PROFESSIONAL LICENSURE DIVISION[645]

Notice of Intended Action

Proposing rulemaking related to practice of physician assistants and providing an opportunity for public comment

The Board of Physician Assistants hereby proposes to rescind Chapter 327, "Practice of Physician Assistants," Iowa Administrative Code, and to adopt a new chapter with the same title.

Legal Authority for Rulemaking

This rulemaking is proposed under the authority provided in Iowa Code sections 147.36, 147.76, 148C.3, 148C.5, 272C.3 and 272C.4.

State or Federal Law Implemented

This rulemaking implements, in whole or in part, Iowa Code chapters 17A, 147, 148C and 272C.

Purpose and Summary

This proposed rulemaking articulates the medical scope of practice that a physician assistant can provide based on the physician assistant's education, training, and experience. The rulemaking provides Iowans, licensees, and their employers with more information on the accepted minimum standards for the practice of this profession in this state.

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rulemaking, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking would result in hardship or injustice to that person may petition the Department of Inspections, Appeals, and Licensing for a waiver of the discretionary provisions, if any, pursuant to 645—Chapter 18.

Public Comment

Any interested person may submit written or oral comments concerning this proposed rulemaking. Written or oral comments in response to this rulemaking must be received by the Department no later than 4:30 p.m. on February 14, 2024. Comments should be directed to:

Michele Royer Iowa Department of Inspections, Appeals, and Licensing/Bureau of Board Support 6200 Park Avenue Des Moines, Iowa 50321 Phone: 515.281.5234 Email: michele.royer@iowa.gov

Public Hearing

Public hearings at which persons may present their views orally or in writing will be held as follows:

February 13, 2024 1:10 to 1:30 p.m.

February 14, 2024 1:10 to 1:30 p.m.

6200 Park Avenue Des Moines, Iowa Video call link: meet.google.com/isb-pmab-qob Or dial: 1.813.252.1868 PIN: 724 486 884# Phone numbers: tel.meet/isb-pmab-qob?pin=8352415222450

6200 Park Avenue Des Moines, Iowa Video call link: meet.google.com/isb-pmab-qob Or dial: 1.813.252.1868 PIN: 724 486 884# Phone numbers: tel.meet/isb-pmab-qob?pin=8352415222450

Persons who wish to make oral comments at a public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rulemaking.

Any persons who intend to attend a public hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Department and advise of specific needs.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rulemaking by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rulemaking at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rulemaking action is proposed:

ITEM 1. Rescind 645—Chapter 327 and adopt the following **new** chapter in lieu thereof:

CHAPTER 327 PRACTICE OF PHYSICIAN ASSISTANTS

645—327.1(148C,88GA,ch1020) Duties. The medical services to be provided by the physician assistant are those for which the physician assistant has been prepared by education, training, or experience and is competent to perform. 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. The high degree of responsibility a physician assistant may assume requires that, at the conclusion of the formal education, the physician assistant possess the knowledge, skills, and abilities necessary to provide those services appropriate to the practice setting. The physician assistant's services may be utilized in any clinical settings including but not limited to the office, the ambulatory clinic, the hospital, the patient's home, extended care facilities, and nursing homes.

327.1(1) A physician assistant's duties relating to prescribing, dispensing, ordering, administering, and procuring drugs and medical devices include all of the following:

a. Administering any drug.

b. Prescribing, dispensing, ordering, administering, and procuring drugs and medical devices. A physician assistant may plan and initiate a therapeutic regimen that includes ordering and prescribing nonpharmacological interventions including but not limited to durable medical equipment, nutrition, blood and blood products; and diagnostic support services including but not limited to home health care, hospice, and physical and occupational therapy. The prescribing and dispensing of drugs may include Schedule II through V substances, as described in Iowa Code chapter 124, and all legend drugs.

c. A physician assistant may prescribe drugs and medical devices subject to all of the following conditions:

(1) The physician assistant will have passed the national certifying examination conducted by the National Commission on Certification of Physician Assistants or its successor examination approved by the board.

(2) The physician assistant must comply with appropriate federal and state regulations.

(3) If a physician assistant prescribes or dispenses controlled substances, the physician assistant must register with the federal Drug Enforcement Administration.

(4) The physician assistant may prescribe or order Schedule II controlled substances that are listed as depressants in Iowa Code chapter 124.

(5) The physician assistant may prescribe, supply, and administer drugs and medical devices in all settings, including but not limited to hospitals, health care facilities, health care institutions, hospice, clinics, offices, health maintenance organizations, and outpatient and emergency care settings.

