARD O'NEIL, ROBERT WOOD JOHNSON FOUND., RESEARCH SYNTHESIS REPORT NO. 22: PRIMARY CARE HEALTH WORKFORCE IN THE UNITED STATES, 6 (2011), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2011/rwjf402104/subassets/rwjf402104_1 ("Primary care NPs make up the majority of the profession, with over 60 percent reporting their main clinical specialty to be family care.").

31. *See, e.g.*, EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 99 (describing range of services); NGA PRIMARY CARE PAPER, *supra* note 4, at 3-4.

32. While this policy paper does not specifically discuss them, other FTC staff advocacy comments have addressed issues pertaining to specialized APRNs, as well as specific business models within which APRNs may practice (such as limited service clinics). *See, e.g.*, Comment from FTC Staff to the Ky. Cabinet for Health and Family Servs. (Jan. 2010), http://www.ftc.gov/os/2010/02/100202kycomment.pdf (regarding proposed restrictions on limited service clinics staffed chiefly by APRNs); Comment from FTC Staff to the Hon. Jeanne Kirkton, Mo. House of Representatives (Mar. 2012), http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf (regarding restrictions on one category of specialized APRNs). In addition, this policy paper does not discuss Physician Assistant (PA) scope of practice issues, although PAs and APRNs typically are subject to similar types of rules. For a general discussion, see, e.g., Edward S. Sekscenski et al., *State Practice Environments and the Supply of Physician Assistants, Nurse Practitioners, and Certified Nurse-Midwives*, 331 N. ENGL. J. MED. 1266 (1994). Proposals to increase access to primary care often consider expanding the role of both APRNs and PAs. *Id.*; *see also* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 88, 97-98.

33. For a general discussion of these and other types of professional regulations, see, e.g., COX & FOSTER, *supra* note 23.

independently.[34] While entry qualifications for APRNs are increasingly similar from state to state, the regulations that define APRN scope of practice continue to vary widely.[35] Some scope of practice restrictions are procedure-oriented, limiting APRNs' ability to prescribe medicines, refer for, order, or perform certain tests or procedures, or treat certain indications.[36] Other restrictions focus on the types of patients APRNs may see. For example, APRNs may not be allowed to "examine a new patient, or a current patient with a major change in diagnosis or treatment plan,

34. TRACY YEE ET AL., NAT'L INST. FOR HEALTH CARE REFORM, RESEARCH BRIEF NO. 13, PRIMARY CARE WORKFORCE SHORTAGES: NURSE PRACTITIONER SCOPE-OF-PRACTICE LAWS AND PAYMENT POLICIES 2 (Feb. 2013), http://www.nihcr.org/PCP-Workforce-NPs.

    As with other health care professionals, the states may define professional prerogatives and limits broadly or narrowly, through statutory law, administrative rules and decisions, and judicial decisions. *Compare, e.g.,* ALA. CODE §§ 34-21-81(4) (2012), which defines "Advanced Practice Nursing" as "[t]he delivery of health care services by registered nurses who have gained additional knowledge and skills through successful completion of an organized program of nursing education that prepares nurses for advanced practice roles as certified registered nurse practitioners, certified nurse midwives, certified nurse anesthetists, and clinical nurse specialists;" *with* LA. REV. STAT. ANN. § 37:913(3)(a)-(b) (2012), which describes APRN scope of practice as including:

    (i) Assessing patients, analyzing and synthesizing data, and knowledge of and applying nursing principles at an advanced level.

    (ii) Providing guidance and teaching.

    (iii) Working with patients and families in meeting health care needs.

    (iv) Collaborating with other health care providers.

    (v) Managing patients' physical and psychosocial health-illness status with regard to nursing care.

    (vi) Utilizing research skills.

    (vii) Analyzing multiple sources of data and identifying and performing certain acts of medical diagnosis in accordance with the collaborative practice agreement.

    (viii) Making decisions in solving patient care problems and selecting treatment regimens in collaboration with a licensed physician, dentist, or other health care provider as indicated.

    (ix) Consulting with or referring patients to licensed physicians, dentists, and other health care providers in accordance with a collaborative practice agreement.

    See also LA. ADMIN. CODE TIT. 46, PT. XLVII, § 4505 (2012) (Louisiana State Board of Nursing regulations regarding APRNs).

35. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98.; *see also* NGA PRIMARY CARE PAPER, *supra* note 4, at 2.

36. For example, under Florida law, an APRN may "[m]onitor and alter drug therapies," FLA. STAT. § 464.012(3)(a), but may not prescribe controlled substances, FLA. STAT. § 83902(2) and 8390.5(1) (restricting controlled substance prescription to certain "practitioners" and defining practitioners to include physicians, but not APRNs).

unless the patient is seen and examined by a supervising physician within a specified period of time."[37]

In addition, somewhat more than half of U.S. states maintain physician supervision requirements for APRNs.[38] In other words, besides limits on the types of patients APRNs may see or the types of procedures APRNs may perform, these states' scope of practice rules restrict the degree to which APRNs may practice independently. Physician supervision may be required for all APRN practice,[39] or for particular practice activities such as prescribing medications.[40] Supervision rules sometimes define the parameters of supervision more specifically. Some require that APRN patient charts be reviewed at some particular frequency;[41] some limit the number of independent APRNs one physician may supervise,[42] or restrict the physical distance permitted between a supervising physician and a supervised APRN. Florida law, for example, imposes broad supervision requirements on APRN practice, while also specifying that an APRN cannot

37. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 101. The report catalogues various regulatory restrictions on nursing practice. *Id.* at 100-02 box 3-1, 157-61 annex 3-1 (regarding state scope of practice restrictions for nurse practitioners).

38. *See id.*, especially 157-61 annex 3-1 (specifying state-by-state requirements for supervision or mandatory "collaborative practice" for, e.g., APRN treatment, diagnosis, or prescribing). According to the National Council of State Boards of Nursing, 27 states require supervision or a collaborative practice agreement for APRN practice. *See APRN Maps*, *supra* note 25 (follow "CNM" hyperlink under "Independent Practice" heading) (22 states plus District of Columbia permit independent practice).

39. *See, e.g.*, FLA. STAT. § 464.012(3) (2012) (APRN can perform functions within S.O.P. only after "entering into a supervisory relationship with a physician" and subsequently filing established practice protocol with regulator). LA. REV. STAT. ANN. § 37:913(8) (2012) (formal written collaborative practice agreement required for both "acts of medical diagnosis and prescription").

40. Regarding more general and particular statutory definitions, see *supra* note 34 (comparing general Alabama definition with more specific enumeration of APRN practice under Louisiana law). Regarding prescribing, *see APRN Maps*, *supra* note 25 (follow "CNM" hyperlink under "Independent Prescribing" heading) (22 states plus District of Columbia permit independent practice); *see also, e.g.*, LA. REV. STAT. ANN. § 37:913(8) (2012) (formal collaborative practice agreement required for prescribing); W.VA. CODE §§ 30-7-15(a)-(b) (signed collaborative practice agreement with physician required for APRN prescribing).

41. *See, e.g.*, MISS. CODE ANN. § 73-15-20(3) (2012) (requiring establishment of a "collaborative/consultative relationship"); *Id.* § 73-15-20(C)(3) (each "collaborative/consultative relationship" must include "formal quality assurance/quality improvement program," including at review of at least the lesser of 20 or 10% of APRN's charts each month.)

42. *See, e.g.*, FLA. STAT. § 458.348(4)(a)-(b), (c) (2012) (subsections a-b restrict number of offices physician may supervise).

practice more than a certain distance from the primary place of practice of his or her supervising physician.[43]

Some supervision rules use different terminology to the same or similar effect. A state may require physician "delegation" of responsibilities to an APRN; Texas law, for example, imposes various supervision and delegation restrictions on APRN prescribing and diagnosis.[44] Alternatively, a state may impose certain "collaborative practice" requirements on APRNs, requiring that an APRN enter into a written agreement with a physician to define the parameters of the APRN's permitted practice.[45] This can be viewed as a *de facto* supervision requirement, to the extent that the APRN cannot practice without securing the approval of an individual physician, whereas the terms of physician practice are in no way dependent on APRN input. In Louisiana, for example, an APRN must practice under a formal written collaborative practice agreement if he or she is to work to the full extent of APRN scope of practice, including "acts of medical diagnosis and prescription," as otherwise permitted under Louisiana law.[46] West Virginia and Kentucky law require written collaborative practice agreements for APRN prescribing.[47]

II.B. Competition Perspectives on Professional Regulations that Restrict APRN Scope of Practice

Together, licensure and scope of practice regulations for APRNs and other health care professionals serve important consumer protection objectives, including safety and quality. To meet fully the interests of health care consumers, however, requires weighing competition considerations when evaluating the potential costs and benefits of particular scope of practice

43. *Id.*, § 458.348(4) (c) (requires either on-site supervision or, "[a]ll such offices that are not the physician's primary place of practice must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to the county of the physician's primary place of practice. . . ."); *see also* MO. CODE REGS. ANN. tit. 20 § 2150-5.100 (2) (A)-(B) (2012) ("an APRN who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons" may not be more than 50 miles by road in federally-designated health professional shortage areas and not more than 30 miles by road otherwise).

44. TEX. OCC. CODE ANN. § 157.051 (2012).

45. FTC staff are not aware of any state that imposes comparable requirements of collaborative practice on physician scope of practice, although some states impose various requirements on physicians who elect to enter into collaborative practice agreements with APRNs or others. Whether a state explicitly requires a physician to supervise a collaborating APRN or not, asymmetrical collaboration requirements imposed on APRNs effectively create *de facto* supervision requirements where an APRN can only practice under terms agreeable to a licensed physician. For a general discussion of the relationship between supervision and collaboration requirements, see Lauren E. Battaglia, *Supervision and Collaboration Requirements: the Vulnerability of Nurse Practitioners and Its Implications for Retail Health*, 87 WASH. U. L. REV. 1127, 1137-38 (2010).

46. LA. REV. STAT. ANN. § 37:913(8)-(9) (2012) (requiring collaborative practice and a collaborative practice agreement).

47. KY. REV. STAT. § 314.042 (2013); W. VA. CODE § 30-7-15A (2012).

rules. The goal should be to avoid imposing restraints that may tend to impair competition in a way that is greater than necessary to address legitimate health and safety concerns.

II.B.1. Framework for Evaluating Licensure and Scope of Practice Regulations

Licensure is, by its nature, a process that establishes the conditions for entry into an occupation. As a threshold matter, any regulation or law that establishes entry conditions for an occupation tends to reduce the supply of individuals otherwise willing to provide the services associated with that occupation.[48] Licensure is commonly required for many occupations, however, and can be justified on a number of grounds. Generally, an applicant for licensure must demonstrate a minimum degree of competence, based on education and training, to obtain the government's permission to provide professional services in a given jurisdiction.[49] Scope of practice rules further define the professional services a licensed health care practitioner is authorized to provide, and may prohibit a health care practitioner from offering certain services without first obtaining a specific license or certification, obtaining and documenting a specific form of supervision, or meeting other regulatory requirements. Unlicensed practice, or the provision of services outside one's scope of practice, generally is prohibited by statute and may be subject to civil or criminal penalties.[50]

Licensure and scope of practice regulations can serve an especially important function in health care. Consumers face serious risks if they are treated by unqualified individuals, and laypersons may find it difficult (if not impossible) to adequately assess quality of care at the

48. George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 13 (1971) ("The licensing of occupations is a possible use of the political process to improve the economic circumstances of a group. The license is an effective barrier to entry because occupational practice without the license is a criminal offense.").

49. *See Competition in the Health Care Marketplace*, *supra* note 15, hyperlink to Jun. 10, 2003 transcript, at 33-34 (statement of Dr. Morris Kleiner, providing context regarding the effects of occupational licensing); *see also* FTC & DOJ, A DOSE OF COMPETITION, *supra* note 21, ch. 2, at 25 ("Through licensure requirements, states may restrict market entry by physicians and allied health professionals . . . .")

50. *See, e.g.*, LA. REV. STAT. ANN. § 37:925 (violations, penalty). Regarding licensure more generally, *see, e.g.*, Morris M. Kleiner, *Occupational Licensing*, 14 J. ECON. PERSP. 189, 191 (2000) ("Occupational licensing is defined as a process where entry into an occupation requires the permission of the government, and the state requires some demonstration of a minimum degree of competency.").

time of delivery.[51] Without entry standards for medicine or nursing, consumers might have difficulty sorting capable practitioners from charlatans and quacks.[52] For similar reasons, consumers might have difficulty distinguishing between professionals who possess certain basic or general competencies and those with more specialized training and experience, as may be appropriate for particular health needs.[53] In addition, the oversight required for ongoing licensure can help identify seriously impaired or malfeasant practitioners (for example, those who have been sanctioned for repeated malpractice or substance abuse). For these reasons, some types of licensure and scope of practice regulations for health care professionals are in the public

51. *See, e.g.*, Cox & Foster, *supra* note 23, at 5-6, 9-10. In economic terms, licensure-related regulations can be an efficient response to several potential types of market failure, including: information asymmetries between professionals and consumers (as when providers know much more than consumers about both the quality of services at the point of consumption and the potential benefits and risks facing the consumer); costly quality information (as when health care consumers find it difficult to obtain reliable and pertinent quality information about various alternative providers); striking externalities (as when, e.g., there are public health implications of private health care consumption); or professionals serving as both diagnosticians and treatment providers. *Id.; cf.* James C. Cooper, *Public Versus Private Restraints on the Online Distribution of Contact Lenses: A Distinction with a Difference*, 3 J.L. ECON. & POL'Y 331, 343-44 (2007) (with respect to eye care and optical goods, describing consumer reliance on prescribing by eye doctors as due not just to the legal requirement of a prescription but also to consumers' general technical inability to know which contact lenses are most appropriate for their conditions). In his seminal scholarship regarding medical care markets, Arrow considered high information costs and the problem of information asymmetries between buyers and sellers of medical care to be central problems. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 951-52 (1963) ("Uncertainty as to the quality of the product is perhaps more intense here than in any other important commodity.").

52. While licensure and scope of practice regulations may not wholly eliminate quackery and bogus health treatments, the twin histories of medical school and medical licensing requirements help to illuminate why minimum standards are desirable. Certification of medical schools and the development of state licensure acts in the late 19th and early 20th centuries proceeded from serious professional concerns about inadequate institutions and untrained practitioners. For a general account, see W.F. Bynum, *The Rise of Science in Medicine, 1850-1913*, *in* THE WESTERN MEDICAL TRADITION 1800-2000, at 111, 132-35, 165-75 (Bynum et al. eds., 2006).

53. This may be a general concern with the health care professions, distinguishing not just APRNs from physicians but among classes of nurses or doctors. For example, regulations may distinguish licensed practical nurses from registered nurses, registered nurses from APRNs, etc. Analogously, a patient may be well-served by specialty or sub-specialty licensure or certification within medicine if, say she is poorly placed to evaluate a particular doctor's training and experience in cardiac care, but can refer to board certification in cardiology or, jointly, in cardiology and cardiothoracic surgery.

interest.[54] More generally, proponents of licensure also claim that quality of services may be higher in licensed professions.[55]

At the same time, APRN licensure and scope of practice regulations may sometimes restrict competition unnecessarily, which can be detrimental to health care consumers and have broader public health consequences. APRNs are trained, and in most states licensed, to provide a broad range of primary care services that are also provided by primary care physicians; indeed, there is increasing agreement among health authorities that APRNs could safely provide an even broader range of primary care services, if regulatory and reimbursement policies would permit them to do so.[56] Additional scope of practice restrictions, such as physician supervision requirements, may hamper APRNs' ability to provide primary care services that are well within the scope of their education and training. When APRN access to the primary care market is restricted, health care consumers – patients – and other payors are denied some of the competitive benefits that APRNs, as additional primary care service providers, can offer. In addition, to a certain extent, some

54. The suggestion of a net social loss is not often made with regard to physician or nursing licensure in particular, and we do not make it here. *But see generally* Daniel B. Hogan, *The Effectiveness of Licensing: History, Evidence, and Recommendations,* 7 LAW AND HUM. BEHAV. 117 (1983) (arguing that licensure has not effectively accomplished its purpose and that there may be more efficient means to provide for minimum standards and curtail quackery).

55. The consistency or magnitude of this effect has not been generally established. Still, while FTC advocacy comments regarding APRNs raise questions about particular scope of practice limits that may be imposed upon APRNs, they do not question the general utility of scope of practice rules or other types of licensure-related requirements for APRNs or other health care professionals. Arrow, in 1963, suggested both the importance of rigid entry barriers via licensure (at least for medicine), Arrow, *supra* note 51, at 966, and also the notion that "the present all-or-none approach could be criticized as being insufficient with regard to complicated specialist treatment, as well as excessive with regard to minor medical skills." *Id.* at 966-67.

56. The ability of APRNs to provide safe and effective primary care services is a central observation of the IOM report and many other studies. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 4, 8 ("key message" and policy recommendation regarding scope of practice); OTA HEALTH TECH. CASE STUDY, *supra* note 8, at 39-40 ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants]."); *see generally* NGA PRIMARY CARE PAPER, *supra* note 4, at 7-8 (concluding "Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures. Moreover, the studies suggest that NPs may provide improved access to care."); KAISER FAMILY FOUND., IMPROVING ACCESS TO ADULT PRIMARY CARE IN MEDICAID: EXPLORING THE POTENTIAL ROLE OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS (Mar. 2011), http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8167.pdf [hereinafter KAISER FOUND., IMPROVING ACCESS]; MINN. HEALTH CARE REFORM TASK FORCE, ROADMAP TO A HEALTHIER MINNESOTA: RECOMMENDATIONS OF THE MINNESOTA HEALTH CARE REFORM TASK FORCE 25-26 (2012), http://mn.gov/health-reform/images/TaskForce-2012-12-14-Roadmap-Final.pdf.

incumbent physicians may be insulated against the degree of competition APRNs can offer.[57] It may be in the economic self-interest of those physicians to propose and advocate the adoption of restrictions on APRN licensure and scope of practice; and such physicians might be biased towards doing so.[58] Other factors, such as historically entrenched forms of training and care delivery, dated or erroneous beliefs about the training or performance of unfamiliar professions, or even professional bias, may contribute to advocacy on behalf of excessive APRN regulation.[59]

As discussed in greater detail below,[60] a growing body of evidence suggests that APRNs can, based on their education and training, safely perform many of the same procedures and services provided by physicians. Thus, scope of practice restrictions may eliminate APRNs as an important source of safe, lower-cost competition. Such a reduction of competition may lead to a number of anticompetitive effects.[61]

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57. This is true even though APRNs and physicians are not perfect substitutes, and even though many of the services provided by APRNs and physicians are complementary rather than competitive. FTC staff do not suggest that APRN and physician scope of practice should be the same, but that both APRNs and physicians are able to provide an overlapping set of services. "Most observers conclude that most primary care traditionally provided by physicians can be delivered by NPs and PAs." OTA HEALTH TECH. CASE STUDY, *supra* note 8, at 39. *See also* ASS'N OF AMER. MED. COLLS., PHYSICIAN SHORTAGES TO WORSEN WITHOUT INCREASES IN RESIDENCY TRAINING (n.d.), https://www.aamc.org/download/150584/data/physician_shortages_factsheet.pdf [hereinafter AAMC, PHYSICIAN SHORTAGES]. In its projections of physician supply and demand, the AAMC assumes that each additional two NPs (APRNs or physician assistants) reduce physician demand by one, which suggests that APRNs and primary care doctors are actual or potential competitors for at least some set of services.

58. For a general account of the "capture theory" of regulation applied to professionals' interest in limiting entry via licensure, see, e.g., Stigler, *supra* note 48, at 13-14 ("A central thesis of this paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit" *Id.* at 3). *See also* COX & FOSTER, *supra* note 23, at 18-20 (arguing that income is a significant factor in professionals' desire for regulation via licensing); Kleiner, *supra* note 50, at 192 ("The most generally held view on the economics of occupational licensing is that it restricts the supply of labor to the occupation and thereby drives up the price of labor as well as of services rendered."). Recent research regarding other state-licensed professions is "consistent with the hypothesized role by members of an occupation to raise wages by using the powers of government to drive up requirements and capture work for the regulated workers for larger geographic areas." Morris M. Kleiner & Alan B. Kreuger, *Analyzing the Extent and Influence of Occupational Licensing on the Labor Market*, 31 J. LAB. ECON. S173, S198-99 (2013), *available at* http://www.hhh.umn.edu/people/mkleiner/pdf/Final.occ.licensing.JOLE.pdf (finding substantially higher wages associated with licensure of a profession at the state or federal, instead of local, level, adjusting for educational attainment, age, experience, and other variables, consistent with a monopoly theory of licensure).

59. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27, 107-14; Barbara J. Safriet, *Federal Options for Maximizing the Value of Advanced Practice Nurses in Providing Quality, Cost-Effective Health Care*, *in* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 451-57.

60. *See* Section III.B., *infra*.

61. In addition to potential competition concerns when one group of competitors seeks to exclude other competitors via regulation, the question whether or to what extent one professional board may regulate the conduct of another profession sometimes raises other complex legal questions as well. *See, e.g.*, Missouri Ass'n of Nurse Anesthetists v. State Bd. of Registration for the Healing Arts, 343 S.W.3d 348, 358 (Mo. 2011) (Missouri board "without authority to make policies, interpretations or determinations that define the scope of practice for APNs" under Missouri law).

Licensure and scope of practice regulations thus have potential positive and negative consequences for health care consumers. Consumers are protected by assurances that their health care providers meet minimum criteria for education, training, knowledge and skills, which supports critical safety and quality objectives. At the same time, however, when licensure and scope of practice restrictions are broader than necessary to protect patient health and safety, they may increase the cost of APRN-delivered services and impede APRNs' ability to enter the market or expand the range of services they offer. These effects, in turn, may diminish competitive pressures that would otherwise apply to price and quality of some physician-delivered services.

II.B.2. Analysis of Scope of Practice Limitations Should Account for the Value of Competition

Policy changes should be based on the best information available, and decisionmakers should strive to identify and evaluate the potential benefits of laws and regulations as well as their potential costs. We urge that the regulatory review process consider the benefits of competition and the potential adverse competitive impact of regulations, along with other legitimate policy goals.[62]

The approach proposed by FTC staff takes into account the potential competitive impact of professional regulations, as well as any potential countervailing health and safety benefits, the likelihood that the regulations will redress those concerns, and the availability of any less restrictive means of achieving the same legitimate results. This approach also recognizes that competition can work to favor, rather than undermine, health care quality, which means that policymakers do not necessarily have to choose between protecting consumers and promoting competition: increased consumer protection and increased competition can occur at the same time. We urge legislators and policymakers to apply the following analytical framework to evaluate the reasonably available evidence:

- Will the regulation significantly impede competition by, for example, making it more costly or difficult for the regulated group of professionals to enter into competition, or expand their practices, or by otherwise increasing the cost of health care services or reducing their availability?

62. We do not mean to suggest that physician or nursing licensure generally leads to net social loss. Specifically, for purposes of this policy paper, we assume that both a baseline APRN licensing regime and some regulatory limits on APRN scope of practice are necessary and desirable, even where additional scope of practice restrictions may be overly burdensome. *See supra* notes 51-55 and accompanying text. A detailed discussion of the potential competitive harms done by particular undue regulatory restrictions on APRN practice is the subject of Section III.A of this policy paper, *infra*.

- Are there any significant and non-speculative consumer health and safety needs that particular regulatory restrictions, extant or proposed, are supposed to meet?
- Do those particular regulations actually provide the intended benefits – such as improvements in health care outcomes or a reduced risk of harm from poor-quality services – or are there good grounds to think they are likely to provide those benefits?
- Are there other demonstrated or reasonably likely consumer benefits associated with the proposed regulation (e.g., reduced information or transaction costs for consumers who are choosing among providers, reduced consumer confusion in distinguishing among different types of providers, etc.)?
- When consumer benefits are slight, insubstantial, or highly speculative, a regulation that imposes non-trivial impediments to competition is not justified. [63]
- If pertinent consumer harms have occurred, or risks are found to be substantial, is the proposed regulation likely to redress those harms or risks?
- Are the regulations narrowly tailored to serve the state's policy priorities? When particular regulatory restrictions address well-founded consumer protection concerns but – at the same time – appear likely to harm competition, consider whether the regulations are narrowly tailored to address those concerns without undue harm to competition, or whether less restrictive alternatives are available.

The next section of this policy paper explains how FTC staff recommend applying this basic framework to proposed APRN scope of practice regulations. In each of the APRN advocacy comments, FTC staff have identified pertinent market information and suggested how it might fit into a more comprehensive policy analysis. None of these advocacies, however, has attempted to provide a comprehensive cost-benefit analysis of existing or proposed APRN scope of practice rules. State legislators and policymakers – who are most familiar with local markets and consumer needs – are urged to consider which specific pieces of information are relevant to assessing the costs and benefits associated with a policy proposal, as well as the relative weight and importance of various policy priorities of interest to consumers in their jurisdictions.

63. *Cf.* FTC v. Ind. Fed. of Dentists, 476 U.S. 447, 459 ("Absent some countervailing procompetitive virtue . . . . such an agreement limiting consumer choice by impeding the 'ordinary give and take of the marketplace' . . . cannot be sustained . . . ." (internal citations omitted)).

III. APRN SCOPE OF PRACTICE COMPETITION ADVOCACY COMMENTS AND ADDITIONAL ANALYSIS BY FTC STAFF

In the last three years, FTC staff have issued competition advocacy comments analyzing the likely competitive effects of proposed changes to APRN regulations in Massachusetts,[64] Connecticut,[65] West Virginia,[66] Louisiana,[67] Kentucky,[68] Texas,[69] and Florida.[70] All of these comments were requested by state legislators. While each comment considered somewhat different statutory and regulatory restrictions, all of the comments addressed policy proposals regarding mandatory physician supervision of APRN practice or "collaborative practice" requirements that could operate as *de facto* supervision requirements. Some of the proposals would have required additional or heightened supervision of APRNs. Other proposals would have removed or lessened pre-existing requirements that APRNs operate under some specified form of physician supervision to provide some or all of the health care services otherwise within the APRNs' scope of practice, as defined under other state laws and regulations.

Some physician groups have suggested that supervision requirements are justified by the advantages of a team-based approach to health care, and that primary care physicians are best positioned to lead health care teams because they have completed substantially longer programs of education and training than APRNs. For example, a recent report by the American Academy of Family Physicians recommends a "medical home" model of care with a primary care physician

64. FTC Staff Comment Before the Mass. House of Representatives Regarding House Bill 2009 Concerning Supervisory Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 2014), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettnursesletter.pdf [hereinafter FTC Staff Massachusetts Comment].

65. Comment from FTC Staff to the Hon. Theresa W. Conroy, Conn. House of Representatives (Mar. 19, 2013), http://www.ftc.gov/os/2013/03/130319aprnconroy.pdf [hereinafter FTC Staff Connecticut Letter].

66. Written Testimony from FTC Staff to Subcomm. A of the Joint Comm. on Health of the State of W. Va. Legislature (Sept. 10-12, 2012), http://www.ftc.gov/os/2012/09/120907wvatestimony.pdf [hereinafter FTC Staff West Virginia Testimony].

67. Comment from FTC Staff to the Hon. Thomas P. Willmott & Hon. Patrick C. Williams, La. House of Representatives (Apr. 20, 2012), http://www.ftc.gov/os/2012/04/120425louisianastaffcomment.pdf [hereinafter FTC Staff Louisiana APRN Comment].

68. Comment from FTC Staff to the Hon. Paul Hornback, Commonwealth of Ky. State Senate (Mar. 26, 2012), http://www.ftc.gov/os/2012/03/120326ky_staffletter.pdf [hereinafter FTC Staff Kentucky Letter].

69. Comment from FTC Staff to the Hon. Rodney Ellis & Hon. Royce West, Senate of the State of Tex. (May 11, 2011), http://www.ftc.gov/os/2011/05/V110007texasaprn.pdf [hereinafter FTC Staff Texas Letter].

70. Comment from FTC Staff to the Hon. Daphne Campbell, Fla. House of Representatives (Mar. 22, 2011), http://www.ftc.gov/os/2011/03/V110004campbell-florida.pdf [hereinafter FTC Staff Florida Letter].

leading each "patient-centered" team.[71] As noted above, the FTC staff has not questioned the utility of team-based care or the notion that some types of care may require extensive medical training. At the same time, particular supervision requirements can burden, rather than facilitate, team-based care. The FTC staff questions, therefore, whether evidence supports a statutory mandate for some particular model of team-based care that is always led by a primary care physician. The FTC staff also asks whether evidence supports the contention that patients receive substandard care, or are harmed, when the law does not impose specific supervision requirements on APRNs and their patients.

This section of the paper synthesizes the points raised in the seven prior advocacy comments, supplemented by additional FTC research and learning. It sets forth the analytical approach recommended by FTC staff to legislators who are weighing the costs and benefits of these types of physician supervision requirements.

The FTC does not purport to advocate a simple or uniform model for how best to coordinate health care, define the scope of APRN practice, or specify the appropriate role for physician supervision. Ultimately, those decisions must be made by state legislators and regulators, and by health care providers themselves, based on their expertise and the best available evidence. The FTC's role, based on its institutional mission and expertise, is to highlight why, as part of their regulatory review process, policymakers should consider the impact of regulations on competition and consumer protection. Regulatory choices that affect APRN scope of practice may have a direct impact on health care prices, quality, and innovation, often without countervailing benefits.

The discussion below evaluates in greater detail the potential competitive harms that may flow from these types of APRN scope of practice restrictions, as well as the justifications often proffered by their proponents.

71. AMER. ACAD. OF FAMILY PHYSICIANS, PRIMARY CARE FOR THE 21ST CENTURY *i-ii* (2012), http://www.aafp.org/dam/AAFP/documents/about_us/initiatives/AAFP-PCMHWhitePaper.pdf; *cf.* Letter from James L. Madara, Amer. Med. Ass'n, to the Hon. David G. Perry & the Hon. Dan Foster, W. Va. Legislature 2 (Sept. 10, 2012), http://www.ama-assn.org/resources/doc/arc/ama-letter-ftc-wv.pdf ("health care delivery is evolving to a physician-led team approach to ensure better care coordination and outcomes for patients.").

III.A. Potential Competitive Harms from APRN Physician Supervision Requirements

APRN physician supervision requirements raise several related competitive concerns. By restricting APRNs' access to the marketplace, supervision requirements may deprive health care consumers of the many benefits of competition among different types of health care providers. This reduction in competition may exacerbate provider shortages and thereby contribute to access problems, particularly for underserved populations that already lack adequate and cost-effective primary care services. Supervision requirements also can impact the cost and quality of health care services. Finally, rigid "collaborative practice agreement" requirements may be inconsistent with a truly collaborative and team-based approach to health care. Such requirements can impede collaborative care rather than foster it, because they limit what health care professionals and providers can do to adapt to varied health care demands and constrain provider innovation in team-based care.

III.A.1. Restrictive Physician Supervision Requirements Exacerbate Well-Documented Provider Shortages that Could Be Mitigated via Expanded APRN Practice

Expanded APRN practice is widely regarded as a key strategy to alleviate provider shortages, especially in primary care, in medically underserved areas, and for medically underserved populations.[72] Imposing greater restrictions on APRNs will only exacerbate existing and projected health care workforce shortages by limiting the ability of APRNs to fill gaps in patients' access to primary care services.

The United States faces a substantial and growing shortage of physicians, especially primary care physicians, which has significant consequences for basic health care access for many American

72. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27-28; *see also* EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 100 ("Given widespread agreement that there is a critical shortage of primary care physicians in the Commonwealth, expanding scope-of-practice laws could be a viable mechanism for increasing primary care capacity and reducing health care costs." *Id.*); MINN. HEALTH CARE REFORM TASK FORCE, *supra* note 56, at 25-26 (remove regulatory barriers to APRN practice and expand supply of primary care practitioners, including APRNs); NGA PRIMARY CARE PAPER, *supra* note 4, at 11 ("Expanded utilization of NPs has the potential to increase access to health care, particularly in historically underserved areas.") We do not suggest that reforming APRN scope of practice restrictions is a panacea for primary care access problems in the U.S. Rather, reducing undue restrictions on APRN scope of practice can be one significant way to help ameliorate existing and projected access problems. *Cf.* David I. Auerbach et al., *Nurse-Managed Health Centers and Patient-Centered Medical Homes Could Mitigate Expected Primary Care Physician Shortage*, 32 HEALTH AFFAIRS 1933, 1938-40 (2013) (projected shortages very unlikely to be met by increase in number of primary care practitioners under current delivery models, but can be substantially alleviated by increased use of, e.g., nurse managed health centers, which depend on changes in scope of practice restrictions, among other things).

consumers.[73] Beyond aggregate or average projected shortages, the United States suffers from widespread distributional problems in the supply of health care professionals.[74] Reduced access has the greatest impact on America's poorest citizens, including Medicaid beneficiaries. Physicians are less likely to practice in low-income areas or to participate in state Medicaid programs.[75] Rural communities, too, are particularly vulnerable to provider shortages and access problems.[76] According to the U.S. Department of Health and Human Services, by late 2013 there were approximately 5,800 primary care Health Professional Shortage Areas (HPSAs) in

73. *See* BUREAU OF HEALTH PROFESSIONS, HEALTH RESOURCES & SERVS. ADMIN., THE PHYSICIAN WORKFORCE: PROJECTIONS AND RESEARCH INTO CURRENT ISSUES AFFECTING SUPPLY AND DEMAND 70-72, ex. 51-52 (2008), http://bhpr.hrsa.gov/healthworkforce/reports/physwfissues.pdf [hereinafter HRSA PHYSICIAN WORKFORCE REPORT] (projecting increased shortages of both primary care physicians and specialists); KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1 (by 2020 "the U.S. States will face an estimated shortage of 91,000 physicians, split about evenly between primary care physicians and specialists); AAMC, PHYSICIAN SHORTAGES, *supra* note 57, at 1 (projected shortfall of approximately 45,000 primary care physicians and 46,000 specialists in the next decade). For a searchable database of HRSA Medically Underserved Areas and Populations ("MUA/P"), *see Find Shortage Areas: MUA/P by State and County*, HEALTH RESOURCES & SERVS. ADMIN., http://muafind.hrsa.gov/index.aspx (last visited Nov. 7, 2013) [hereinafter HRSA MUA/P Database]. These projected shortages are important for present concerns and others. We note, however, that such projections of health care needs are, however pertinent, not quite the same as projections of aggregate demand.

74. *See generally Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/ Populations,* HEALTH RESOURCES & SERVS. ADMIN., http://www.hrsa.gov/shortage/ (last visited Nov. 19, 2013) ("As of November 14, 2013: There are currently approximately 5,800 designated Primary Care HPSAs [health professional shortage areas]."); *Primary Care Workforce Facts and Stats,* AGENCY FOR HEALTHCARE RESEARCH & QUALITY, http://www.ahrq.gov/research/findings/factsheets/primary/pcwork3/index.html (last visited Nov. 21, 2013) ("Uneven geographic distribution of the health care workforce creates problems with access to primary care."); *cf.* Scott A. Shipman et al., *Geographic Maldistribution of Primary Care for Children*, 127 PEDIATRICS 19, 19 (2011) ("Undirected growth of the aggregate child physician workforce has resulted in profound maldistribution of physician resources.").

75. *See* KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1; DOWER & O'NEIL, *supra* note 30, at 7 ("Physician supply is lower in communities with high proportions of minority and low-income residents with greater health needs, known as the "inverse care law.")

76. *See generally* CTR. WORKFORCE STUDIES, AMER. ASS'N MED. COLLS., RECENT STUDIES AND REPORTS ON PHYSICIAN SHORTAGES IN THE US (Oct. 2012), https://www.aamc.org/download/100598/data/ (reviewing 33 state reports on physician shortages, 16 national reports on physician shortages, and 22 specialty shortage reports).

the United States.[77] It has been estimated that approximately sixty-five million Americans live in such officially designated shortage areas.[78]

In many areas, those shortages are expected to persist or worsen, especially in light of health care reform efforts that will enable many more Americans to obtain health care insurance.[79] As a result, millions of Americans soon will have a greater ability to pay for health care – especially routine primary care and preventive services they currently do without[80] – but it is unclear how the existing population of practitioners can meet this increasing demand.[81]

Each of the seven FTC staff advocacy comments cites state-specific data to underscore national concerns about access to care. In Louisiana, for example, FTC staff noted that

77. *Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations*, HEALTH RESOURCES & SERVS. ADMIN., http://www.hrsa.gov/shortage/ (last visited Feb. 3, 2014) (estimating that approximately 7,500 additional primary care physicians would be required to change these HPSA designations, based on a population to practitioner ratio of 3,500:1. HRSA had previously estimated shortages of about 16,000 primary care physicians based on a different model, and continues to recognize that other sources and models suggest higher shortage numbers); *see also* HRSA PHYSICIAN WORKFORCE REPORT, *supra* note 73, at 70-72; KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1 (inadequate supply of primary care providers is one of the "major health care challenges facing the U.S. today"; and it is estimated that "U.S. will face an estimated shortage of 91,000 physicians, split about evenly between primary care physicians and specialists," by 2020.).

78. Thomas Bodenheimer & Hoangmai H. Pham, *Primary Care: Current Problems and Proposed Solutions, 29* HEALTH AFFAIRS 799 (2010) ("Sixty-five million Americans live in what are officially deemed primary care shortage areas, and adults throughout the United States face difficulty obtaining prompt access to primary care.")

79. That is, broader coverage will increase the demand for health care services, independent of its other effects. *See, e.g.*, KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 1 ("Under health reform, the pressures on access are certain to grow as millions of newly insured people enter the health care system.").

80. *See* HRSA PHYSICIAN WORKFORCE REPORT, *supra* note 73, at 70-74 (projected physician shortages will be even worse if ability to pay for care and public expectations of care increase). A number of studies have sought to estimate the extent to which health care reform – including the Patient Protection and Affordable Care Act (ACA) – is likely to exacerbate primary care provider shortages. All of these studies project substantial shortages, but their estimates differ. *See, e.g.*, Adam N. Hofer et al., *Expansion of Coverage under the Patient Protection and Affordable Care Act and Primary Care Utilization*, 89 MILBANK Q. 69, 84 (2011) (estimating predicted demand for primary care utilization stimulated by ACA and predicting 2019 shortfall of 4,307-6,940 primary care physicians, subject to "considerable" geographic variation); Elbert S. Huang & Kenneth Finegold, *Seven Million Americans Live in Areas Where Demand for Primary Care May Exceed Supply by More Than 10 Percent*, 32 HEALTH AFFAIRS 1 (2013); Stephen M. Petterson et al., *Projecting US Primary Care Physician Workforce Needs: 2010-2025*, 10 ANNALS FAMILY MED. 503, 506-07 (2012) (projecting 2025 shortfall of 52,000 primary care physicians, based on increased coverage and, to greater extent, population growth and aging of population). Ku et al. estimate state-by-state primary care needs based on projections for expanded Medicaid populations. Leighton Ku et al., *The States' Next Challenge – Securing Primary Care for Expanded Medicaid Populations*, 364 NEW ENG. J. MED. 493 (2011).

81. Auerbach et al., *supra* note 72, at 1937-40 (projecting continued shortages of primary care practitioners, despite upswing in primary care medical residencies, if delivery models and scope of practice remain constant).

> more than half of Louisiana's population lives in a federally-designated [HPSA]. All 64 Louisiana Parishes contain HPSAs, and 53 entire Parishes comprise primary care shortage areas. An estimated 765,000 Louisianans – more than 17 percent of the State's population – lack health insurance.[82]

FTC staff cited a Louisiana Department of Health and Hospitals report indicating that "[s] hortages affecting the accessibility and availability of primary-care physicians . . . pose a significant problem in the delivery of healthcare in Louisiana."[83] Staff also cited state-specific sources projecting that health care reform would exacerbate shortages as more Louisiana consumers gain health insurance and seek access to primary health care services.[84] FTC staff have raised analogous concerns about existing professional shortages and access to basic health care services in other APRN advocacy materials.[85]

Health policy experts have long considered the role APRNs might play in alleviating provider shortages, particularly if APRNs are subject to fewer and less costly restrictions. For example, in 1986, what was then the U.S. Congress Office of Technology Assessment observed,

> The use of nurse practitioners (NPs) and physician assistants (PAs) to provide primary health care traditionally provided only by physicians developed during the 1960s in response to a perceived shortage and maldistribution of physicians. Societal support for this innovation in the delivery of health-care was based on the

82. FTC Staff Louisiana APRN Comment, *supra* note 67, at n.25-28 and accompanying text (internal citations omitted). *See also Primary Care: State Profiles*, NAT'L CONFERENCE OF STATE LEGISLATURES, http://www.ncsl.org/issues-research/health/primary-care-state-profiles.aspx (last updated Nov. 2011) (map indicating Louisiana as one of three states with 49-62% of population in HPSA); *Find Shortage Areas: HPSA by State and County*, HEALTH RESOURCES & SERVS. ADMIN., http://hpsafind.hrsa.gov/HPSASearch.aspx (last visited Nov. 7, 2013).

83. OFFICE OF PUB. HEALTH, LA. DEP'T OF HEALTH AND HOSPITALS, 2009 LOUISIANA HEALTH REPORT CARD 203 (2010), http://new.dhh.louisiana.gov/assets/oph/Center-RS/healthstats/DHHHlthCreRprtCrd_2009.pdf; *id.* at 224-26 (describing large majority of state as "health professional shortage area" under LA criteria as well as federal MUA/P criteria); Bureau of Primary Care & Rural Health, *Primary Care HPSA Map of Louisiana*, LA. DEP'T OF HEALTH AND HOSPITALS (Oct. 3, 2012), http://new.dhh.louisiana.gov/assets/oph/pcrh/10-03-2012_PC_MAP.jpg (indicating primary care shortages in most of state); HRSA MUA/P Database, *supra* note 73 (indicating shortage areas throughout Louisiana's 64 Parishes according to HRSA MUA/P criteria).

84. FTC Staff Louisiana APRN Comment, *supra* note 67, at 2 (citing LA. CTR. FOR NURSING, LA. STATE BD. OF NURSING, NURSING WORKFORCE DEMAND REPORT, 1, 3 (2012)). The FTC staff letter supported a bill that would have reduced supervision requirements for certain APRNs practicing in medically underserved areas or treating underserved populations.

85. *See, e.g.*, FTC Staff Massachusetts Comment, *supra* note 64, at 1-2, 4-5; FTC Staff West Virginia Testimony, *supra* note 66, at notes 23-25 and accompanying text; FTC Staff Kentucky Letter, *supra* note 68, at notes 21-24 and accompanying text; FTC Staff Texas Letter, *supra* note 69, at 4 n.21 and accompanying text; FTC Staff Florida Letter, *supra* note 70, at 2 n.6, 4 n.19, 5 n.24 and accompanying text; FTC Staff Connecticut Letter, *supra* note 65, text accompanying notes 20-30.

> potential for NPs and PAs to improve access and to lower costs while maintaining the quality of care.[86]

Moreover, although "[m]ost observers conclude that most primary care traditionally provided by physicians can be delivered by NPs and PAs,"[87] OTA also observed that APRNs (NPs) faced certain obstacles in meeting emerging demands for their services, such as such as physician opposition and restrictive state laws and regulations.[88]

For similar reasons, the IOM and other expert bodies continue to recommend that access problems be addressed – at least in part – by increased reliance on APRNs.[89] APRNs are the fastest-growing segment of the primary care professional workforce in the United States. Between the mid-1990s and the mid-2000s, the number of APRNs per capita grew an average of more than nine percent annually, compared with just one percent per capita growth for primary care physicians.[90] A recent study suggests that the supply of APRNs should roughly double by 2025.[91]

APRNs provide a broad range of primary care services and are responsible for a significant share of primary care in the United States. A 2008 CDC study noted that, by 2006, patients saw an APRN, NMW, or PA at sixteen percent of U.S. primary care visits, with nearly twelve percent of such patient visits attended *solely by an APRN, NMW, or PA.* [92] Today, APRNs "are

86. OTA HEALTH TECH. CASE STUDY, *supra* note 8, at 3; *see generally id.* at 29-32.

87. *Id.* at 39.

88. *Id.* at 3.

89. *See supra* note 72 and accompanying text.

90. *See* KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 3; *see also* Yong-Fang Kuo et al., *States with the Least Restrictive Regulations Experienced the Largest Increase in Patients Seen by Nurse Practitioners*, 32 HEALTH AFFAIRS 1236, 1236 (2013) (increase in number of practicing NPs and training programs over past two decades); AAMC, PHYSICIAN SHORTAGES, *supra* note 57, at 1 (projecting shortage of approximately 45,000 primary care physicians over next decade, and noting that "the impact will be most severe on vulnerable and underserved populations. These groups include the approximately 20 percent of Americans who live in rural or inner-city locations designated as health professional shortage areas.").

91. David I. Auerbach, *Will the NP Workforce Grown in the Future, 50* MED. CARE 606 (2012) (projecting 94% increase in practitioners with APRN or NP training, and 130% increase in those identifying themselves with "NP" title).

92. ESTHER HING ET AL., CDC NATIONAL HEALTH STATISTICS REPORT NO. 4, NATIONAL AMBULATORY MEDICAL CARE SURVEY: 2006 OUTPATIENT DEPARTMENT SUMMARY 6 (2008), http://www.cdc.gov/nchs/data/nhsr/nhsr004.pdf.

the most common non-physician health care providers of primary care services,"[93] and they provide a large number of primary care services – independently in some states, and subject to collaborative practice agreements or supervision requirements in other states.[94] APRNs "[t]ake health histories and provide complete physical exams; diagnose and treat acute and chronic illnesses; provide immunizations; prescribe and manage medications and other therapies; order and interpret lab tests and x-rays; provide health teaching and supportive counseling."[95]

As primary care provider shortages have worsened, APRNs have played an even greater role in alleviating the effects of shortages and mitigating access problems. For example, APRNs make up a greater share of the primary care workforce in less densely populated areas, less urban areas, and lower income areas, as well as in HPSAs.[96] Relative to primary care physicians, APRNs are more likely to practice in underserved areas and care for large numbers of minority patients, Medicaid beneficiaries, and uninsured patients.[97] In addition, the shorter and less costly education and training requirements of APRN practice suggest that APRNs may be able to meet

93. NGA PRIMARY CARE PAPER, *supra* note 4, at 4. One recent study, based on Medicare billing data, suggests 9.5% growth in the number of Medicare patients seen by NPs, from 1998 to 2010. Kuo et al., *supra* note 90, at 1238. An April, 2013 Berkeley Forum Report suggests a roughly 10% NP share of primary care visits in the state, with data from other states ranging from 5.1% (New Jersey) to 29.8% (Missouri). BERKELEY FORUM, UNIV. OF CALIFORNIA, BERKELEY, A NEW VISION FOR CALIFORNIA'S HEALTHCARE SYSTEM: INTEGRATED CARE WITH ALIGNED FINANCIAL INCENTIVES app IX, at 7 (2013) ("Nurse Practitioners & Physician Assistants (Initiative Memorandum)").

94. NGA PRIMARY CARE PAPER, *supra* note 4, at 1 ("Research suggests that NPs can perform many primary care services as well as physicians do.").

95. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 27; *see also* NGA PRIMARY CARE PAPER, *supra* note 4, at 4 (NPs "provide comprehensive services"); EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 99 (enumerating range of NP services).

96. *See, e.g.*, Christine M. Everett et al., *Division of Primary Care Services Between Physicians, Physician Assistants, and Nurse Practitioners for Older Patients with Diabetes*, 70 MEDICAL CARE RES. & REV. 531, 536-37 (2013) ("Panels with PAs/NPs as usual providers appear to have a higher proportion of socially complex patients, when defined according to poverty (Medicaid), disability, and comorbid dementia and depression."); KAISER FOUND., IMPROVING ACCESS, *supra* note 56, at 3; IOM FUTURE OF NURSING REPORT, *supra* note 2, at 107-08; Christine M. Everett et al., *Physician Assistants and Nurse Practitioners as Usual Sources of Primary Care*, 25 J. RURAL HEALTH 407, 408 (2009).

97. *See, e.g.*, Everett et al., *Division of Primary Care Services*, *supra* note 96, at 5 ("participants without insurance or on public insurance other than Medicare had 1.71 times the odds of reporting utilizing at AP/NP"; and observing that women were 1.77 times more likely to recognize a PA/NP as their usual source of care as men); *see also* Michael J. Dill, et al., *Survey Shows Consumers Open to a Greater Role for Physician Assistants and Nurse Practitioners*, 32 HEALTH AFFAIRS 1135, 1137-38 (2013) (women less likely to see APRN than men, and "[w]hites were less likely than other racial or ethnic groups to have reported seeing a physician assistant or nurse practitioner for their most recent medical care, and the most likely to have never seen one.").

fluctuations in demand more quickly or efficiently than the medical profession, at least for some health care needs.[98]

APRNs in many states already strive to fill the widening gap between demand and supply for health care services. To the extent that legislators and regulators reduce unnecessary limits on APRN scope of practice, populations facing shortages of primary care professionals may see those shortages diminished. Consider the overlapping set of health care services that – independent of regulatory restrictions – could be supplied by both physicians and APRNs. Relaxing the regulatory limits on APRN scope of practice will tend to expand the supply of providers who are willing and able to offer those services at any given price. Either of two sorts of regulatory changes might expand supply. First, to the extent that scope of practice rules are changed to permit APRNs to deliver a given type of service they were trained to provide, but were previously prohibited from providing, the population of providers will increase for that service. Second, when the APRN scope of practice already includes a given service, but the regulatory costs of APRN service provision are lowered (e.g., by removing particular physician supervision requirements), the supply of professionals willing to offer those services at any given price will increase. In underserved areas and for underserved populations, the benefits of expanding supply are clear: consumers will have access to services that were otherwise unavailable. Even in well-served areas, the supply expansion will tend to lower prices for any given level of demand, thus lowering healthcare costs.

The National Governors Association (NGA) recognized the impact of this supply expansion in its paper, "The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care,"[99] which emphasized APRNs' critical role in expanding access to care and also echoed many of the other themes in FTC staff's scope of practice competition advocacy comments. The NGA paper specifically noted that

> [t]he demand for primary care services in the United States is expanding as a result of the growth and aging of the U.S. population and the passage of the 2010 [Patient Protection and Affordable Care Act], and this trend is expected to continue over the next several years. NPs may be able to mitigate projected shortages of primary

98. Dill et al., *supra* note 97, at 1135 (2013) (citing shorter training period and greater flexibility to shift specialties as reasons to think APRNs and PAs may be especially suited to filling gaps in access to health care). *But cf.* Auerbach et al., *supra* note 72, at 1938-40 (recognizing some efficiencies in APRN and other nurse training, but nonetheless projecting continued primary care shortages *unless* balance of delivery models change to include greater use of nurse managed care.).

99. NGA PRIMARY CARE PAPER, *supra* note 4.

> care services. . . . Expanded utilization of NPs has the potential to increase access to health care, particularly in historically underserved areas.[100]

Conversely, when additional and unnecessary restrictions are imposed on APRNs, access problems are more likely to be exacerbated, with patients deprived of basic care. One study suggests that relatively stringent APRN scope of practice rules are associated with fewer per capita practitioners,[101] and analogous evidence has been developed regarding restrictions on specialized APRNs[102] and other non-physician health care providers.[103] A recent study attempts to assess, at least for Medicare patients, the share of primary care treatment undertaken by APRNs or NPs, depending on the state regulatory environment in which they practice.[104] We encourage additional empirical research regarding the effects of alternative scope of practice regulations on access to primary care in underserved areas, and for underserved populations, as well as research regarding the health effects associated with changes in access.

III.A.2. Excessive Supervision Requirements May Increase Health Care Costs and Prices

When particular physician supervision requirements are required for APRN practice, some costs are imposed on both the supervising physician and the supervised APRN. Similarly, when an APRN is required to secure and maintain a collaborative practice agreement with a physician in

100. *Id.* at 11.

101. Sekscenski et al., *supra* note 32.

102. *See id.* (regarding NMWs); Eugene R. Declercq et al., *State Regulation, Payment Policies, and Nurse-Midwife Services*, 17 HEALTH AFFAIRS 190 (1998) (NMW rules "supportive" of practice associated with increased distribution of NMWs and NMW services).

103. For example, some research regarding state dentistry regulations suggests that increasingly stringent licensing requirements may not be associated with better dental health outcomes, but may be associated with fewer dentists per capita. Morris M. Kleiner & Robert T. Kurdle, *Does Regulation Effect Economic Outcomes? The Case of Dentistry*, 43 J. LAW & ECON. 547, 575-76 (2000). *But cf.* Arlene Holen, Pub. Research Inst., Ctr. for Naval Analyses, The Economics of Dental Licensure (1978), *available at* http://www.cna.org/sites/default/files/research/0203440000.pdf (finding some positive correlation between stringency of certain dental rules and a proxy for quality of care – lower average malpractice insurance rates – although reaching no conclusions about net benefits).

104. Kuo et al., *supra* note 90, at 1238-40 (study based on 5% sample of Medicare claims data). For various reasons, particular treatments conducted by APRNs may not be accurately reflected in the claims data. *See* David I. Auerbach, *Nurse Practitioner Billing Practices Could Obscure True Numbers,* Reply to Kuo, et al., HEALTH AFFAIRS ONLINE (JULY 2013), http://content.healthaffairs.org/content/32/7/1236/reply.

order to practice independently,[105] at least some costs are imposed on both contracting parties.[106] Either sort of cost may harm patients, to the extent that higher costs diminish access to care, and may harm health care consumers, as well as public and private third-party payors to the extent that some increased costs may be passed along as higher prices. These concerns should be considered against the backdrop of the general issue of supply expansion (or contraction), as explained above. Moreover, we note that APRNs tend to be relatively low cost providers, which might enhance savings associated with a supply expansion.[107]

Typically, such laws require an APRN to secure an agreement with a particular licensed physician in order to engage in some or all of the APRN's otherwise permitted practice. Those requirements can be akin to physician supervision requirements. Independent of his or her education, training, certification, and experience, an APRN can practice only on terms acceptable to a particular licensed physician. Depending on the particular statutory requirements, those terms might include, for example, the number of times the physician reviews the APRN's charts, the frequency with which, or situations in which, the APRN will consult with the physician, or the physician's approval of the APRN's practice plans or protocols.[108] Each transaction to secure an agreement imposes costs on both the APRN and the physician. Compliance with the contract also can imply costs and benefits for both parties.[109]

It is important to remember that collaboration and professional oversight are the norm in states that do not require direct physician supervision or "collaborative practice" agreements. Patterns

105. For purposes of this policy paper, "independent" APRN practice means the APRN is neither employed nor directly supervised by a physician.

106. *See, e.g.*, LA. REV. STAT. ANN. § 37:913(8)-(9) (2012); KY. REV. STAT. § 314.042; W. VA. CODE § 30-7-15a; FTC Staff Connecticut Letter, *supra* note 65, text accompanying notes 32-37. Although costs are imposed on both parties, the immediate impact is asymmetrical: it largely disfavors APRNs. Hence, physicians may tend to be less concerned about these regulatory costs.

107. A study conducted for the Commonwealth of Massachusetts by the RAND Corporation suggests concrete savings that might be associated with expanded APRN (and PA) scope of practice, due to the lower costs and prices that tend to be associated with APRN-delivered services: "between 2010 and 2020, Massachusetts could save $4.2 to $8.4 billion through greater reliance on NPs and PAs in the delivery of primary care." EIBNER ET AL., MASSACHUSETTS REPORT, *supra* note 6, at 103-04 (describing conditions for upper and lower bound estimates and projections). A California report by the Berkeley Forum estimates that expanded use of APRNs and PAs, facilitated by scope of practice and reimbursement reform, should result in a "healthcare expenditure decrease of between $1.4 billion and $1.8 billion in current-year dollars from 2013-2022," in that state. BERKELEY FORUM, *supra* note 93, at 2.

108. A summary table of supervisory requirements, state by state, can be found at IOM FUTURE OF NURSING REPORT, *supra* note 2, at 157-61 (annex 3-1, table 3-A1).

109. This cost assumption presumes that the physician is required to provide certain services to the APRN, and invest time in supervising the APRN, as part of the collaborative practice agreement. This may not always be the case, however. *See infra*, text accompanying notes 113-114.

of collaboration are independently established by institutional providers, from large hospital systems to small physician practices, to individual practitioners, with the particulars varying according to resources and demands at the point of service.[110] Health and safety standards may be established by the professions themselves, institutional providers, health and safety regulators, and the courts.[111] Individual APRNs – even those practicing independently – can and do refer patients to physicians or hospitals. They also may choose to consult or collaborate with physicians where the APRNs (and professional standards) deem it useful or important, and they may develop models of consultation and collaboration that they and collaborating physicians deem useful or important, under terms agreeable to all collaborating parties. None of our questions about the costs (or benefits) of particular legal or regulatory requirements is meant to impugn any privately implemented model of professional collaboration or oversight.

However, to the extent that a "collaboration" agreement covers physician services for which neither party would choose to contract, absent a regulatory requirement, and for which there are no good grounds to suppose that health and safety benefits accrue to patients, those costs are unnecessary. Some of these added costs may be passed on to individual health care consumers, as well as public and private third-party payors.

These types of "collaboration" and supervision requirements establish physicians as gatekeepers who control APRNs' independent access to the market. Thus positioned, some physicians may simply refuse to enter into such agreements, which could effectively preclude certain APRNs from practicing at all. Other physicians may be willing to form agreements, but may offer prices and other terms that are not competitive; they may be particularly able to do so in markets where potential supervising physicians are in short supply and where APRNs must contract to work at all. Hence, the prices APRNs must pay to obtain collaborative practice agreements may tend to rise, even where the APRNs can find physicians with whom to contract. Consequently, some APRNs who manage to secure mandatory collaboration agreements may pay more for them than

110. It has been reported that more than half of all nurse practitioners are employed in private physician practices (27.9%) or hospitals (24.1%), among other institutional provider settings. John K. Iglehart, *Expanding the Role of Advanced Practice Nurse Practitioners – Risks and Rewards, 368* N. ENGL. J. MED. 1935, 1937 (2013).

111. Regarding diverse practice settings and APRN collaboration, see IOM FUTURE OF NURSING REPORT, *supra* note 2, at 23, 58-59, 65-67, 72-76; INST. OF MED., NAT'L ACAD. OF SCIENCES, DELIVERING HIGH QUALITY CANCER CARE: CHARTING A NEW COURSE FOR A SYSTEM IN CRISIS, 171-81 (2013) (importance of and different approaches to team-based care in cancer treatment, and roles of APRNs). Regarding the evolution and diversity of team-based care, see generally Pamela Mitchell et al., Nat'l Acad. of Sciences, Inst. of Med. Discussion Paper, *Core Principles & Values of Effective Team-Based Health Care* (2012), http://www.iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Team-Based-Care-Principles-Values.pdf (IOM-sponsored inquiry into collaborative or team-based care).

they would in independent practice states. Those APRNs are likely to try to pass the increased costs along to their patients or third-party payors, potentially raising the prices of APRN services and further insulating physicians from price competition.[112]

Competitive harm is especially likely when state law requires an independently-practicing APRN to secure a physician collaboration agreement, and allows a physician to charge a fee for this agreement, but does not specify any particular services that the physician must provide under the agreement, such as chart review or availability for consultation.[113] In extreme cases, a physician may charge a high fee to enter into an agreement that neither promises nor delivers value in return.[114] The APRN may obtain a signature and thereby secure the state's permission to practice, but the APRN receives no other administrative benefits, and the APRN's patients do not receive whatever health or safety benefits might be associated with substantial physician input or oversight. The added costs imposed on the APRN and patients are real, but with no clinical benefits to justify the cost.