(6) A physician assistant may request, receive, and supply sample drugs and medical devices.

d. Supplying properly packaged and labeled prescription drugs, controlled substances, or medical devices when pharmacist services are not reasonably available or when it is in the best interest of the patient.

(1) If the physician assistant is the prescriber of the medications supplied pursuant to this paragraph, the medications supplied will be for the purpose of accommodating the patient and will not be sold for more than the cost of the drug and reasonable overhead costs as they relate to supplying prescription drugs to the patient and not at a profit to the physician assistant.

(2) A nurse or staff assistant may assist the physician assistant in supplying medications.

327.1(2) The medical services to be provided by the physician assistant also include, but are not limited to, the following:

a. The initial approach to a patient of any age group in any setting to elicit a medical history and perform a physical examination.

b. Assessment, diagnosis and treatment of medical or surgical problems and recording the findings.

c. Order, interpret, or perform laboratory tests, X-rays or other medical procedures or studies.

d. Performance of therapeutic procedures such as injections, immunizations, suturing and care of wounds, removal of foreign bodies, ear and eye irrigation and other clinical procedures.

e. Performance of office surgical procedures including, but not limited to, skin biopsy, mole or wart removal, toenail removal, removal of a foreign body, arthrocentesis, incision and drainage of abscesses.

f. Assisting in surgery.

g. Prenatal and postnatal care and assisting a physician in obstetrical care.

h. Care of orthopedic problems.

i. Performing and screening the results of special medical examinations including, but not limited to, electrocardiogram or Holter monitoring, radiography, audiometric and vision screening, tonometry, and pulmonary function screening tests.

j. Instruction and counseling of patients regarding physical and mental health on matters such as diets, disease, therapy, and normal growth and development.

k. Function in the hospital setting by performing medical histories and physical examinations, making patient rounds, recording patient progress notes and other appropriate medical records, assisting in surgery, performing or assisting with medical procedures, providing emergency medical services and issuing, transmitting and executing patient care orders.

l. Providing services to patients requiring continuing care (i.e., home, nursing home, extended care facilities).

m. Referring patients to specialty or subspecialty physicians, medical facilities or social agencies as indicated by the patients' problems.

n. Immediate evaluation, treatment and institution of procedures essential to providing an appropriate response to emergency medical problems.

o. Order drugs and supplies in the office, and assist in keeping records and in the upkeep of equipment.

p. Admit patients to a hospital or health care facility as defined in Iowa Code section 135C.1.

q. Order diets, physical therapy, inhalation therapy, or other rehabilitative services as indicated by the patient's problems.

r: At the request of the peace officer, withdraw a specimen of blood from a patient for the purpose of determining the alcohol concentration or the presence of drugs.

s. Direct medical personnel, health professionals, and others involved in caring for patients and the execution of patient care.

t. Authenticate medical forms by signing the form.

u. Perform other duties appropriate to a physician assistant's practice.

v. Health care providers will consider the instructions of a physician assistant to be authoritative.
327.1(3) Emergency medicine duties.

a. A physician assistant may be a member of the staff of an ambulance or rescue squad pursuant to Iowa Code chapter 147A.

b. A physician assistant will document skills, training and education equivalent to that required of a certified advanced emergency medical technician or a paramedic.

c. A physician assistant must apply for approval of advanced care training equivalency on forms supplied by the board of physician assistants.

d. Exceptions to this subrule include:

(1) A physician assistant who accompanies and is responsible for a transfer patient;

(2) A physician assistant who serves on a basic ambulance or rescue squad service; and

(3) A physician assistant who renders aid within the physician assistant's skills during an emergency.

645—327.2(148C) Prohibition. No physician assistant engaged in independent practice, as defined in Iowa Code section 148C.1(5), will be permitted to measure the visual power and visual efficiency of the human eye, as distinguished from routine visual screening, except in the personal presence of a supervising physician at the place where these services are rendered.

645—327.3(147,88GA,ch1020) Identification as a physician assistant. The physician assistant will be identified as a physician assistant to patients and to the public, regardless of the physician assistant's educational degree.

645—327.4(147) Prescription requirements.

327.4(1) Each written outpatient prescription drug order issued by a physician assistant will contain the following:

a. The date of issuance.

b. The name and address of the patient for whom the drug is prescribed.

c. The name, strength, and quantity of the drug, medicine, or device prescribed and directions for use.

d. The physician assistant's name and the practice address.

e. The signature of the physician assistant followed by the initials "PA."

f. The Drug Enforcement Administration (DEA) number of the physician assistant if the prescription is for a controlled substance.