FTC staff have seen some evidence that the costs of collaborative practice agreements, including prices paid by APRNs to physicians, may be especially high in markets exhibiting certain characteristics.[115] For example, APRNs may find it particularly difficult to form such contracts in rural or other underserved areas where collaborating physicians are in short supply.[116] As

112. As discussed above, price competition can be enhanced simply by increasing the supply of health care practitioners who offer a given service or set of services (and in that sense, compete). *See* pp. 27-28, *supra*. We note, in addition, that APRNs often tend to be lower-cost providers. Of course, for any professional or provider (and throughout health care), the ability to pass increased costs along may be subject to pressures from, and reimbursement choices of, payors. Still, constraints on the provider/practitioner (supply) side limit options on the payor (demand) side.

113. *See, e.g.*, FTC Staff Louisiana APRN Comment, *supra* note 67, at n.18 and accompanying text; FTC Staff West Virginia Testimony, *supra* note 66, at n.20 and accompanying text.

114. See *supra* note 109.

115. For example, the Louisiana comment notes that, according to information submitted by the Louisiana legislators who requested FTC input, "APRNs often must pay ten to forty-five percent of their collected fees to physicians for entering into collaborative practice agreements." FTC Staff Louisiana APRN Comment, *supra* note 67, at 5 (citing letter from Louisiana State Representatives Willmott & Williams); *see also* FTC Staff West Virginia Testimony, *supra* note 66, at n.33 and accompanying text; FTC Staff Kentucky Letter, *supra* note 68; FTC Staff Connecticut Letter, *supra* note 65, at 5. We are not suggesting that any particular fee is appropriate to some particular collaborative agreement. Rather, we are pointing to ad hoc reports of fees that seem high relative to the services actually provided, on top of general competitive concerns about the way such agreements are negotiated.

116. There may be an absolute shortage of practitioners available to supervise APRNs, or a *de facto* shortage may arise when physicians are restricted in the number of APRNs with whom they may collaborate. *See* IOM Future of Nursing Report, *supra* note 2, at 157-61, Table 3-A1 (state-by-state requirements for physician supervision, collaborative practice, or other physician involvement in APRN practice).

explained above, under these circumstances, the prices physicians charge for collaborative agreements may tend to rise, or the quantity or quality of collaborative input may tend to fall.[117]

In some cases, the costs imposed on independent APRNs seeking collaborative practice agreements may be prohibitive, destroying the economic viability of an existing APRN practice or deterring entry by others. The viability of an APRN practice also may be compromised by uncertainty or instability in states where APRNs must obtain collaborative agreements in order to practice, but physicians retain the power to terminate agreements at will and without cause, or may simply refuse to renew them.[118] In addition, all independent APRNs subject to collaboration agreement requirements face challenges if their collaborating physician moves, retires, or dies and they cannot quickly find a substitute physician willing to sign a collaborative practice agreement.[119]

III.A.3. Fixed Supervision Requirements May Constrain Innovation in Health Care Delivery Models

As the health care marketplace evolves, new models of provider organization and collaboration typically represent an important form of innovation in health care delivery and quality.[120] Proponents of team-based care have recognized the importance of innovation in this area, and the diversity of approaches to team-based care that may be successful in different practice settings, or in treating different patient populations.[121] In general, laws and regulations should promote rather than limit this kind of innovation. Rigid physician supervision requirements not only inhibit competition by independent APRNs, but also may constrain the ability of physician

117. *See supra* notes 112-14 and accompanying text; *see also, e.g.*, FTC Staff Louisiana APRN Comment, *supra* note 67, at 3, 5. Where potential supervising physicians may be in short supply and high demand, physicians may have little incentive to compete for collaborative practice agreements. That may result not only in higher prices charged to enter into such agreements, but also in less pressure to offer higher quality contract terms (frequency of chart review, availability for consultation, etc.) in agreements into which they do enter.

118. FTC Staff Kentucky Letter, *supra* note 68, at 4; FTC Staff West Virginia Testimony, *supra* note 66, at 5.

119. FTC Staff Louisiana APRN Comment, *supra* note 67, text accompanying note 23 (citing letter from Louisiana Representatives Willmott & Williams); *cf.* FTC Staff Kentucky Letter, *supra* note 68, at 4 (difficulty contracting and instability when physician can revoke agreement at will); FTC Staff West Virginia Testimony, *supra* note 66, at 5.

120. *See* IOM Future of Nursing Report, *supra* note 2, at 92-94 (regarding APRN primary care initiatives at the Department of Veterans Affairs, Geisinger Health System, and Kaiser Permanente); IOM, Delivering High Quality Cancer Care, *supra* note 111, at 171-81 (importance of team-based approaches generally and models of team-based care employing APRNs at, e.g., the University of Pennsylvania and Memorial-Sloan Kettering Cancer Center); *cf.* Mitchell et al., *supra* note 111 (IOM-sponsored inquiry into collaborative or team-based care generally).

121. Mitchell et al., *supra* note 111, at 3; *Id.* at 6 ("Each health care team is unique—it has its own purpose, size, setting, set of core members, and methods of communication.").

practices, hospitals, retail clinics, and other providers to experiment with flexible oversight and collaboration arrangements for employed or otherwise-affiliated APRNs.

Health care providers that employ or contract with APRNs typically develop and implement their own practice protocols and their own team-based collaboration and supervision protocols, to promote improved quality of care, satisfy their business objectives, and comply with applicable regulatory requirements.[122] They do so independent of the question whether their states impose particular supervision or "collaboration" strictures. Rigid supervision requirements – imposed by statute or regulation – can arbitrarily constrain this type of innovation, as they can impose limits or costs on new and beneficial collaborative arrangements, limit a provider's ability to accommodate staffing changes across central and satellite facilities or preclude some provider strategies altogether.[123] For example, if supervision requires a specific written agreement between an individual APRN and an individual physician,[124] or restricts the number of APRNs a physician may supervise,[125] providers may be constrained in their ability to develop and implement more variable or flexible models of team-based care, consultation, and oversight, according to patient needs and institutional needs and resources.[126] In addition, as addressed in FTC staff's Florida comments, restrictions on the permissible physical distance between APRNs and supervising

122. *See id.*; Julie Sochalski & Jonathan Weiner, *Health Care System Reform and the Nursing Workforce: Matching Nursing Practice and Skills to Future Needs, Not Past Demands*, *in* IOM FUTURE OF NURSING REPORT, *supra* note 2, at app. F.

123. *See* Julie Fairman, *Factors Influencing Value – Enhancing Entrepreneurship in Health Care Delivery* (RAND Policy Symposium, Oct. 4, 2011). We recognizing that not all such requirements are costly or limiting for all providers and that, there may be practical limits to effective supervision, wherever some form of supervision is desirable.

124. *See, e.g.*, LA. REV. STAT. ANN. § 37:913(3)(a) (2012); *see also* LA. ADMIN. CODE tit. 46, pt. XLVII, § 4505 (2012).

125. *See, e.g.*, MO. CODE REGS. ANN. TIT. 20 § 2150-5.100 (2) (D) (no more than 3 APRNs per collaborating physician); FLA. STAT. § 458.348(4)(a)-(b) (restricting number of offices primary and specialty care physicians may supervise). FTC staff recognize that there may be practical limits to effective supervision of APRNs by physicians (assuming such supervision is sometimes needed), and these kinds of limitations may make sense under particular circumstances. Indeed, some APRNs might welcome them. It might sometimes be important that a physician (or specialist, or sub-specialist) is in the same room, the next room, or at least quickly accessible in the same building. We question, however, whether these kinds of limitations are inherently beneficial in all contexts, such that there is a legitimate basis to impose them arbitrarily across the board, as these regulations do.

126. *Cf.* Christine Everett et al., *Physician Assistants and Nurse Practitioners Perform Effective Roles on Teams Caring for Medicare Patients with Diabetes*, 32 HEALTH AFFAIRS 1942, 1946-47 (2013) (analyzing diabetes quality of care indicators according to profession of caregiver and finding that local factors, including patient characteristics, can influence best team composition, and suggesting that "policies related to system redesign and workforce development should preserve the capacity for flexibility in team implementation and role definition.").

doctors may restrict providers' ability to develop new models of networked or telemedicine-facilitated collaboration.[127]

APRNs also have played a central role in the development of alternative settings for care delivery, notably retail clinics. Retail clinics – sometimes called "store-based" or "limited service" clinics – typically are located within larger retail stores, such as chain drugstores, and typically are staffed by APRNs. Consumers have found retail clinics to be a convenient, flexible, and cost-effective choice for basic medical care comprising a limited set of primary care services including, for example, treatment for minor infections (sore throats, ear infections, sinus infections, etc.), the provision of immunizations, and routine preventive screening.[128] Clinics offer accessible locations, expanded hours, and favorable pricing, as well as the ability to fill prescriptions on-site at adjoining pharmacies.[129] Indeed, there is some evidence that physicians have responded to retail clinic innovation and competition by offering extended hours themselves, in order to meet consumer demand.[130] To the extent that rigid APRN supervision requirements may inhibit the growth of APRN-staffed retail clinics or prevent alternative settings from operating at all, such restrictions may deny consumers important price and non-price benefits of innovation in health care delivery.

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127. FTC Staff Florida Letter, *supra* note 70, at 5 (regarding impact on innovation associated with FLA. STAT. § 458.348(4)(c)); *see also* MO. CODE REGS. ANN. tit. 20 § 2150-5.100 (2) (A)-(B) (requiring that a physician and supervised APRN "shall not be so geographically distanced . . . as to create an impediment to effective collaboration" and, in particular, for "an APRN who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons" that they be not more than 50 miles by road in federally-designated health professional shortage areas and not more than 30 miles by road otherwise).

    Providers (either individual or institutional) whose businesses span state lines are doubly restricted. Not only are their permissible collaboration and supervision arrangements limited by the physical distances specified by statute, but providers may not be able to collaborate across state lines unless they hold multiple state licenses. Regarding competition issues raised by physician licensure and telemedicine, see, e.g., Daniel J. Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospect of Practicing Globally While Regulating Locally*, 14 J. HEALTH CARE L. & POL'Y 87 (2011).

128. ROBIN M. WEINICK ET AL., RAND CORP. TECH. REPORT PREPARED FOR THE DEP'T OF HEALTH & HUMAN SERVS., POLICY IMPLICATIONS OF THE USE OF RETAIL CLINICS, 6 (2010); *see also* Ateev Mehrotra & Judith R. Lave, *Visits to Retail Clinics Grew Fourfold from 2007 to 2009, Although Their Share of Overall Outpatient Visits Remains Low*, 31 HEALTH AFFAIRS 1, 5-6 (Web First) (2012).

129. WEINICK ET AL. *supra* note 128, at 6, 9-10.

130. *See, e.g.*, AMER. MED. ASS'N, REPORT 7 OF THE COUNCIL ON MED. SERV. (A-06), STORE-BASED HEALTH CLINICS, 1 (June 2006) (noting that, "[a]s a result of the emergence of store-based health clinics, many physicians have begun to evaluate making changes to their practices in order to become more accessible to patients.")

III.A.4. Mandated Collaboration Agreements Between APRNs and Physicians Are Not Needed to Achieve the Benefits of Physician-APRN Coordination of Care

Collaboration and coordination among health care providers are very often beneficial.[131] Indeed, improved collaboration and coordination among health care providers are fundamental goals of many current health care quality and cost-containment initiatives. Antitrust law and policy recognize the potential for procompetitive provider collaborations, consistent with such initiatives. But effective collaboration does not require that physicians formally supervise APRNs. On the contrary, as noted in the discussion of innovation, above, rigid supervision requirements may impede, rather than foster, development of effective models of team-based care.[132]

Collaboration between APRNs and physicians is common in all states, including those that permit APRNs to practice independently.[133] Every day, providers routinely communicate with each other, seek each other's opinions, and refer patients to each other. [134] Physicians consult their colleagues and, where appropriate, refer patients to other health care professionals. For example, a primary care physician often refers patients to specialists who, as a result of their education, training, and experience, are better suited to address particular symptoms or conditions. The majority of APRNs, who work for institutional providers or physician practices, regularly collaborate with physicians and other health care professionals, and even "independently" practicing APRNs typically consult physicians and refer patients as appropriate,

131. For a general discussion of the value of diverse approaches to team based care, *see generally* Mitchell et al., *supra* note 111.

132. *Cf.* IOM, DELIVERING HIGH QUALITY CANCER CARE, *supra* note 111, at 173-74 (IOM Committee "recommends that federal and state legislative and regulatory bodies eliminate ... scope-of-practice barriers to team-based care.")

133. Regarding diverse practice settings and collaboration, see IOM FUTURE OF NURSING REPORT, *supra* note 2, at 23, 58-59, 65-67, 72-76; *see generally* Mitchell et al., *supra* note 111.

134. Mitchell et al., *supra* note 111, at 11-12 (questions of team roles and leadership may often be less problematic in the field than when tied to policy debates about, e.g., scope of practice restrictions).

based on the APRN's training, certification, licensure, and experience.[135] State-level APRN licensure and certification requirements already require safe and responsible practice, including collaboration and referral to meet patients' needs.

Improved collaboration and coordination among *all* health care providers is a fundamental goal of many health care quality and cost-containment initiatives. Team based care, in particular, has been the focus of many private and public innovations in health care delivery.[136] Effective collaboration does not, however, inherently require that physicians formally supervise APRNs. Unless there are legitimate and substantiated health and safety justifications for mandatory physician supervision of APRNs, state legislators and regulators should carefully consider whether the goals of collaboration and coordination can be achieved via less restrictive alternatives. Under many circumstances, licensed APRNs can safely decide for themselves when their scope of practice requires or encourages collaboration with a physician – just as licensed physicians are trusted to decide when to collaborate with other physicians.

III.B. APRN Supervision Requirements Should Serve Well-Founded Patient Protection Concerns

FTC staff fully recognize the critical importance of patient health and safety. None of the forgoing discussion is meant to undercut the valid health and safety concerns that motivate many regulations governing health care professionals. We defer to state legislators to survey the available evidence, determine the optimal balance of policy priorities, and define the appropriate scope of practice for APRNs and other health care providers.

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135. A report by the Robert Wood Johnson Foundation describes several private and public models of innovative ways to use APRNs in team-based care. ROBERT WOOD JOHNSON FOUND., HOW NURSES ARE SOLVING SOME OF PRIMARY CARE'S MOST PRESSING CHALLENGES (2012), http://www.rwjf.org/content/dam/files/rwjf-web-files/Resources/2/cnf20120810.pdf. For example, HealthPartners, a large, non-profit provider in Minnesota, has expanded the use of NPs as primary care providers in their "Care Model Process," employing standardized best practices and telemedicine to coordinate care. *Id.* at 3. The report also describes public initiatives in Pennsylvania, *id.* at 4, and Vermont, *id.* at 5. The Department of Veterans Affairs has generally expanded its use of APRNs/NPs in delivering primary care, at least since the mid-90s. In particular, the VA has employed APRNs as "clinical nurse leaders," who coordinate team-based care and provide care directly. *See* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 72, 91-92. The IOM Report also describes innovative use of APRNs in team-based care by Geisinger Health System, *id.* at 92-93, and Kaiser Permanente, *id.* at 93-95. Whereas some of these efforts comprise new or reconfigured roles for APRNs in "medical home" types of approaches, others do not. For example, many retail clinics employ APRNs as primary care practitioners for episodic care, "using written protocols with electronic recordkeeping, decision-support software, and telephonic physician supervision." William M. Sage, *Out of the Box: The Future of Retail Medical Clinics*, 3 HARV. L. & POL'Y REV. ONLINE, 1, 3 (2009).

136. *See id.; see generally* Mitchell et al., *supra* note 111; *supra* notes 120-121 and accompanying text.

However, in the course of preparing previous advocacy comments addressing particular supervision requirements, FTC staff have looked to the findings of the IOM and other expert bodies – analyses based on decades of research and experience – on issues of APRN safety, effectiveness, and efficiency.[137] We have also conducted our own reviews of pertinent literature and considered stakeholder input. Based on our research, the kinds of supervision requirements examined in FTC staff's APRN advocacies do not appear to be justified by legitimate health and safety concerns. Specifically, our research did not identify significant evidentiary support for either the claim that independent APRN practice gives rise to significant safety concerns, or the claim that mandatory supervision requirements redress such concerns. In Louisiana, for example, there was no record of patient harm associated with expired or defective collaborative practice agreements. Similarly, in Florida, it appeared that statutory restrictions on independent APRN practice were imposed despite, rather than because of, a legislative history suggesting that APRNs had been providing safe care under prior, less restrictive, supervision standards.[138]

FTC staff thus encourage state legislators considering APRN supervision requirements to familiarize themselves with ongoing "natural experiments" in many locations across the United States. As the IOM observed, APRNs have provided diverse primary care services for decades, and in many jurisdictions and care settings they have done so without mandatory physician

137. *See, e.g., supra* notes 6, 8, 86-89 (observations from IOM, the Office of Technology Assessment, and the National Governors' Association, among others); *see also* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98-99 (citing S.A. Brown & D. E. Grimes, *A Meta-analysis of Nurse Practitioners and Nurse Midwives in Primary Care*, 44(6) NURSING RESEARCH 332 (1995); JULIE FAIRMAN, MAKING ROOM IN THE CLINIC: NURSE PRACTITIONERS AND THE EVOLUTION OF MODERN HEALTH CARE (2008); S.W. Groth et al., *Long-term Outcomes of Advanced Practice Nursing*, in NURSE PRACTITIONERS: EVOLUTION AND FUTURE OF ADVANCED PRACTICE (5th ed., E. M. Sullivan-Marx et al., eds. 2010); M. Hatem et al., *Midwife-led Versus Other Models of Care for Childbearing Women*, 4 COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD004667 (2008); P.F. Hogan et al., *Cost Effectiveness Analysis of Anesthesia Providers*, 28 NURSING ECONOMIC$ 159 (2010); S.E. Horrocks et al., *Systematic Review of Whether Nurse Practitioners Working in Primary Care Can Provide Equivalent Care to Doctors*, 324 BMJ 819 (2002); F. Hughes et al., *Research in Support of Nurse Practitioners*, in NURSE PRACTITIONERS: EVOLUTION AND FUTURE OF ADVANCED PRACTICE (5th ed., E. M. Sullivan-Marx et al., eds. 2010); M. Laurant et al., *Substitution of Doctors by Nurses in Primary Care*, 2 Cochrane Database of Systematic Reviews, CD001271 (2004); M.O. Mundinger et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A randomized Trial*, 283 JAMA 59 (2000); OTA HEALTH TECH. CASE STUDY, *supra* note 8; *see also* Robin P. Newhouse et al., *Advanced Practice Nurse Outcomes 1990-2008: A Systematic Review*, 29 NURSING ECON. 1, 18 (2011) ("APRNs provide effective and high-quality patient care."); P. Venning et al., *Randomised Controlled Trial Comparing Cost Effectiveness of General Practitioners and Nurse Practitioners in Primary Care*, 320 BMJ 1048 (2000) (no significant difference in patterns of prescribing or health status outcome); *see also* Everett et al., *supra* note 126, at 1942, 1945-46 (outcomes generally equivalent for NP, PA, and MD caregivers in 13 comparisons, superior for NP or PA care in 4, and superior for MD care in 3; "PAs and NPs can fill a range of roles on primary care teams, even for older patients with clinically challenging conditions such as diabetes.").

138. FTC Staff Florida Letter, *supra* note 70, at n. 7 (citing Florida House of Representatives Staff Analysis, Bill # HB 699 CS Health Care (Mar. 8, 2006).

supervision or collaborative practice requirements. For this reason, the IOM concluded, "the contention that APRNs are less able than physicians to deliver care that is safe, effective, and efficient is not supported by the decades of research that has examined this question."[139] To the contrary, a large body of empirical research strongly suggests that APRNs are safe and effective providers of diverse primary care services.[140] Similarly, we have not seen research suggesting that the safety or quality of primary care services declines when APRN supervision or collaborative practice requirements are lessened or eliminated.

FTC staff recognizes that particular contexts of care – including particular kinds of patients, procedures, or health care settings – might require some form of supervision. We specifically note, however, that independent prescribing authority does not appear to fall within this category. The ability to write prescriptions – at least for non-controlled substances,[141] such as prescribing antibiotics to treat strep throat – is one of the defining criteria for independent APRN practice and has been an ongoing source of contention.[142] Studies have examined outcomes associated with APRNs with independent prescribing authority, and the results have suggested comparable outcomes between APRNs and physicians.[143] FTC staff are not aware of any contrary empirical evidence to support the contention that there are patient harms or risks associated with APRN

139. IOM FUTURE OF NURSING REPORT, *supra* note 2, at 98-99.

140. *See supra* note 137. FTC staff had reviewed citations provided in the IOM Report, among others, as part of its literature review.

141. We do not suggest that APRNs cannot safely prescribe controlled substances. Some states permit APRNs to prescribe controlled substances, and we are not aware of any literature indicating that health and problems are associated with this practice. We recognize, simply, that the laws of many states impose special restrictions on the prescribing and distribution of controlled substances, as does federal law, and that special regulatory concerns may be associated with, or justified by, controlled substances, independent of the prescribing professional. *See, e.g.*, Prescription Drug Diversion: Combating the Scourge: Hearing Before the H. Subcomm. On Commerce, Manufacturing and Trade of the H. Comm. on Energy and Commerce, 112th Cong. (Mar. 1, 2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Admin., U.S. Dep't Justice); Nora D. Volkow et al., *Research Letter: Characteristics of Opioid Prescriptions in 2009*, 305 JAMA 1299, 1300 (2011) (noting increases in opioid prescriptions and associated increases in abuse and overdoses as cause of concern and need for further research).

142. *See* FTC Staff Louisiana APRN Comment, *supra* note 67, at 3, 5; FTC Staff West Virginia Testimony, *supra* note 66, at 3-6; *cf.* IOM FUTURE OF NURSING REPORT, *supra* note 2, at 110-11 (regarding opposition by physicians, including the American Medical Association).

143. *See, e.g.* Mundinger et al., *supra* note 137 (comparing outcomes for 1316 ambulatory care patients randomly assigned to APRN and MD primary care providers, where APRNs had "same authority to prescribe, consult, refer, and admit patients" found no significant difference in patients' health status or physiologic test results); Elizabeth R. Lenz et al., *Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: Two-year Follow-up*, 61 MED. CARE RES. & REV. 332 (2004) (2-year follow-up data for Mundinger et al. consistent with preliminary results); Ann B. Hamric et al., *Outcomes Associated with Advanced Nursing Practice Prescriptive Authority*, 10 J. AMER. ACAD. NURSE PRACTITIONERS 113 (1998) (safety and effectiveness in study of 33 APRNs in 25 primary care sites); Venning et al., *supra* note 137, at 1048 (no significant difference in patterns of prescribing or health status outcome).

prescribing of non-controlled substances. As the NGA paper concluded, "[m]ost studies showed that [APRN]-provided care is comparable to physician-provided care on several process and outcome measures"[144] and "[e]xisting research suggests that [APRNs] can perform a subset of primary care services as well as or better than physicians."[145]

IV. CONCLUSION

Consumer health and safety are paramount concerns in the regulation of the health professions, and competition is an important mechanism to promote high quality health care. Competition is also a key means of controlling health care costs and allocating health care resources. APRN licensure and scope of practice restrictions, like other professional regulations, may advance important consumer interests. But when these restrictions restrain competition and are not closely tied to legitimate policy goals, they may do more harm than good.

Our nation faces significant challenges in moderating health care spending and in providing adequate access to health care services, especially for our most vulnerable and underserved populations. Numerous expert health policy organizations have concluded that expanded APRN scope of practice should be a key component of our nation's strategy to deliver effective health care efficiently and, in particular, to fill gaps in primary care access. Based on our extensive knowledge of health care markets, economic principles, and competition theory, we reach the same conclusion: expanded APRN scope of practice is good for competition and American consumers.

As explained herein and in prior FTC staff APRN advocacy comments, mandatory physician supervision and collaborative practice agreement requirements are likely to impede competition among health care providers and restrict APRNs' ability to practice independently, leading to decreased access to health care services, higher health care costs, reduced quality of care, and less innovation in health care delivery. For these reasons, we suggest that state legislators view APRN supervision requirements carefully. Empirical research and on-the-ground experience demonstrate that APRNs provide safe and effective care within the scope of their training, certification, and licensure. Moreover, effective and beneficial collaboration among health

144. NGA PRIMARY CARE PAPER, *supra* note 4, at 8.

145. *Id.* at 11 (internal citation omitted). Reviews of patient satisfaction with APRN care also are favorable. *See, e.g.*, Mary Naylor and Ellen T. Kurtzman, *The Role of Nurse Practitioners in Reinventing Primary Care*, 29 HEALTH AFFAIRS 893, 894-5 (2010); Dill, *supra* note 97.

care providers can, and typically does, occur even without mandatory physician supervision of APRNs.

When faced with proposals to narrow APRN scope of practice via inflexible physician supervision and collaboration requirements, legislators are encouraged to apply a competition-based analytical framework and carefully scrutinize purported health and safety justifications. In many instances, legislators may well discover that there is little or no substantiation for claims of patient harm. If, however, health and safety risks are credible, regulations should be tailored narrowly, to ensure that any restrictions on independent APRN practice are no greater than patient protection requires.

This policy paper will be available on the FTC website, along with related resources and an up-to-date index of FTC staff comments on APRN issues. The FTC hopes to continue to serve as a resource for state legislators who seek our views on these and other competition policy issues, and we welcome a continued dialogue with all interested stakeholders.

APPENDIX 1

APRN Scope of Practice Advocacies

FTC Staff Comment Before the Massachusetts House of Representatives Regarding House Bill 2009 Concerning Supervisory Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 2014), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettnursesletter.pdf.

FTC Staff Letter to the Hon. Theresa W. Conroy, Connecticut House of Representatives, Concerning the Likely Competitive Impact of Connecticut House Bill 6391 on Advance Practice Registered Nurses (March 2013), http://ftc.gov/os/2013/03/130319aprnconroy.pdf.

FTC Staff Testimony Before Subcommittee A of the Joint Committee on Health of the State of West Virginia Legislature on The Review of West Virginia Laws Governing the Scope of Practice for Advanced Practice Registered Nurses and Consideration of Possible Revisions to Remove Practice Restrictions (September 2012), http://www.ftc.gov/os/2012/09/120907wvatestimony.pdf.

FTC Staff Comment Before the Louisiana House of Representatives on the Likely Competitive Impact of Louisiana House Bill 951 Concerning Advanced Practice Registered Nurses (APRNs) (April 2012), http://www.ftc.gov/os/2012/04/120425louisianastaffcomment.pdf.

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FTC Staff Letter to the Hon. Daphne Campbell, Florida House of Representatives, Concerning Florida House Bill 4103 and the Regulation of Advanced Registered Nurse Practitioners (March 2011), http://www.ftc.gov/os/2011/03/V110004campbell-florida.pdf.

FTC Staff Comment Before the Council of the District of Columbia Concerning Proposed Bill 6-317 to Create Specific Licensing Requirements for Expanded Role Nurses (Nov. 1985).

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Retail Clinics / Limited Service Clinics

FTC Staff Comment Before the Kentucky Cabinet for Health and Family Services Concerning Regarding Proposed Rule to Regulate Limited Service Clinics (Jan. 2010), http://www.ftc.gov/os/2010/02/100202kycomment.pdf.

FTC Staff Comment to Representative Elaine Nekritz of the Illinois General Assembly Concerning H.B. 5372 to Regulate Retail Health Facilities (Jun. 2008), http://www.ftc.gov/os/2008/06/V080013letter.pdf.

FTC Staff Comment Before the Massachusetts Department of Public Health Concerning Proposed Regulation of Limited Service Clinics (Oct. 2007), http://www.ftc.gov/os/2007/10/v070015massclinic.pdf.

Certified Registered Nurse Anesthetists

FTC Staff Comment Before the Massachusetts House of Representatives Regarding House Bill 6 (H.2009) Concerning Supervisory Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 2014), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettnursesletter.pdf.

FTC Staff Comment to the Hon. Heather A. Steans, Illinois State Senate, Concerning Illinois Senate Bill 1662 and the Regulation of Certified Registered Nurse Anesthetists (CRNAs) (April 2013), http://www.ftc.gov/os/2013/04/130424illinois-sb1662.pdf.

FTC Staff Letter to the Hon. Jeanne Kirkton, Missouri House of Representatives, Concerning Missouri House Bill 1399 and the Regulation of Certified Registered Nurse Anesthetists (March 2012), http://www.ftc.gov/os/2012/03/120327kirktonmissouriletter.pdf.

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Competition
Bureau of Economics

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Via USPS and email to susan.reynolds@idph.iowa.gov

Susan Reynolds
Professional Licensure Division
Department of Public Health
Lucas State Office Building
Des Moines, Iowa 50319-0075

RE: Iowa Board of Physician Assistants, Proposed New Rules: 645—327.8: Definition of physician supervision of a physician assistant[1]

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition ("FTC staff") [2] appreciate the opportunity to respond to the request for public comments on the Iowa Board of Physician Assistants' ("PA Board") proposed rule, "Definition of physician supervision of a physician assistant" ("Proposed Rule").[3]

Iowa patients would likely benefit if physician assistants ("PAs") in Iowa can practice with as few restrictions as possible, consistent with their education, training, skills, and experience. PAs can provide more choice among health care providers, leading to more accessible, affordable, safe, and effective health care. Thus, FTC Staff support the PA Board's initiative to comply with its legislative mandate to establish specific minimum standards ***or*** a definition of supervision [4] while maintaining maximum flexibility at the practice level to allow physician-owned practices, hospitals, clinics, and other practice sites to best employ PAs' capabilities in a safe manner.

Specifically, the Proposed Rule would maintain the statutory and regulatory status quo by allowing supervising physicians and PAs flexibility to determine, implement, and document the appropriate level of supervision at the practice site. Based on FTC staff's prior examination of the impact of professional regulations on health care provider competition, we believe the Proposed Rule would allow Iowa physicians and health care facilities to employ and deploy PAs in the most efficient and effective manner, consistent with patient safety.

In contrast, the PA Board's previously proposed regulations, and the regulations adopted by the Iowa Board of Medicine ("BOM"), appear to limit such flexibility and impose potentially new and more costly supervision requirements.[5] Absent evidence of public health or safety concerns about the care that PAs and their supervising physicians provide under current laws and regulations, we believe the PA Board's Proposed Rule would likely preserve competition and

maintain and improve access to needed health care services for Iowa patients, particularly in medically underserved areas.[6]

I. INTEREST AND EXPERIENCE OF THE FTC

The FTC is charged with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[7] Competition is at the core of America's economy,[8] and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, and greater innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key focus of FTC law enforcement,[9] research,[10] and advocacy.[11]

FTC staff have submitted many comments, and published a policy paper, explaining that competition and consumers benefit if advanced practice registered nurses ("APRNs") can practice free of supervision requirements that are not justified by legitimate patient health and safety concerns.[12] Although FTC staff have not previously submitted comments focused specifically on PA supervision and scope of practice issues, our APRN comments and the APRN policy paper have suggested that a similar interplay between competition and scope of practice regulation may apply to PAs as well.[13] This prior FTC staff work informs the review of proposed regulations in Iowa concerning PAs. The link between APRN and PA scope of practice regulation and how it may affect competition and consumers is further supported by the Centers for Medicare and Medicaid Services ("CMS"), which recently proposed regulatory revisions to eliminate certain language that had treated PAs differently than APRNs. CMS suggested that APRNs and PAs should be treated similarly with respect to their scope of practice, stating "PAs are trained on a medical model that is similar in content, if not duration, to that of physicians. Further, PA training and education is comparable in many ways to that of APRNs and in some ways, more extensive."[14]

II. BACKGROUND

A. Overview of the PA Profession

The PA profession emerged in the 1960s to address primary care physician shortages, as well as to train military veterans who were corpsmen and medics to provide medical care under physician oversight.[15] PAs are educated in the medical model in master's level accredited programs, with the typical program of didactic and clinical education lasting 27 continuous months and including approximately 2,000 hours of supervised clinical practice.[16] Approximately 108,000 PAs practice across all medical and surgical specialties nationwide, with about 30,000 PAs in primary care practice.[17]

PAs constitute ten percent of the primary care work force and nine percent of clinicians in community health centers, and play a significant role in staffing federally designated rural health clinics.[18] The Bureau of Labor Statistics projects that the PA profession will grow over 30 percent by 2024.[19] At the same time, the Association of American Medical Colleges ("AAMC") projects significant physician shortages in both primary and specialty care by 2025.[20] The AAMC also reported that Iowa ranked 42nd among the states in the number of active physicians per 100,000 people, 45th in the total number of active patient care physicians, and that 38 percent

of Iowa's active physicians were over the age of 60.[21] Thus, it appears that encouraging the greater use of PAs could help to alleviate these projected physician shortages in the U.S. generally and Iowa specifically.

B. Background on PA Statutes and Regulations in Iowa

In 1988, the Iowa legislature created the PA Board and moved regulatory authority from the BOM to the PA Board.[22] In taking this action, the Iowa legislature granted PAs a certain degree of regulatory autonomy over their profession, subject to specific supervisory requirements mandated by the legislature.[23]

Iowa law requires that PAs be licensed and allows PAs to perform certain medical services under a physician's supervision. A physician cannot supervise more than five PAs at the same time. Several restrictions have eased over time, including an increase in the number of PAs whom a physician can supervise from two to five. The statute requires the PA Board to adopt rules "requiring a licensed physician assistant to be supervised by physicians" and states that a "licensed physician assistant shall perform only those services for which the licensed physician assistant is qualified by training or not prohibited by the board."[24]

1. PA Board Regulations

The PA Board has adopted various regulations to implement the broad statutory requirements, as well as additional specifications governing the relationship between physicians and PAs. Existing PA Board regulations define "supervision" as follows:

> [A] supervising physician retains ultimate responsibility for patient care, although a physician need not be physically present at each activity of the physician assistant or be specifically consulted before each delegated task is performed. Supervision shall not be construed as requiring the physical presence of the supervising physician at the place where such services are rendered except insofar as the physical presence is expressly required by these rules or by Iowa Code chapter 148C.[25]

Existing regulations also require that PAs pass a national certification exam and identify their supervising physicians on board-approved forms before practicing in Iowa and when renewing their license. The regulations incorporate the statutory requirements that at least one physician must supervise a PA and that a physician cannot supervise more than five PAs at the same time. The regulations specify that it is the PA's and physician's responsibility to ensure adequate supervision, and if the designated supervisor is not available, the PA cannot practice unless a substitute physician can supervise during that time. The regulations require both the PA and the physician to know and comply with the supervision provisions and to review the PA's patient care on an ongoing basis, as appropriate based on the clinical condition of the patient.[26]

Neither Iowa law nor existing PA Board rules require a supervising physician to review every chart or visit, and the rules allow for the review of patient care in person or via telephone or other telecommunication means. If physician signatures are necessary as part of supervision, the rules permit electronic signatures if certain safeguards are in place.[27] The regulations set forth

the types of medical services a physician can delegate to a PA and state that "the ultimate role of the physician assistant cannot be rigidly defined because of the variations in practice requirements due to geographic, economic, and sociologic factors."[28]

The PA Board regulations also set forth specific requirements for remote medical sites, which are defined as practice locations at which the supervising physician is present less than 50 percent of the time. For remote medical sites, the supervising physician must visit the remote site at least every two weeks, or less frequently under special circumstances that require notification to the PA Board.[29]

2. New legislative charge to both PA Board and BOM in 2015

In 2015, the legislature adopted a provision known as Senate File 505 ("SF505"), which states:

> The boards of medicine and physician assistants shall jointly adopt rules pursuant to chapter 17A to establish specific minimum standards ***or*** a definition of supervision for appropriate supervision of physician assistants by physicians. The boards shall jointly file notices of intended action pursuant to section 17A.4, subsection 1, paragraph "a", on or before February 1, 2016, for adoption of such rules.[30] [Emphasis added].

In compliance with SF505, subcommittees of both the BOM and the PA Board worked together to develop a proposed regulation and issued notices of proposed rulemaking to set minimum standards for physician supervision of PAs.[31] In response to public comments, both boards issued identical amended proposed rules – ARC 2531C by the PA Board and ARC 2532C by the BOM.[32]

The BOM adopted ARC 2532C, the amended rule, which we discuss below. The BOM press release and other actions suggest that – despite legislative language that seems to require a jointly adopted rule – the BOM appears to consider its rule effective and enforceable[33] even without a parallel rule adopted by the PA Board.[34]

The PA Board received additional comments on ARC 2531C, held another hearing on June 3, 2016, and held two subsequent board meetings to discuss ARC 2531C.[35] Based on the public comments, the PA Board expressed concern that ARC 2531C (and ARC 2532C, the identical version adopted by the BOM) would have significant adverse effects and would be likely to negatively impact access to care for Iowans.[36] As a result, the PA Board has issued and seeks public comment on the Proposed Rule.[37]

III. THE PA BOARD'S CURRENTLY PROPOSED RULE

The PA Board's Proposed Rule expands upon the existing definition of physician supervision in the PA Board's current rules, without specifying additional minimum standards of supervision. The Proposed Rule states:

327.8(1) *Definition of supervision.* Supervision means an ongoing process by which a supervising physician and physician assistant jointly ensure that the medical services provided by the physician assistant are appropriate. A supervising physician retains ultimate responsibility for patient care. A physician need not be physically present at each activity of the physician assistant or be specifically consulted before each delegated task is performed. Supervision shall not be construed as requiring the physical presence of the supervising physician at the place where such services are rendered except insofar as the physical presence is expressly required by Iowa Code chapter 148C.

327.8(2) *Additional elements of supervision.*

a. Supervision must be tailored to the individual practice setting and take into account the experience of both the physician and physician assistant.
b. Individual practice requirements must guide how to best use health information technology to enhance patient care by ensuring effective and timely communication between physician and physician assistant.
c. The supervising physician and physician assistant must determine appropriate methods of evaluation for each practice. This evaluation may include, but is not limited to, review of delegated services, periodic chart review, and existing evaluation tools as determined by the practice.
d. Both the supervising physician and physician assistant must review all of the requirements of physician assistant licensure, practice, supervision and delegation of medical services as set forth in the Iowa Code.[38]

IV. LIKELY IMPACT OF THE PA BOARD'S PROPOSED RULES

FTC staff recognize that certain professional licensure requirements and scope-of-practice restrictions may be necessary to protect patients.[39] Consistent with patient safety, however, we have urged regulators and legislators to consider whether removing unnecessary practice restrictions for non-physician providers may promote competition and benefit patients.[40] With respect to the Proposed Rule, if PAs can better practice to the full extent of their education, training, and abilities – as determined by their physician supervisors – health care consumers will likely reap competitive benefits. Those gains would flow from an expanded supply of quality health care providers, including improved access to health care, lower costs, and additional innovation.[41]

When analyzing competition in various health care professions, FTC staff consistently recommend that policy makers carefully examine purported safety justifications for restrictions on health care practitioners – especially when the scope of practice for one health care profession overlaps to some degree with that of another profession over which it exercises supervisory authority. We have recommended that state legislators, regulators, and other policy decision makers:

- Evaluate what, if any, pertinent evidence exists to maintain or add scope-of-practice restrictions;
- Evaluate whether purported health and safety justifications are well founded; and

- Consider whether less restrictive alternatives would protect patients without imposing undue burdens on competition and undue limits on patients' access to health care services.[42]

FTC staff urge the PA Board, as well as the BOM,[43] to apply a similar analytical framework as they consider regulations governing physician supervision of PAs. We recognize that Iowa law requires PAs to practice under the supervision of physicians. This requirement gives supervising physicians some control over PAs' ability to access the health care marketplace, including for services where those PAs may compete with physicians.[44] But regulations to implement this legislative requirement can, and should, minimize restrictions that are not justified by legitimate patient safety concerns. Even well-intentioned laws and regulations may include unnecessary or overbroad restrictions, including those that may limit competition or frustrate the development of innovative and effective models of team-based health care.[45] Such undue restrictions on health care services can raise costs or prices to patients or third-party payers, limit access to important health care services, or both, without providing countervailing consumer protection benefits.