327.4(2) Each oral prescription drug order issued by a physician assistant will include the same information required for a written prescription, except for the written signature of the physician assistant and the physician assistant's practice address.

327.4(3) Prior to prescribing an opioid, a physician assistant will review the patient's information contained in the prescription monitoring program database, unless the patient is receiving inpatient hospice care or long-term residential facility patient care.

327.4(4) Beginning January 1, 2020, every prescription issued for a prescription drug will be transmitted electronically unless exempted pursuant to Iowa Code section 124.308 or 155A.27. Beginning January 1, 2020, a licensee who fails to comply with the electronic prescription mandate

may be subject to a nondisciplinary administrative penalty of \$250 per violation, up to a maximum of \$5,000 per calendar year.

645—327.5(147) Supplying—requirements for containers, labeling, and records.

327.5(1) Containers. A prescription drug will be supplied in a container that meets the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. §1471-1476 (1976), which relate to childproof closure, unless otherwise requested by the patient. The containers must also meet the requirements of Section 502G of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 et seq. (1976), which pertain to light resistance and moisture resistance needs of the drug supplied.

327.5(2) *Labeling.* A label bearing the following information will be affixed to a container in which a prescription drug is supplied:

a. The name and practice address of the supervising physician and physician assistant.

b. The name of the patient.

c. The date supplied.

d. The directions for administering the prescription drug and any cautionary statement deemed appropriate by the physician assistant.

e. The name, strength and quantity of the prescription drug in the container.

f. When supplying Schedule II, III, or IV controlled substances, the federal transfer warning statement must appear on the label as follows: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

327.5(3) Samples. Prescription sample drugs will be provided without additional charge to the patient. Prescription sample drugs supplied in the original container or package will be deemed to conform to labeling and packaging requirements.

327.5(4) *Records.* A record of prescription drugs supplied by the physician assistant to a patient will be kept that contains the label information required by paragraphs 327.7(2) "b" to "e." Noting such information on the patient's chart or record is sufficient.

645—327.6(147,148C,272C) Standards of practice—telemedicine. This rule establishes standards of practice for the provision of telemedicine services.

327.6(1) Telemedicine, generally.

a. Technological advances have made it possible for licensees in one location to provide medical care to patients in another location with or without an intervening health care provider.

b. Telemedicine is a useful tool that, if applied appropriately, can provide important benefits to patients, including increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and potential cost savings.

c. Licensees using telemedicine will be held to the same standards of care and professional ethics as licensees using traditional in-person medical care.

d. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may subject the licensee to potential discipline by the board.

327.6(2) *Definitions.* For the purposes of this rule:

"Asynchronous store-and-forward transmission" means the collection of a patient's relevant health information and the subsequent transmission of the data from an originating site to a health care provider at a distant site without the presence of the patient.

"Board" means the Iowa board of physician assistants.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996, PL 104-191, August 21, 1996, 110 Stat. 1936.

"In-person encounter" means that the physician assistant and the patient are in the physical presence of each other and are in the same physical location during the physician assistant-patient encounter.

"Licensee" means a physician assistant licensed by the board.

"Telemedicine" means the practice of medicine using electronic audiovisual communications and information technologies or other means, including interactive audio with asynchronous store-and-forward transmission, between a licensee in one location and a patient in another location with

or without an intervening health care provider. Telemedicine includes asynchronous store-and-forward technologies, remote monitoring, and real-time interactive services, including teleradiology and telepathology. Telemedicine, for the purposes of this rule establishing standards of practice, does not include the provision of medical services only through an audio-only telephone, email messages, facsimile transmissions, or U.S. mail or other parcel service, or any combination thereof.

"Telemedicine technologies" means technologies and devices enabling secure electronic communications and information exchanges between a licensee in one location and a patient in another location with or without an intervening health care provider.

327.6(3) *Practice guidelines.* A licensee who uses telemedicine will utilize evidence-based telemedicine practice guidelines and standards of practice, to the degree they are available, to ensure patient safety, quality of care, and positive outcomes. The board acknowledges that some nationally recognized medical specialty organizations have established comprehensive telemedicine practice guidelines that address the clinical and technological aspects of telemedicine for many medical specialties.

327.6(4) *License required.* A physician assistant who uses telemedicine in the diagnosis and treatment of a patient located in Iowa will hold an active Iowa physician assistant license consistent with state and federal laws. Nothing in this rule will be construed to supersede the exceptions to licensure contained in rule 645—326.17(148C).