The PA Board's Proposed Rule, which would promote greater flexibility and avoid a "one size fits all" approach, likely will enable physician-owned practices and clinics, as well as institutional health care providers, to continue to deploy PAs efficiently and effectively in a variety of patient care situations.[46] The Proposed Rule appears to comply with the statutory mandate in that it provides a more detailed definition of supervision, and does so without creating additional rigid supervision rules that could increase costs and decrease access. Moreover, unlike the previous proposal by the PA Board (ARC 2531C), which was adopted by the BOM (ARC 2532C), the Proposed Rule is unlikely to create confusion or uncertainty as to the regulations with which PAs and physicians must comply.

V. LIKELY IMPACT OF THE PA BOARD'S PREVIOUSLY PROPOSED ARC 2531C AND THE BOM'S ADOPTED ARC 2532C

SF505 appears to contemplate that both the BOM and the PA Board will adopt identical rules. Therefore, we think it is useful to highlight some questions and concerns related to the PA Board's previously proposed ARC 2531C, which the BOM adopted as ARC 2532C (hereinafter collectively referred to as "ARC 2532C"). ARC 2532C would mirror the PA Board's current definitions of supervision and remote medical sites.[47] ARC 2532C would also set forth minimum standards of supervision, which appear to impose additional requirements and restrictions compared to the existing supervisory relationship between physicians and the PAs they supervise. For example, the new BOM regulations would prescribe how or when certain supervisory functions must take place, such as face-to-face meetings and chart reviews.[48] As explained below, FTC staff question whether these additional supervisory requirements are necessary.

In addition to our substantive concerns about ARC 2532C, FTC staff also note an important procedural concern. We understand that ARC 2532C, as well as the Proposed Rule, would be considered *additional* rules that would not replace or supersede the PA Board's currently codified regulations. Because some of the language in ARC 2532C is similar to that of

current PA Board regulations, but is not identical,[49] this layering of old and new requirements may confuse and impose costs on supervisory physicians, health care institutions, and PAs.[50]

A. Face-to-Face Meetings

ARC 2532C would require at least one supervising physician to meet face-to-face with each PA a minimum of twice annually.[51] Neither the Iowa statutes nor the current PA Board regulations require face-to-face meetings, with the exception of certain requirements for PAs working in remote medical sites.

FTC staff query whether there is evidence to support a requirement that formal face-to-face meetings are necessary to address any legitimate health or safety concerns with respect to the large number of PAs who collaborate routinely with physicians. The large majority of Iowa PAs work in physicians' offices, clinics, hospitals, and other health care settings where PAs and their supervising physicians interact regularly, discussing cases and issues as they occur.[52] Public comments indicate that physicians, clinics, hospitals, and PAs are concerned that compliance with an additional face-to-face meeting requirement would add costs in terms of time, potential travel, documentation, reduced patient visits, and lost revenue.[53] They also raise concerns about how compliance might be achieved. For example, faculty from the Carver College of Medicine at the University of Iowa noted that University of Iowa Health Care's ("UIHC") 75 physician assistants "generally have immediate access to a staff physician for consultation at the time of the patient visit, so that PA supervision is accomplished in a manner similar to supervision of resident and fellow physicians." Yet, UIHC did not think this system would "technically meet the requirements in the proposed rule, so additional meetings would be required."[54]

With respect to PAs practicing at remote sites, the current PA Board regulations already require the supervising physician to visit a remote site at least every two weeks in order "to provide additional medical direction, medical services and consultation."[55] The BOM's press release regarding ARC 2532C appears to suggest that, with respect to remote clinics, the two new required face-to-face meetings would be *in addition to* the 26 currently required visits for PAs practicing in remote clinics.[56] If so, FTC staff question whether there is a substantiated health or safety rationale for imposing this additional requirement. We also respectfully suggest that in-person, face-to-face meetings should not be mandated by legislation or regulation. Absent demonstrable evidence that face-to-face meetings are necessary to promote health care quality and protect patients, the supervising physician and supervised PA should have flexibility to determine the most effective and efficient way to maintain an appropriate supervisory relationship.[57]

Even if the intent is to substitute two required face-to-face meetings per year for PAs practicing at remote sites and thereby eliminate the 26 current site visits, FTC staff note that 28 states and the District of Columbia impose no on-site or face-to-face meeting requirements for the supervision of PAs.[58] Similarly, in 2014, CMS also eliminated biweekly onsite physician visits to critical access hospitals ("CAHs"), rural health clinics ("RHCs"), and federally qualified health centers ("FQHCs").[59] In response to comments on the proposed rule implementing that change, CMS noted that:

> specifying a precise timeframe for a physician to visit the CAH, RHC, or FQHC, and provide the general oversight required . . .would not guarantee better health care. With the development of technology such as telemedicine, we believe a CAH, RHC, or FQHC should have the flexibility to use a variety of ways and timeframes for physician(s) to provide the necessary medical direction and oversight.[60]

CMS also estimated that removal of the on-site provision would produce estimated annual savings of approximately nearly $75.6 million for CAHs, RHCs, and FQHCs.[61]

If the BOM and the PA Board nevertheless decide there is a legitimate and substantiated justification to keep the face-to-face requirement, FTC staff urge the PA Board and the BOM to consider whether meetings via telecommunications or video conferencing could address any purported health and safety concerns, while minimizing the costs and burdens for a supervising physician to travel to a remote clinic.[62] FTC staff have submitted a number of comments supporting the increased use of telehealth by various types of health care providers under appropriate circumstances,[63] and we respectfully suggest to the BOM and the PA Board that telehealth consultations might be adequate substitutes for some or all visits at the remote sites.

B. Chart Reviews

ARC 2532C would require that "[e]ach supervising physician shall conduct and document an ongoing review of a representative sample of the physician assistant's patient charts encompassing the scope of the physician assistant's practice provided under the physician's supervision and discuss the findings of the reviews with the physician assistant." It appears that this chart review requirement would be a completely new imposition for most PAs and physicians in Iowa. Chart review is now required only for Iowa PAs with less than one year of experience when practicing in a remote site.[64]

Twenty-eight states and the District of Columbia have no comparable chart review requirement.[65] Similarly, CMS, during its rulemaking to eliminate specified onsite visits to CAHs, RHCs, and FQHCs also chose to eliminate a specified timeframe for reviewing charts. CMS noted that it would instead allow for periodic review to provide these health care entities "with the flexibility to manage patient care activities in such a way as to maximize staff time to provide patient access to quality care in rural and remote areas."[66]

This new chart review requirement could be a confusing and costly provision, depending on whether it adds new chart review and documentation obligations beyond existing requirements for physicians, hospitals, and other health care entities in connection with physician supervision of PAs. Public comments submitted in response to the proposed rules raised these types of concerns. Many organizations (e.g., physician practices, clinics, hospitals) noted they already have chart review systems in place – some on a daily basis, and often via electronic health records – but it is unclear what else ARC 2532C might require.[67] They wondered, for example, whether organizations would have to implement entirely new systems for chart reviews, and whether a supervising physician would need to set aside time on "an ongoing basis" to talk to the PA and formally discuss chart reviews even when the supervising physician had

reviewed the course of action, agreed with everything, and initialed the chart at the time of care. In many of these organizations, if there is a question about treatment, it is handled "in the moment," and it is unclear how ARC 2532C would require this be documented.[68]

VI. CONCLUSION

FTC staff support the PA Board's efforts to comply with the legislative mandate in SF505 by providing a definition of "physician supervision" without the additional burdens contained in previously noticed rules or those in ARC 2532C, unless there is substantiated health and safety evidence supporting such requirements. Those additional burdens could decrease access to care and potentially increase health care costs for Iowa consumers, as well as to physicians and health care institutions that employ PAs. Accordingly, we encourage the PA Board to continue its efforts, including continued collaboration with the BOM to jointly adopt the PA Board's Proposed Rule, to improve access to care for Iowa patients as effectively and efficiently as possible.

Respectfully submitted,

Tara Isa Koslov, Acting Director
Office of Policy Planning

Ginger Jin, Director
Bureau of Economics

Deborah Feinstein, Director
Bureau of Competition

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[1] ARC 2832C, Amended Notice of Intended Action, 39 Iowa Admin. Bull. 1108 (Dec. 7, 2016) (to be codified at IOWA ADMIN. CODE r. 645-327.8(1) & (2), http://idph.iowa.gov/Portals/1/userfiles/26/PA/SECOND%20AMENDED%20NOTICE%20OF%20INTENDED%20ACTION%20-%20IAC%20327_8.pdf (establishing definition of physician supervision of a physician assistant). According to its agenda, the PA Board adopted this version at its November 15, 2016 meeting. Iowa Bd. of Physician Assistants, *Agenda* (Nov. 15, 2016), http://idph.iowa.gov/Portals/1/Meetings/MeetingFiles/13/Agendas/4eec981c-0db4-4c26-aba8-ada213aad4a3.pdf.

[2] This letter expresses the views of staff in the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission or of any individual Commissioner. The Commission, however, has authorized us to submit these comments.

[3] ARC 2832C, Amended Notice of Intended Action, *supra* note 1.

[4] See discussion concerning statutory and regulatory background, *infra* at Section II.B.2.

[5] 38 Iowa Admin. Bull. 2169, 2162 (May 11, 2016) (PA Board proposed ARC 2531C and Notice of PA Board's June 3, 2016, Public Hearing on the proposed regulations).

[6] *See generally* INST. OF MED., THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH (2011), https://www.nap.edu/catalog/12956/the-future-of-nursing-leading-change-advancing-health [hereinafter IOM

FUTURE OF NURSING REPORT]; *see id.* at 98 (noting that the "growing use of APRNs and physician assistants has helped ease access bottlenecks, reduce waiting times, increase patient satisfaction, and free physicians to handle more complex cases."); OFFICE OF TECH. ASSESSMENT, U.S. CONG., HEALTH TECH. CASE STUDY 37, NURSE PRACTITIONERS, PHYSICIAN ASSISTANTS, AND CERTIFIED NURSE- MIDWIVES: A POLICY ANALYSIS 39 (1986), https://www.princeton.edu/~ota/disk2/1986/8615/8615.PDF ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].").

[7] 15 U.S.C. § 45.

[8] Standard Oil Co. v. Fed. Trade Comm'n, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

[9] *See, e.g.*, *Competition in the Health Care Marketplace*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.

[10] *See, e.g.*, FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

[11] FTC and staff advocacy may consist of letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.*, Comment from FTC Staff to La. State Representative Timothy G. Burns (May 1, 2009), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-louisiana-house-representatives-concerning-louisiana-house-bill-687-practice/v090009louisianadentistry.pdf (regarding proposed restrictions on mobile dentistry); Joint Comment from the FTC and DOJ to the Ill. Task Force on Health Planning Reform (Sept. 15, 2008), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-and-department-justice-written-testimony-illinois-task-force-health-planning-reform-concerning/v080018illconlaws.pdf (concerning Illinois certificate of need laws); Brief of Amicus Curiae Federal Trade Commission, in Support of Appellants and Urging Reversal, In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-amicus-curiae-brief-re-ciprofloxacin-hydrochloride-antitrust-litigation-concerning-drug-patent/080129cipro.pdf; FTC & DOJ, IMPROVING HEALTH CARE, *supra* note 10.

[12] *See, e.g.*, Fed. Trade Comm'n Staff, *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses* (2014), https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf; Comment from FTC Staff to the Dep't of Veterans Affairs (July 25, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/comment-staff-ftc-office-policy-planning-bureau-competition-bureau-economics-department-veterans/160725vastaffcomm1.pdf [hereinafter Comment to the VA] (regarding proposed rule on APRNs); Comment from FTC Staff to W. Va. State Senator Kent Leonhardt (Feb. 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-senate-west-virginia-concerning-competitive-impact-wv-senate-bill-516-regulation/160212westvirginiacomment.pdf [hereinafter Comment to the Hon. Kent Leonhardt] (regarding legislation on APRNs); Comment from FTC Staff to the S.C. State Representative Jenny A. Horne (Nov. 2, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-south-carolina-representative-jenny.horne-regarding-house-bill-3508-3078-advanced-practice-registered-nurse-regulations/151103scaprn.pdf (regarding legislation on APRNs); Comment from FTC Staff to the Mo. State Representative Jeanne Kirkton 5 n.11 (Apr. 21, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-representative-jeanne-kirkton-missouri-house-representatives-regarding-competitive/150422missourihouse.pdf [hereinafter Comment to the Hon. Jeanne Kirkton] (regarding collaborative practice arrangements between physicians and APRNs); Comment from FTC Staff to Mass. State Representative Kay Khan (Jan. 17, 2014), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettnursesletter.pdf (regarding supervisory requirements for nurse practitioners and nurse anesthetists).

[13] *See, e.g.*, FTC Staff, *Policy Perspectives*, *supra* note 12, at 8 n.32 (noting the policy paper "does not discuss Physician Assistants (PA) scope of practice issues, although PAs and APRNs typically are subject to similar types of rules"); Comment to the Hon. Jeanne Kirkton, *supra* note 12 (FTC staff noted that Missouri "HB633, as approved by the Committee of Professional Registration and Licensing on March 12, 2015, would amend the statute to also include physician assistants and . . . [a]lthough these comments and our March 2014 policy paper refer specifically

to APRNs, we also encourage the legislature to consider our comments, and scrutinize available health and safety evidence, as it evaluates whether and how to impose mandatory collaborative practice arrangements on physician assistants."). *See generally* Edward S. Sekscenski et al., *State Practice Environments and the Supply of Physician Assistants, Nurse Practitioners, and Certified Nurse-Midwives*, 331 N. ENGL. J. MED. 1266 (1994) (noting that proposals to increase access to primary care often consider expanding the role of both APRNs and PAs); *see also* IOM FUTURE OF NURSING REPORT, *supra* note 5, at 88, 97-98.

[14] Medicare and Medicaid Programs; Hospital and Critical Access Hospital Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 81 Fed. Reg. 39,448, 39,452 (proposed June 16, 2016) (to be codified at 42 C.F.R. pt. 482, 485).

[15] *See* Nat'l Governors Ass'n, *The Role of Physician Assistants in Health Care Delivery* (2014), https://www.nga.org/files/live/sites/NGA/files/pdf/2014/1409TheRoleOfPhysicianAssistants.pdf; Kaiser Comm'n on Medicaid and the Uninsured, Kaiser Family Found., *Improving Access to Adult Primary Care in Medicaid: Exploring the Potential Role of Nurse Practitioners and Physician Assistants* (Mar. 2011), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8167.pdf.

[16] Am. Acad. of Physician Assistants, *PA Education: Preparation for Excellence* (Dec. 2016), https://www.aapa.org/WorkArea/DownloadAsset.aspx?id=580.

[17] Nat'l Governors Ass'n, *supra* note 15 (citing statistics and information from *Primary Care Workforce Facts and Stats No. 3.*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (last updated Oct. 2014), http://www.ahrq.gov/research/findings/factsheets/primary/pcwork3/index.html; Ctrs. for Medicare & Medicaid Servs., *Rural Health Clinic* (Jan. 2016), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/RuralHlthClinfctsht.pdf).

[18] Nat'l Governors Ass'n, *supra* note 15, at 2 & nn. 6-7 (again citing statistics and information from AHRQ and CMS); Kaiser Comm'n on Medicaid and the Uninsured, *supra* note 15, at 3 (noting that "NPs and PAs are more likely than primary care physicians to practice in underserved areas and to care for large numbers of minority patients, Medicaid beneficiaries, and uninsured patients" and noting "that these clinicians perform as well as physicians on important clinical outcome measures" for primary care).

[19] *Employment Projections, Fastest Growing Occupations*, BUREAU OF LABOR STATISTICS (last updated Apr., 16, 2016), http://data.bls.gov/cgi-bin/print.pl/emp/ep_table_103.htm.

[20] *See* Sarah Mann, *AAMC Research Confirms Looming Physician Shortage*, ASS'N OF AM. MED. COLLS. (Sept. 27, 2016), https://news.aamc.org/medical-education/article/aamc-research-physician-shortage/ (AAMC summary based on a 2016 update to a 2015 report by IHS Inc., Life Sciences Division, which AAMC commissioned). The AAMC projects the U.S. "will face a shortage of between 61,700 and 94,700 physicians by 2025, with particularly large shortfalls in certain surgical specialties." By 2025, projected shortages for primary care physicians range from 14,900 to 35,600 and for surgeons, both general and specialty, from 25,200 to 33,200. The AAMC noted the "primary factors driving demand are population growth and an increase in older Americans," with the population expected to grow by approximately 8.6 percent and the population of those over 65 years of age expected to increase by 41 percent. Because those over 65 years of age "tend to require more specialized care than younger populations, the shortage in certain specialties . . . will not keep pace with demand." *Id.* Ass'n of Am. Med. Colls., *Physician Shortages to Worsen Without Increases in Residency Training* (n.d.), https://www.aamc.org/download/150584/data/physician_shortages_factsheet.pdf; BUREAU OF HEALTH PROFESSIONS, HEALTH RESOURCES & SERVS. ADMIN., THE PHYSICIAN WORKFORCE: PROJECTIONS AND RESEARCH INTO CURRENT ISSUES AFFECTING SUPPLY AND DEMAND 70-72, ex. 51-52 (2008), https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/projections/physiciansupplyissues.pdf (HRSA's most recent workforce report on physician supply and demand, projecting increased shortages of both primary care physicians and specialists).

[21] Ass'n of Am. Med. Colls., *Iowa Physician Workforce Profile* (2015), https://www.aamc.org/download/447176/data/iowaprofile.pdf.

[22] Physician Assistants, Title IV, IOWA CODE §148C (2016) (includes reference to the 1988 Act establishing the Board of Physician Assistants).

[23] FTC staff have suggested that licensed professionals not be granted the authority to regulate those with whom they compete. *See, e.g.,* Comment to the Hon. Kent Leonhardt, *supra* note 12 (noting that "we strongly suggest that it may be problematic to have independent regulatory boards dominated by medical doctors and doctors of osteopathy serve as regulators of APRN prescribing"); Comment from FTC Staff to the Miss. State Representative Mark Formby (Mar. 22, 2011), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf (noting that because pharmacists and pharmacy benefit managers (PBMs) "have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board," may increase prescription drug prices and reduce competition within the state, and that "the antitrust laws recognize that there is a real danger that regulatory boards composed of market participants may pursue their own interests rather than those of the state"); N.C. State Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101 (2015). *See also* BUREAU OF HEALTH PROFESSIONS, HEALTH RESOURCES AND SERVICES ADMIN., THE PROFESSIONAL PRACTICE ENVIRONMENT OF DENTAL HYGIENISTS IN THE FIFTY STATES AND THE DISTRICT OF COLUMBIA, 2001, at 80-81 (2004), http://docplayer.net/13728482-The-professional-practice-environment-of-dental-hygienists-in-the-fifty-states-and-the-district-of-columbia-2001-april-2004.html ("Dental hygiene is idiosyncratic in that most health professions are self-regulated. Dental hygiene is largely under the purview of dentistry. This is not true for similarly situated medical professionals who are principally self-regulated"). *See generally id.* at 73 (noting "[t]he dental hygiene profession has progressed less quickly than most other health professions. This is largely due to the regulation of the profession of dentistry, a condition that is unusual in health regulation since most other professions are provided with autonomy in governing their constituents.").

[24] IOWA CODE § 148C.3. Section 148C.3(6) also states that the PA Board "shall adopt rules pursuant to this section after consultation with the board of medicine."

[25] IOWA ADMIN. CODE r. 645-326.1, Definitions.

[26] r. 645-326.8(1)-(4), Supervision Requirements.

[27] r. 645-326.8(4)*c*.(1), (2).

[28] r. 645-327.1(1), Duties.

[29] r. 645-327.4, Remote Medical Site. The PA at a remote site must have practiced for at least one year or if less than one year, then the PA must have practiced for at least six months, worked with the supervising physician at the same location for at least three months, and the supervising physician must review patient care at least weekly and sign all patient charts unless there is documentation that the PA directly consulted with the physician for a specific patient. Finally, there is an exception to these stringent requirements if a physician and PA provide a written statement to the PA Board that the PA is qualified to provide the needed medical services and that the medical care will be unavailable at the remote site unless the PA is allowed to practice there. The physician still must make weekly visits and sign all charts unless direct consultation has occurred.

[30] S.F. 505, 86th Gen. Assemb. 1st Session, div. XXXI, sec. 113 (Iowa 2015). This appears to be the only provision in Iowa law addressing directly the authority of the BOM to adopt rules concerning PAs, as opposed to disqualification or discipline of MDs related to PA supervision.

[31] 38 Iowa Admin. Bull. 1415 (Jan. 20, 2016) (BOM's originally proposed rule, ARC 2372C); 38 Iowa Admin. Bull. 1521 (Feb. 17, 2016) (PA Board's originally proposed rule, ARC 2417C).

[32] 38 Iowa Admin. Bull. 2169 (May 11, 2016) (PA's proposed amended rule, ARC 2531C); 38 Iowa Admin. Bull. 2190 (May 11, 2016) (BOM's adopted amended rule, ARC 2532C). It is unclear whether the BOM took into account additional public comments on the amended rule.

[33] See Iowa Board of Medicine website page (stating the rule becomes effective June 15, 2016). *Iowa Code, Rules, Policy*, IOWA BD. OF MED., http://medicalboard.iowa.gov/iowa_code/index.html; Press Release, Iowa Bd. of Med., New Rule Establishes Minimum Standards for Supervision of Physician Assistants (Aug. 18, 2016), http://medicalboard.iowa.gov/Board%20News/2016/Press%20release%20-%20New%20rule%20establishes%20minimum%20standards%20for%20supervision%20of%20physician%20assistants%20-%20August%2018%202016.pdf (stating the rule is effective).

[34] See Iowa Bd. of Med., Teleconference Meeting Open Minutes (Apr. 15, 2016), http://medicalboard.iowa.gov/Minutes/2016/PubMin%204-15-16%20Tele.pdf.pdf (adopting rule and suggesting it would be effective on June 15, 2016, "presuming the Board of Physician Assistants follows suit").

[35] 38 Iowa Admin. Bull. 2162 (May 11, 2016) (Notice of PA Board's June 3, 2016, Public Hearing on ARC 2531C). The additional board meetings took place on July 20, 2016 and October 19, 2016. The Proposed Rule was suggested at the PA Board meeting on October 19, 2016. The PA Board thereafter drafted the Proposed Rule, and voted to issue this proposal for public comment via a November 15, 2016 teleconference.

[36] ARC 2832C, Amended Notice of Intended Action, *supra* note 1.

[37] *Id.*

[38] *Id.*

[39] For example, licensure requirements or scope-of-practice restrictions may sometimes offer an efficient response to certain types of market failure arising in professional services markets. *See* CAROLYN COX & SUSAN FOSTER, FED. TRADE COMM'N, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION 5–6 (1990), https://www.ftc.gov/system/files/documents/reports/costs-benefits-occupational-regulation/cox_foster_-_occupational_licensing.pdf.

[40] *See, e.g.*, Comment to the Hon. Jeanne Kirkton, *supra* note 12, at 5 n.11(encouraging the Missouri "legislature to consider our comments, and scrutinize available health and safety evidence, as it evaluates whether and how to impose mandatory collaborative practice arrangements on physician assistants"). *See also* discussion of FTC comments *supra* at notes 12 and 13 and accompanying text.

[41] *See, e.g.*, CHRISTINE E. EIBNER ET AL., RAND, CONTROLLING HEALTH CARE SPENDING IN MASSACHUSETTS: AN ANALYSIS OF OPTIONS 103-104 (2009), http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR733.pdf (suggesting concrete savings that might be associated with expanded APRN and PA scope of practice, due to the lower costs and prices that tend to be associated with services delivered by PAs and APRNs: "between 2010 and 2020, Massachusetts could save $4.2 to $8.4 billion through greater reliance on NPs and PAs in the delivery of primary care"); Edward J. Timmons, *Healthcare License Turf Wars: The Effects of Expanded Nurse Practitioner and Physician Assistant Scope of Practice on Medicaid Patient Access* 17-18 (Mercatus Working Paper, 2016) https://www.mercatus.org/system/files/Timmons-Scope-of-Practice-v2.pdf (finding broader scope of practice for PAs is correlated with less expensive "outpatient care (an 11.8 to 14.4 percent reduction, depending on specification) without negatively affecting access to health care" . . . and that the "results of this paper, combined with findings of other researchers, suggest that broader scope of practice for NPs and PAs has little effect on the quality of care delivered, increases access to health care, and also potentially reduces the costs of providing health care to patients."); Morris M. Kleiner, et al., *Relaxing Occupation Licensing Requirements: Analyzing Wages and Prices for a Medical Service*, 59 J. L. & ECON. 261, 286 (2016) (study of the costs associated with regulation of APRNs, finding "more rigid regulations increase the price of a well-child visit by 3-16 percent" but found no impact on infant mortality or malpractice claims, suggesting relaxing regulations was unlikely to have adverse medical outcomes).

[42] *See Barriers to Entrepreneurship: Examining the Anti-Trust Implications of Occupational Licensing: Hearing Before the H. Comm. on Small Bus.*, 113th Cong. 1–3 (2014) (statement of Fed. Trade Comm'n on Competition and the Potential Costs and Benefits of Professional Licensure), https://www.ftc.gov/public-statements/2014/07/prepared-statement-federal-trade-commission-competition-potential-costs; Comment to the Hon. Jeanne Kirkton, *supra* note 12, at 5 n.11; Comment to the VA, *supra* note 12, at 2. It is unclear what, if any, health and safety concerns that ARC 2532C, the BOM's adopted rule, would address.

[43] It is our understanding that because the PA Board is proposing a regulation that differs from the one adopted by the BOM, the two Boards must reconcile their differences and adopt parallel rules to comply with the statutory mandate. See discussion of legislative and regulatory background, *supra* at Section II.B.

[44] IOWA CODE § 148C.3, Licensure (2016); IOWA ADMIN. CODE r. 645-326.8 (148C), Supervision Requirements (2016). *See also* discussion of legislative and regulatory background, *supra* at Section II.B.

[45] *See* FTC Staff, *Policy Perspectives*, *supra* note 12, at 37.

[46] Current Iowa statutes and regulations appear to permit such flexibility. Importantly, we are not aware of any studies or other evidence that would lead to concerns with how the current supervision requirements are being implemented, or the quality and safety of health care services delivered to patients by supervised PAs.

[47] *Compare* ARC 2532C, 653-21.4(1) Definitions *with*, IOWA ADMIN. CODE r. 645-326.1. Definitions.

[48] ARC 2532C, 653-21.4 (2), Minimum Standards, 653-21.4(2)*b*. Face-To-Face Meetings; and 653-21.4(2)*e*. Chart Reviews.

[49] *Compare* ARC 2532C, 653-21.4, Specific Minimum Standards for Appropriate Supervision of a Physician Assistant by a Physician *with*, IOWA ADMIN. CODE r. 645-326.8 (specifying supervision requirements); ARC 2532C, 653-21.4(2)*a.* Review of Requirements *with*, IOWA ADMIN. CODE r. 645-326.8(4) (PA and supervising physician are each responsible for knowing and complying with the supervision provisions of these rules); ARC 2532C, 653-21.4(2)*c.* Assessment of Education, Training, Skills, And Experience *with*, IOWA ADMIN. CODE r. 645-327.1 Duties and 327.1(1) (the supervising physician must have sufficient training or experience with the delegated tasks and must determine the PA's proficiency and competence); ARC 2532C, 653-21.4(2) *d.* Communication, *g.* Timely Consultation, and *h.* Alternate Supervision, *with*, IOWA ADMIN. CODE r. 645-326.8(4), 645-326.8(4)*a.* and *b.*(PA cannot practice if supervision is unavailable and supervisor and PA must review patient care on an ongoing basis as indicated by the clinical condition of the patient, which can occur in person, by telephone or by other telecommunicative means); ARC 2532C, 653-21.4(3), Amendment *with*, IOWA CODE § 148C.3.1. (specifying only that the PA "board shall adopt rules to govern the licensure of physician assistants"); and ARC 2532C, 653-21.4(4) Joint Waiver or Variance *with*, IOWA ADMIN. CODE r. 645-327.4(1)*c*. and 327.4(2) (specifying when the PA Board may permit variances with respect to care provided at a remote site). *But cf.* ARC 2532C, 653-21.4(2)*f.*, Delegated Services, which expressly incorporates by reference one of the PA Board's existing regulations (stating in part: "The medical services and medical tasks delegated to and provided by the physician assistant shall be in compliance with 645—subrule 327.1(1).").

[50] *See, e.g.*, Comments from Faculty of the Dept. of Physician Assistant Studies & Services, Carver College of Medicine, University of Iowa to the Iowa Bd. of Physician Assistants (Jan. 19, 2016; April 20, 2016) (explaining that University of Iowa Health Care ("UIHC") has "a pre-existing chart review QI in place in each department for all providers (physicians, PA's, ARNP's, etc.) . . . but that system would not meet the chart review requirements of the proposed rule, so supervising physicians would have to specifically add more chart review time to go over PA charts"). *See also* public comments referenced, *infra,* at note 54; Comment from Libby Coyte, PA, former chair, Iowa Bd. of Physician Assistants and former member, Iowa Bd. of Med. to Iowa Bd. of Physician Assistants (Mar. 8, 2016) (noting "rules 327.8(b-J) are restatements of what is already in the PA rules but are more restrictive and vary enough to be confusing to licensees"); Nat'l Governors Ass'n, *supra* note 15, at 11 (noting state policy should consider whether "[u]nclear statutes or regulations may inadvertently limit PAs' ability to participate in innovations" and that "[o]verly strict statutes or regulations may interfere with physicians' ability to delegate tasks to PAs").

[51] ARC 2532C states:

> At least one supervising physician shall meet face-to-face with each physician assistant a minimum of twice annually. If the physician assistant is practicing at a remote site, both meetings shall be at the remote site. Each party shall ensure that the face-to-face meetings are documented. The meetings are for the purpose of discussing topics deemed appropriate by the physician or the physician assistant, including supervision requirements, assessment of education, training, skills, and experience, review of delegated services, and medical services provided by the physician assistant.

[52] *See, e.g.*, American Academy of PAs, *Iowa PA Practice Profile* (2015), https://www.aapa.org/WorkArea/DownloadAsset.aspx?id=1610 (approximately 64% of PAs are employed by a physician group or solo practice, 26.4% practice in hospital settings, and 41.1% practice in rural areas); Comments from Paul A. James, MD, Chair, Dept. of Family Medicine, Carver College of Medicine, University of Iowa to the Iowa Bd. of Medicine (Mar. 9, 2016) (stating the proposed minimum standards are not necessary and noting that at the Family Medicine Clinic at the University of Iowa Hospitals and Clinics there are over 20 supervising physicians for two highly trained PAs, who "are under the direct observation of physicians every day, seeking guidance or reassurance in the course of caring for patients").

[53] *See, e.g.*, Comment from American Academy of PAs to Bd. of Physician Assistants (June 2, 2016) (public comment on ARC 2531C) (noting economic impact analysis conducted jointly with the Iowa Society of Physician Assistants estimates a $2.9 million burden on Iowa's healthcare system and a loss of approximately 44,500 patient encounters).

[54] *See, e.g.*, Comments from Faculty of the Dept. of Physician Assistant Studies & Services, *supra* note 50 (UIHC estimated that the originally proposed rules would have cost UIHC $502,200 for the 75 PAs it employs; its updated cost estimate to implement ARC 2532C projected $315,000 in additional costs per year); Iowa Bd. of Physician Assistants, *Jobs Impact Analysis: ARC 2417C* (Mar. 3, 2016) (although the Job Impact Analysis conclusions were based on the original rule, there were 84 comments from PAs, physicians, and hospitals in response to the survey, many of which raised concerns about what perceived need was being addressed by the proposed rules and how or whether existing review systems would meet the requirements of the proposed rules. For example, one hospital (comment No. 76) noted "Because our mid-levels work side-by-side with our physicians their work is being evaluated on an on-going basis. Additional formal chart review beyond the chart review we already provide would essentially [be] an exercise in pushing additional paper around in order to meet requirement and would not improve quality."). ARC 2532C also does not appear to contemplate any flexibility to the requirement for face-to-face meetings based on the PA's experience and training, how long the PA and physician have worked together, diverse circumstances and clinical needs, new models of consultation and supervision, or new technologies or institutional resources.

[55] IOWA ADMIN. CODE r. 645-327.4(2).

[56] Press Release, Iowa Bd. of Med., *supra* note 33.

[57] See discussion *infra* at notes 58-63 and accompanying text (discussing the costs associated with such face-to-face meeting requirements, the fact that many states and CMS do not have such requirements, and the potential use of telehealth or other innovations in health care delivery that might be stymied by such requirements). Increasingly, telehealth is being used successfully to facilitate supervision and collaboration among health care providers, as well as for the direct provision of health care services. *See, e.g.,* Comment from FTC Staff to the Delaware Bd. of Occupational Therapy Practice (Aug. 3, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-occupational-therapy-concerning-its-proposed-telehealth-regulation/v160014_delaware_ot_proposed_advocacy.pdf (noting proposed telehealth regulation would likely enhance competition and improve access to occupational therapy services by "not imposing rigid and unwarranted in-person care and supervision requirements"); Brian J. Miller, et al., Commentary, *Telemedicine and the Sharing Economy: The "Uber" for Healthcare*, 22 AM. J. MANAGED CARE, Dec. 2016, at 294, 295 (noting that telehealth platforms can "expand access to general medical services by reaching out to consumers in underserved areas and providing access to highly specialized consult services . . . [and] that physicians have successfully practiced telemedicine for over 100 years by using the telephone to conduct physician-to-physician consults, diagnose and treat patients, prescribe medications, and order diagnostic tests").

[58] Am. Acad. of Physician Assistants, *Six Key Elements of a Modern PA Practice Act* (Oct. 26, 2016), https://www.aapa.org/WorkArea/DownloadAsset.aspx?id=799 (chart of status for all states and the District of Columbia). South Dakota became the 28th state (29th including DC) when its Board of Medical and Osteopathic Examiners ("SDBOME") repealed its remote site visit requirement in September 2016. S.D. Bd. of Med. & Osteopathic Examiners, *Notice of New Rules* (Sept. 2016), http://www.sdbmoe.gov/sites/default/files/Notice%20of%20New%20Rules.pdf (SDBOME explained changes to its regulations concerning PAs, noting they removed the requirement that a supervising physician must visit each PA practice location every 90 days; eliminated the required in-person meeting as a condition of the supervision agreement; and allow the Physician/PA team to determine the best supervision arrangement).

[59] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II, Final Rule, 79 Fed. Reg. 27,106, 27,131 (May 12, 2014) (to be codified at 42 CFR pt. 413, 416, 440, 442, 482, 483, 485, 486, 491, 493), https://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf [hereinafter CMS 2014 Burden Reduction].

[60] CMS 2014 Burden Reduction, *supra* note 59, at 27,131.

[61] *Id.* at 27,150 (CMS estimated a total annual savings of $75,639,190 million by eliminating face-to-face visits and specified chart reviews for CAHs, RHCs, and FQHCs).

[62] *See, e.g.*, *Id.* at 27,131 & 27,149-50 (discussing both out-of-pocket costs and loss of patient encounters resulting from inflexible face-to-face meeting requirements); Comment from Nancy Bucklew, President, Iowa Ass'n of Rural Health Clinics to Bd. of Physician Assistants (Mar. 9, 2016) ("requiring face to face meetings prevents RHCs from fully utilizing our PAs for tele-emergency and tele-psychiatry to the detriment of our patients").

[63] *See, e.g.*, Comment from FTC Staff to the Delaware Board of Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers (Nov. 29, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-speech/language-pathologists-audiologists-hearing-aid-dispensers-regarding-its-proposed-revisions-its/161130_ftc_dealers_final_.pdf (commenting positively on the board's proposal "to remove existing restrictions on service by telecommunication and allow licensees to determine whether telepractice is an appropriate level of care, . . . which could enhance consumer choice by providing an alternative to in-person care, potentially reducing travel expenditures, increasing access to care, and increasing competition, as well as suggesting additional procompetitive steps the board might consider); Comment from FTC Staff to the Del. Bd. of Dietetics/Nutrition (Aug. 16, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-dietetics/nutrition-regarding-its-proposed-telehealth-regulation/staff_comment_delaware_diet_telehealth_signed.pdf (same, but noting the proposed rules would limit flexibility by requiring all initial evaluations to be performed face-to-face and not through telehealth); Comment from FTC Staff to Steve Thompson, Representative, Alaska State Legislature (Mar. 25, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-alaska-state-legislature-regarding-telehealth-provisions-senate-bill-74-which/160328alaskatelehealthcomment.pdf (noting telehealth provisions that eliminate the in-state requirement for Alaska-licensed physicians appear to be a procompetitive improvement in the law and likely would expand the supply of telehealth providers, promote competition, and increase access to safe and cost-effective care, as well as reduce transportation costs for Alaska patients and providers).

[64] IOWA ADMIN. CODE r. 645-327.4 *b*(4).

[65] Am. Acad. of Physician Assistants, *supra* note 58.

[66] CMS 2014 Burden Reduction, *supra* note 59, at 27,131. *See also id.* at 27,133 (CMS noted if "the applicable State law does not require a record review or cosignature, or both, by a collaborating physician, then CMS does not require such periodic record review" and that there is no CMS "regulatory requirement for the review of records to be performed onsite and in person").

[67] See discussion *supra* at notes 50 and 54 and accompanying text.

[68] *See* UIHC Comment and other public comments discussed *supra* at notes 53 and 54 and accompanying text.

FOLEY
FOLEY & LARDNER LLP

ATTORNEYS AT LAW
3000 ONE AMERICAN CENTER, 600 CONGRESS AVENUE
AUSTIN, TX 78701-3056
512.542.7000 TEL
512.542.7100 FAX
WWW.FOLEY.COM

WRITER'S DIRECT LINE
512.542.7070
eburbach@foley.com

CLIENT/MATTER NUMBER
103650-0109

October 15, 2020

Via email

smackey@ftc.gov
Sarah Mackey
Associate General Counsel for Project Management, Office of the General Counsel

dgilman@ftc.gov
Dan Gilman
Attorney Advisor
Office of Policy Planning

jhamburger@ftc.gov
Jacob Hamburger
Research Attorney
Office of Policy Planning
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Maine: September 30, 2020, Notice of Rulemaking Proposal
Board of Licensure in Medicine
Board of Osteopathic Licensure
Comment Deadline: **Friday, Oct. 30, 2020 at 4:30 p.m.**

Dear Ms. Mackey, Mr. Gilman, and Mr. Hamburger,

On behalf of the American Academy of PAs ("AAPA"), we are writing to respectfully request that the Federal Trade Commission Office of Policy Planning provide comments in response to the attached September 30, 2020, Notice of Rulemaking Proposal jointly issued by the Maine Board of Licensure in Medicine and the Maine Board of Osteopathic Licensure ("the Boards"). As set forth below, the adoption of the proposed rules would result in negative competitive effects and harm to consumers.

I. The AAPA

Founded in 1968, the AAPA is the national professional society for PAs (a/k/a Physician Assistants). It represents a profession of more than 140,000 PAs across all medical and surgical specialties in all 50 states, the District of Columbia, U.S. territories, and the uniformed services.

AAPA advocates and educates on behalf of the profession and the patients PAs serve. We work to ensure the professional growth, personal excellence and recognition of PAs. We also enhance their ability to improve the quality, accessibility and cost-effectiveness of patient-centered healthcare.[1]

II. Background of Maine Law and Recent Rulemaking

Maine is a state that licenses PAs through both its allopathic and osteopathic boards. PAs were historically required to have a supervising physician and a written agreement.

However, in March 2020, Maine Governor Janet Mills signed LD 1660 into law. The legislation was passed in an effort to expand the public's access to health care, including access to PAs. It was part of an emergency package to address the COVID-19 pandemic and went into effect immediately. Attached is a copy of LD 1660 complete with red line changes from the previous law.

Shortly after LD 1660 was signed into law, the Boards began working on joint rulemaking to implement the changes to statute. On July 7, 2020, the Boards released the attached proposed regulations with an August 7, 2020 at 4:30 p.m. deadline for public comment. AAPA and the Maine Association of PAs ("MEAPA") provided comments that were ***in favor*** of the then proposed regulations.