327.6(5) *Standards of care and professional ethics.* A licensee who uses telemedicine will be held to the same standards of care and professional ethics as a licensee using traditional in-person encounters with patients. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may be a violation of the laws and rules governing the practice of medicine and may subject the licensee to potential discipline by the board.

327.6(6) Scope of practice. A licensee who uses telemedicine will ensure that the services provided are consistent with the licensee's scope of practice, including the licensee's education, training, experience, ability, licensure, and certification.

327.6(7) *Identification of patient and physician assistant.* A licensee who uses telemedicine will verify the identity of the patient and ensure that the patient has the ability to verify the identity, licensure status, certification, and credentials of all health care providers who provide telemedicine services prior to the provision of care.

327.6(8) Physician assistant-patient relationship.

a. A licensee who uses telemedicine will establish a valid physician assistant-patient relationship with the person who receives telemedicine services. The physician assistant-patient relationship begins when:

(1) The person with a health-related matter seeks assistance from a licensee;

(2) The licensee agrees to undertake diagnosis and treatment of the person; and

(3) The person agrees to be treated by the licensee whether or not there has been an in-person encounter between the physician assistant and the person.

b. A valid physician assistant-patient relationship may be established by:

(1) In-person encounter. Through an in-person medical interview and physical examination where the standard of care would require an in-person encounter;

(2) Consultation with another licensee. Through consultation with another licensee (or other health care provider) who has an established relationship with the patient and who agrees to participate in, or supervise, the patient's care; or

(3) Telemedicine encounter. Through telemedicine, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.

327.6(9) *Medical history and physical examination.* Generally, a licensee will perform an in-person medical interview and physical examination for each patient. However, the medical interview and physical examination may not be in person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in person. Prior to providing treatment, including issuing prescriptions,

electronically or otherwise, a licensee who uses telemedicine will interview the patient to collect the relevant medical history and perform a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient. An Internet questionnaire that is a static set of questions provided to the patient, to which the patient responds with a static set of answers, in contrast to an adaptive, interactive and responsive online interview, does not constitute an acceptable medical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by a licensee.

327.6(10) *Non-physician assistant health care providers.* If a licensee who uses telemedicine relies upon or delegates the provision of telemedicine services to a non-physician assistant health care provider, the licensee will:

a. Ensure that systems are in place to ensure that the non-physician assistant health care provider is qualified and trained to provide that service within the scope of the non-physician assistant health care provider's practice;

b. Ensure that the licensee is available in person or electronically to consult with the non-physician assistant health care provider, particularly in the case of injury or an emergency.

327.6(11) *Informed consent.* A licensee who uses telemedicine will ensure that the patient provides appropriate informed consent for the medical services provided, including consent for the use of telemedicine to diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record.

327.6(12) Coordination of care. A licensee who uses telemedicine will, when medically appropriate, identify the medical home or treating clinician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. The licensee will provide a copy of the medical record to the patient's medical home or treating clinician(s).

327.6(13) Follow-up care. A licensee who uses telemedicine will have access to, or adequate knowledge of, the nature and availability of local medical resources to provide appropriate follow-up care to the patient following a telemedicine encounter.

327.6(14) *Emergency services.* A licensee who uses telemedicine will refer a patient to an acute care facility or an emergency department when referral is necessary for the safety of the patient or in the case of an emergency.

327.6(15) *Medical records.* A licensee who uses telemedicine will ensure that complete, accurate and timely medical records are maintained for the patient when appropriate, including all patient-related electronic communications, records of past care, physician assistant-patient communications, laboratory and test results, evaluations and consultations, prescriptions, and instructions obtained or produced in connection with the use of telemedicine technologies. The licensee will note in the patient's record when telemedicine is used to provide diagnosis and treatment. The licensee will ensure that the patient or another licensee designated by the patient has timely access to all information obtained during the telemedicine encounter. The licensee will ensure that the patient receives, upon request, a summary of each telemedicine encounter in a timely manner.

327.6(16) *Privacy and security.* A licensee who uses telemedicine will ensure that all telemedicine encounters comply with the privacy and security measures of the Health Insurance Portability and Accountability Act (HIPAA) to ensure that all patient communications and records are secure and remain confidential.

a. Written protocols will be established that address the following:

(1) Privacy;

- (2) Health care personnel who will process messages;
- (3) Hours of operation;
- (4) Types of transactions that will be permitted electronically;

(5) Required patient information to be included in the communication, including patient name, identification number and type of transaction;

- (6) Archiving and retrieval; and
- (7) Quality oversight mechanisms.

b. The written protocols should be periodically evaluated for currency and should be maintained in an accessible and readily available manner for review. The written protocols will include sufficient privacy and security measures to ensure the confidentiality and integrity of patient-identifiable information, including password protection, encryption or other reliable authentication techniques.