However, after receiving multiple comments from the physician community seeking to restrict PA practice in Maine, the Boards released the attached revised proposed regulations on Sept. 30, 2020, with a comment deadline of Oct. 30, 2020.

In releasing the September 30, 2020, proposed regulations, the Boards have exceeded their statutory authority and are attempting to create burdensome and restrictive requirements to improperly restrict PA practice in Maine. The newly proposed rules would add additional requirements for PAs practicing under a collaborative agreement or a practice agreement. However, that is not a requirement of LD 1660. In fact, such requirements ***were not even required before LD 1660 was signed into law***. Further, the proposed regulations would disadvantage PAs by creating additional unnecessary administrative work. In short, the proposed regulations exceeds the intent and authority of the law. The adoption of the proposed rules would result in negative competitive effects and harm to consumers.

[1] Learn more at https://www.aapa.org/about/

III. Proposed Provisions of Concern

Specifically, the proposed provisions which are especially of concern are as follows:

- The proposed rules combine a practice agreement and a collaborative agreement as though they are the same document. That is not the case. As specified in the law, the targeted audience for practice under each agreement is very different.

- (9A1) The documentation requirement would have the practical effect of prohibiting newly graduated PAs from practice. In addition, PAs would be reliant on their previous employers to provide that documentation and without access may not be able to meet that requirement.

- (9A2 and 9A4) Physician reviews are inappropriate as a qualification for PAs to practice. In addition, the physician may not be able to address a PA's competency in all areas because these may not have been skills required during their team practice; this may create unnecessary liability for physicians and could negatively impact PAs.

- (9A5) Specialty Certificates of Added Qualifications (CAQs) are not a requirement for PA practice under the law. Further, they are not available for every specialty and adding this requirement would be prohibitive to PA practice.

- (9A6) The law explicitly eliminates supervision, but in this proposed rule the Boards add it back in.

- (9A7) The Boards may improperly limit a PA's scope of practice by requiring additional education/training.

IV. LD1660 material provisions:

- It increases the membership of the Board of Osteopathic Licensure and the Board of Licensure in Medicine by adding an additional PA for a total of 2 PA members per board

- It establishes provisions for the scope of practice, insurance coverage of services and immunity from liability for providing volunteer medical services during emergencies or disasters

- It clarifies that PAs are primary care providers when practicing in a medical specialty required for a physician to be a primary care provider.

- It removes the two-tiered system of licensure and then registration. Before the law, PAs had to first receive their license, then register to practice. Now only a license is needed.

- It removes supervisory requirements and replaces them with collaborative requirements. Including eliminating written plans of supervision for a majority of PAs in the state.

- It establishes requirements for PAs to collaborate and consult with physicians and other health care professionals.

    - PAs with less than 4,000 hours of practice are required to enter into a collaborative agreement until they reach 4,000 hours

    - PAs who have more than 4,000 hours of practice who are the principal clinical provider in a practice or setting that does not have a physician partner are required to have a practice agreement with a physician.

- It changes the initial licensing fee from $250 to $300.

- It provides a transition provision for physician assistant licenses that are current and not subject to disciplinary action.

LD1660 defines a "collaborative agreement" as follows:

> *"Collaborative agreement" means a document agreed to by a physician assistant and a physician that describes the scope of practice for the physician assistant as determined by practice setting and describes the decision-making process for a health care team, including communication and consultation among health care team members.*

LD 1660 sets forth the following requirements for "Collaborative Agreements":

> *Collaborative agreement requirements. A physician assistant with less than 4,000 hours of clinical practice documented to the board shall work in accordance with a collaborative agreement with an active physician that describes the physician assistant's scope of practice, except that a physician assistant working in a physician group practice setting or a health care facility setting under a system of credentialing and granting of privileges and scope of practice agreement may use that system of credentialing and granting of privileges and scope of practice agreement in lieu of a collaborative agreement. A physician assistant is legally responsible and assumes legal liability for any medical service provided by the physician assistant in accordance with the physician assistant's scope of practice under subsection 2 and a collaborative agreement under this subsection. Under a collaborative agreement, collaboration may occur through electronic means and does not require the physical presence of the physician at the time or place that the medical services are provided. A physician assistant shall submit the*

collaborative agreement, or, if appropriate, the scope of practice agreement, to the board for approval and the agreement must be kept on file at the main location of the place of practice and be made available to the board or the board's representative upon request. Upon submission to the board of documentation of 4,000 hours of clinical practice, a physician assistant is no longer subject to the requirements of this subsection.

LD 1660 defines "Practice agreement" as follows:

"Practice agreement" means a document agreed to by a physician assistant who is the principal clinical provider in a practice and a physician that states the physician will be available to the physician assistant for collaboration or consultation.

LD 1660 sets forth the following requirements for "Practice agreements":

Practice agreement requirements. A physician assistant who has more than 4,000 hours of clinical practice may be the principal clinical provider in a practice that does not include a physician partner as long as the physician assistant has a practice agreement with an active physician, and other health care professionals as necessary, that describes the physician assistant's scope of practice. A physician assistant is legally responsible and assumes legal liability for any medical service provided by the physician assistant in accordance with the physician assistant's scope of practice under subsection 2 and a practice agreement under this subsection. A physician assistant shall submit the practice agreement to the board for approval and the agreement must be kept on file at the main location of the physician assistant's practice and be made available to the board or the board's representative upon request. Upon any change in the parties to the practice agreement or other substantive change in the practice agreement, the physician assistant shall submit the revised practice agreement to the board for approval. Under a practice agreement, consultation may occur through electronic means and does not require the physical presence of the physician or other health care providers who are parties to the agreement at the time or place that the medical services are provided.

LD1660 defines the "Scope of practice" as follows:

Scope of practice. A physician assistant may provide any medical service for which the physician assistant has been prepared by education, training and experience and is competent to perform. The scope of practice of a physician assistant is determined by practice setting, including, but not limited to, a physician employer setting, physician group practice setting or independent

private practice setting, or, in a health care facility setting, by a system of credentialing and granting of privileges.

LD1660 provides the following authorization to the Board of Licensure in Medicine:

Rules. The Board of Licensure in Medicine is authorized to adopt rules regarding the licensure and practice of physician assistants and the agency relationship between the physician assistant. These rules, which must be adopted jointly with the Board of Osteopathic Licensure, may pertain to, but are not limited to, the following matters:

***

D. Scope of practice for physician assistants, including prescribing of controlled drugs;

E. Requirements for collaborative agreements and practice agreements under section 3270-G, including uniform standards and forms;

Shortly after LD 1660 was signed, the Boards began working on joint rulemaking to implement the changes to statute. The major issue with respect to the promulgation of rules is with respect to the removal of the required written agreement with a supervising/collaborating physician.

The July 7, 2020, originally proposed regulations included the following requirements regarding collaborative agreements and practice agreements:

SECTION 7. UNIFORM ELEMENTS OF WRITTEN COLLABORATIVE AND PRACTICE AGREEMENTS

1. All written collaborative agreements and practice agreements shall include at a minimum:

A. The physician assistant's scope of practice and practice setting, including the types of patients and patient encounters common to the practice, a general overview of the role of the physician assistant in the practice setting, and the tasks that the physician assistant will be delegating to medical assistants.

a. Identify any and all active Maine physician(s) who are signatories to a collaborative or practice agreement that describes the physician assistants' scope of practice;

B. Identify the method(s) of consultation with the active Maine physicians who are signatories to a collaborative or practice agreement, and any limitations regarding the ability of the

> physician(s) to provide consultation, including limitations as to scope of practice or availability. The physician(s) who are signatories to a collaborative or practice agreement shall provide consultation only within their scope of practice and must be available for consultation with the physician assistant at all times and for all medical services rendered by the physician assistant.

However, the Sept. 30, 2020 Proposed Rules included the following more stringent requirements regarding collaborative agreements and practice agreements:

> 9. **Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements**
>
> A. In reviewing a proposed scope of practice delineated in a collaborative agreement or a practice agreement, the Board may request any of the following from the physician assistant:
>
> (1) Documentation of at least 24 months of clinical practice within a particular medical specialty during the 48 months immediately preceding the date of the collaborative agreement or practice agreement;
>
> (2) Copies of previous plans of supervision, together with physician reviews;
>
> (3) Copies of any credentialing and privileging scope of practice agreements, together with any employment or practice reviews;
>
> (4) Letter(s) from a physician(s) attesting to the physician assistant's competency to render the medical services proposed;
>
> (5) Completion of Specialty Certificates of Added Qualifications (CAQs) in a medical specialty obtained through the NCCPA or its successor organization;
>
> (6) Preparation of a plan for rendering medical services for a period of time under the supervision of a physician;
>
> (7) Successful completion of an educational and/or training program approved by the Board.

Finally, we attach a copy of an October 17, 2018, letter which our firm sent to the Maine Board of Licensure in Medicine regarding similar anti-competitive policies adopted by the Board.

We appreciate your consideration of this important matter. Please do not hesitate to contact Carson Walker at cwalker@aapa.org or me, should you have any questions.

Sincerely,

FOLEY & LARDNER LLP

Edward D. ("Ed") Burbach

cc:
cwalker@aapa.org
Carson Walker
AAPA

Enclosures:
LD 1660 (including red lined changes to previous law)
July 7, 2020, Maine Notice of Agency Rulemaking Proposal
Agency 02-373: Board of Licensure in Medicine
Agency 02-383: Board of Osteopathic Licensure
August 6, 2020 AAPA comments to Maine Boards' original July 7, 2020 proposed Rules
September 30, 2020, Maine Notice of Agency Rulemaking Proposal (red line of areas of concern)
Agency 02-373: Board of Licensure in Medicine
Agency 02-383: Board of Osteopathic Licensure
October 17, 2018, Foley Letter to Maine Board of Licensure in Medicine

INITIAL PROPOSAL

revised 8-2019

Rulemaking Fact Sheet

(5 MRSA §8057-A)

AGENCY: 02-373 Board of Licensure in Medicine; 02-383 Board of Osteopathic Licensure

NAME, ADDRESS, PHONE NUMBER, EMAIL OF AGENCY CONTACT PERSON:

Dennis E. Smith, Executive Director; Board of Licensure in Medicine, 137 State House Station, Augusta, ME 04333-0137; (tel) 287-3605 (fax) 287-6590; dennis.smith@maine.gov

Susan E. Strout, Executive Secretary; Board of Osteopathic Licensure, 142 State House Station, Augusta, ME 04333-0142; (tel) 287-2480 (fax) 536-5811; susan.e.strout@maine.gov

CHAPTER NUMBER AND RULE TITLE: 2 Joint Rule Regarding Physician Assistants

TYPE OF RULE *(check one)*: ☒ Routine Technical ☐ Major Substantive

STATUTORY AUTHORITY: 32 M.R.S. §§ 2562 and 2594-E(5); §§ 32 M.R.S. 3269(7) and 3270-E(5); 10 M.R.S. § 8003(5)(C)(4)

DATE, TIME AND PLACE OF PUBLIC HEARING: None planned. Requests to hold a public hearing by any interested person may be submitted in writing to the identified agency contact person.

COMMENT DEADLINE: Friday, August 7, 2020 at 4:30 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see* §8057-A(1)(A)&(C)]

To amend an existing joint rule to implement PL 2020, c. 627, "An Act to Improve Access to Physician Assistant Care."

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___YES _x__NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B)&(D)]

This is a consolidated rulemaking proceeding of the Board of Licensure in Medicine and the Board of Osteopathic Licensure to amend a joint rule relating to the licensure and practice of physician assistants. The proposed amendments to the joint rule will implement PL 2020, c. 627, which authorized the Board of Osteopathic Licensure and the Board of Licensure in Medicine to adopt a joint rule.

The proposed amendments to the joint rule would: amend the definition of certain terms to eliminate registration and supervision; add definitions for certain terms, including "Health Care Facility," Health Care Team," Inactive Status License," and "Physician Group Practice;" eliminates registration and supervision requirements; establishes criteria for "Inactive Status Licenses;" establishes uniform continuing clinical competency requirements; amends the uniform fees; establishes criteria for collaborative agreements and practice agreements; amends the uniform notification requirements to include legal change of name; and amends the continuing medical education (CME) requirements, including 3 hours of CME every 2 years regarding opioid prescribing.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [*see* §§8057-A(1)(E) & 8063-B] Maine statutory definitions in PL. 2020, c. 627; Maine statutory definitions for "Health Care Facility;" NCCPA requirements for continuing medical education; Laws, rules, policies and guidelines from other medical licensing boards and commissions and national organizations (Federation of State Medical Boards) and associations (Maine Medical Association) related to standards for maintaining "Continuing Clinical Competency."

INITIAL PROPOSAL

ESTIMATED FISCAL IMPACT OF THE RULE: [*see* §8057-A(1)(C)] Minimal

FOR EXISTING RULES WITH FISCAL IMPACT OF $1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS: [*see* §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [*see* §8057-A(2)(B)]

BENEFITS OF THE RULE: [*see* §8057-A(2)(C)]

Note: If necessary, additional pages may be used.

RE-PROPSAL WITH SUBSTANTIVE CHANGES

revised 8-2019

Rulemaking Fact Sheet

(5 MRSA §8057-A)

AGENCY: 02-373 Board of Licensure in Medicine; 02-383 Board of Osteopathic Licensure

NAME, ADDRESS, PHONE NUMBER, EMAIL OF AGENCY CONTACT PERSON:

Dennis E. Smith, Executive Director; Board of Licensure in Medicine, 137 State House Station, Augusta, ME 04333-0137; (tel) 287-3605 (fax) 287-6590; dennis.e.smith@maine.gov

Susan E. Strout, Executive Secretary; Board of Osteopathic Licensure, 142 State House Station, Augusta, ME 04333-0142; (tel) 287-2480 (fax) 536-5811; susan.e.strout@maine.gov

CHAPTER NUMBER AND RULE TITLE: 2 Joint Rule Regarding Physician Assistants

TYPE OF RULE *(check one)*: ☒ Routine Technical ☐ Major Substantive

STATUTORY AUTHORITY: 32 M.R.S. §§ 2562 and 2594-E(5); §§ 32 M.R.S. 3269(7) and 3270-E(5); 10 M.R.S. § 8003(5)(C)(4)

DATE, TIME AND PLACE OF PUBLIC HEARING: None planned. Requests to hold a public hearing by any interested person may be submitted in writing to the identified agency contact person.

COMMENT DEADLINE: Friday, October 30, 2020 at 4:30 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see* §8057-A(1)(A)&(C)]

To amend an existing joint rule to implement PL 2020, c. 627, "An Act to Improve Access to Physician Assistant Care."

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___YES _x__NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B)&(D)]

This is a consolidated rulemaking proceeding of the Board of Licensure in Medicine and the Board of Osteopathic Licensure ("boards") to amend a joint rule relating to the licensure and practice of physician assistants. The proposed amendments to the joint rule will implement PL 2020, c. 627, which authorized the Board of Osteopathic Licensure and the Board of Licensure in Medicine to adopt a joint rule.

As originally proposed, the amendments to the joint rule : amended the definition of certain terms to eliminate registration and supervision; added definitions for certain terms, including "Health Care Facility," Health Care Team," Inactive Status License," and "Physician Group Practice;" eliminated registration and supervision requirements; establishes criteria for "Inactive Status Licenses;" established uniform continuing clinical competency requirements; amends the uniform fees; established criteria for collaborative agreements and practice agreements; amended the uniform notification requirements to include legal change of name; and amended the continuing medical education (CME) requirements, including 3 hours of CME every 2 years regarding opioid prescribing.

Following receipt and review of written comments to the proposed amendments to the rule, the boards made the following substantive changes to the proposed amendments to the rule: adding a definition for "physician"; amending section 6.8 to add paragraph D establishing criteria for acceptable documentation of clinical practice; amending section 6 to add a new paragraph 9 "Criteria for Reviewing Scope of Practice for Physician Assistants in Collaborative Agreements or Practice Agreements"; and amending section 12 of the rule to require that physician assistants verbally identify themselves as physician assistants whenever greeting patients during an initial encounter and whenever patients incorrectly refer to them as "doctors".

RE-PROPSAL WITH SUBSTANTIVE CHANGES

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [*see* §§8057-A(1)(E) & 8063-B] Maine statutory definitions in PL. 2020, c. 627; Maine statutory definitions for "Health Care Facility;" NCCPA requirements for continuing medical education; Laws, rules, policies and guidelines from other medical licensing boards and commissions and national organizations (Federation of State Medical Boards) and associations (Maine Medical Association) related to standards for maintaining "Continuing Clinical Competency."

ESTIMATED FISCAL IMPACT OF THE RULE: [*see* §8057-A(1)(C)] Minimal

FOR EXISTING RULES WITH FISCAL IMPACT OF $1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS: [*see* §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [*see* §8057-A(2)(B)]

BENEFITS OF THE RULE: [*see* §8057-A(2)(C)]

Note: If necessary, additional pages may be used.

Administrative Procedure Act

CHECKLIST

Agency: 02-383 Board of Osteopathic Licensure

Chapter Number and Title of Rule: 2 Joint Rule Regarding Physician Assistants

INITIAL RULE PROPOSAL:

1. Was this rule listed on the last regulatory agenda? Yes

2. Date of notification of: Anyone on mailing list July 6, 2020

   Any trade publications Posted on Board's website July 8, 2020

3. Date Notice of Rulemaking Proposal (MAPA-3) sent to Secretary of State: June 29, 2020

4. Date Fact Sheet sent to Executive Director of Legislative Council: July 1, 2020

5. Date of publication in Secretary of State's rulemaking ad.: July 8, 2020

6. Date of hearing(s): none held 7. Comment deadline: August 7, 2020

RE-PROPOSAL WITH SUBSTANTIVE CHANGES:

1. Was this rule listed on the last regulatory agenda? Yes

2. Date of notification of: Anyone on mailing list September 25, 2020

   Any trade publications Posted on Board's website September 30, 2020

3. Date Notice of Rulemaking Proposal (MAPA-3) sent to Secretary of State: September 22, 2020

4. Date Fact Sheet sent to Executive Director of Legislative Council: September 23, 2020

5. Date of publication in Secretary of State's rulemaking ad.: September 30, 2020

6. Date of hearing(s): none held 7. Comment deadline: October 30, 2020

ADOPTED RULE:

8. Was comment deadline extended or comment period reopened? Yes

   If yes, date of second notice publication in Secretary of State's rulemaking ad: September 30, 2020

9. Is adopted rule consistent with what was proposed? Yes, however substantive changes were made in response to comments received. (If not, please address the changes in the comments and responses section of your filing.)

10. Is the person signing the Certification Statement (MAPA-1, #9) authorized to do so as stated in your statutes or in 5 MRSA, c.71? Yes

11. Was the rule adopted within 120 days of the comment deadline? Yes

12. Was the rule approved and signed by the Office of the Attorney General within 150 days of the comment deadline? Yes

13. Is a Basis Statement included? Yes Is a copy of the Fact Sheet included? Yes
Are comments, with names and organizations, and your responses included? Yes

Notice of Agency Rulemaking Adoption

AGENCY: 02-373 Board of Licensure in Medicine; 02-383 Board of Osteopathic Licensure

CHAPTER NUMBER AND TITLE: 2 Joint Rule Regarding Physician Assistants

ADOPTED RULE NUMBER: **20xx.xxx**
(LEAVE BLANK - ASSIGNED BY SECRETARY OF STATE)

CONCISE SUMMARY The Board of Licensure in Medicine and the Board of Osteopathic Licensure amended an existing joint rule relating to the licensure and practice of physician assistants to implement PL 2020, c. 627, "An Act to Improve Access to Physician Assistant Care."

EFFECTIVE DATE:
(TO BE FILLED IN BY SECRETARY OF STATE)

AGENCY CONTACT PERSON: Dennis E. Smith, Executive Director
AGENCY NAME: Board of Licensure in Medicine
ADDRESS: 137 SHS, 161 Capitol St, Augusta, ME 04333-0137

TELEPHONE: 287-3605

AGENCY CONTACT PERSON: Susan E. Strout, Executive Secretary
AGENCY NAME: Board of Osteopathic Licensure
ADDRESS: 142 State House Station, 161 Capitol St, Augusta, ME 04333-0142

TELEPHONE: 287-2480