327.6(17) *Technology and equipment.* Broad categories of telemedicine technologies currently exist, including asynchronous store-and-forward technologies, remote monitoring, and real-time interactive services. While some telemedicine programs are multispecialty in nature, others are tailored to specific diseases and medical specialties. The technology and equipment utilized for telemedicine will comply with the following requirements:

a. The technology and equipment utilized in the provision of telemedicine services must comply with all relevant safety laws, rules, regulations, and codes for technology and technical safety for devices that interact with patients or are integral to diagnostic capabilities;

b. The technology and equipment utilized in the provision of telemedicine services must be of sufficient quality, size, resolution and clarity such that the licensee can safely and effectively provide the telemedicine services; and

c. The technology and equipment utilized in the provision of telemedicine services must be compliant with HIPAA.

327.6(18) *Disclosure and functionality of telemedicine services.* A licensee who uses telemedicine will ensure that the following information is clearly disclosed to the patient:

a. Types of services provided;

b. Contact information for the licensee;

c. Identity, licensure, certification, credentials, and qualifications of all health care providers who are providing the telemedicine services;

d. Limitations in the drugs and services that can be provided via telemedicine;

e. Fees for services, cost-sharing responsibilities, and how payment is to be made, if these differ from an in-person encounter;

f. Financial interests, other than fees charged, in any information, products, or services provided by the licensee(s);

g. Appropriate uses and limitations of the technologies, including in emergency situations;

h. Uses of and response times for emails, electronic messages and other communications transmitted via telemedicine technologies;

i. To whom patient health information may be disclosed and for what purpose;

j. Rights of patients with respect to patient health information; and

k. Information collected and passive tracking mechanisms utilized.

327.6(19) *Patient access and feedback.* A licensee who uses telemedicine will ensure that the patient has easy access to a mechanism for the following purposes:

a. To access, supplement and amend patient-provided personal health information;

b. To provide feedback regarding the quality of the telemedicine services provided; and

c. To register complaints. The mechanism will include information regarding the filing of complaints with the board.

327.6(20) *Financial interests.* Advertising or promotion of goods or products from which the licensee receives direct remuneration, benefit or incentives (other than the fees for the medical services) is prohibited to the extent that such activities are prohibited by state or federal law. Notwithstanding such prohibition, Internet services may provide links to general health information sites to enhance education; however, the licensee should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, licensees should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of a preferred relationship with any pharmacy is prohibited. Licensees will not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit from the pharmacy.

327.6(21) Circumstances where the standard of care may not require a licensee to personally interview or examine a patient. Under the following circumstances, whether or not such circumstances

involve the use of telemedicine, a licensee may treat a patient who has not been personally interviewed, examined and diagnosed by the licensee:

a. Situations in which the licensee prescribes medications on a short-term basis for a new patient and has scheduled or is in the process of scheduling an appointment to personally examine the patient;

b. For institutional settings, including writing initial admission orders for a newly hospitalized patient;

c. Call situations in which a licensee is taking calls for another health care provider who has an established provider-patient relationship with the patient;

d. Cross-coverage situations in which a licensee is taking calls for another health care provider who has an established provider-patient relationship with the patient;

e. Emergency situations in which the life or health of the patient is in imminent danger;

f. Emergency situations that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak;

g. Situations in which the licensee has diagnosed a sexually transmitted disease in a patient and the licensee prescribes or dispenses antibiotics to the patient's named sexual partner(s) for the treatment of the sexually transmitted disease as recommended by the U.S. Centers for Disease Control and Prevention; and

h. For licensed or certified nursing facilities, residential care facilities, intermediate care facilities, assisted living facilities, hospice settings, and correctional facilities.

327.6(22) Prescribing based solely on an Internet request, Internet questionnaire or a telephonic evaluation—prohibited. Prescribing to a patient based solely on an Internet request or Internet questionnaire (i.e., a static questionnaire provided to a patient, to which the patient responds with a static set of answers, in contrast to an adaptive, interactive and responsive online interview) is prohibited. Absent a valid physician assistant-patient relationship, a licensee's prescribing to a patient based solely on a telephonic evaluation is prohibited, with the exception of the circumstances described in subrule 327.9(21).

These rules are intended to implement Iowa Code sections 147.10 and 147.107 and chapters 148C and 272C.